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Transnational Legal Ordering and Access to Medicines

(Chapter in Patent Law in Global Perspective, ed. Ruth L. Okediji & Margo A. Bagley, (Oxford University Press, 2014)).

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INTRODUCTION

One can no longer speak meaningfully about national law without speaking of law in its transnational context. Transnational legal ordering now spans public regulatory law, private business law, and human rights law. These transnationally-shaped legal domains interact. For example, at the international level, one cannot speak meaningfully about the international law and politics of trade and intellectual property (IP) law under the World Trade Organization (WTO) without considering other transnational legal norms, such as economic and social rights. The issues that these legal domains cover intersect across levels of social organization, from national legal systems to international regimes.

This chapter proceeds in five parts. Part I examines the complications of normatively assessing intellectual property protection in light of tradeoffs involving multiple goals, including knowledge creation, trade governance, economic development, and public health. Part II discusses the development and interaction of different transnational legal orders (TLOs), by which we refer to legal orders that go all the way down from international law to national law and local legal practice, and that interact recursively in both bottom-up and top-down ways.² Different transnational legal orders reflect diverse, and potentially conflicting, values and priorities that affect national law and practice. The ensuing sections address the tensions between a TLO that prioritizes trade and intellectual property protection, and one that foregrounds human rights values, including public health. Part III presents the rise of the TLO for intellectual property, and the struggles that continue to shape it. Part IV examines the rise of an overlapping and rival TLO based on the human right to health. This emergent TLO directly challenges some of the central tenets of the trade and intellectual property TLO. Suddenly states are pushing back and forth over what they had appeared to have “settled” multilaterally under the TRIPS Agreement. Competing values that once traveled along separate but parallel tracks are now intersecting and directly clashing, forcing hard policy choices. Part V concludes with strategies that developing countries can adopt, and have adopted, to address the challenges of implementing these two transnational legal orders to advance their development goals, including access to medicines.

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² For two broader projects on transnational legal ordering and transnational legal orders respectively, see TRANSNATIONAL LEGAL ORDERS (Terence Halliday & Gregory Shaffer eds., forthcoming 2013); Gregory Shaffer, *Transnational Legal Ordering and State Change*, in TRANSNATIONAL LEGAL ORDERING AND STATE CHANGE (Gregory Shaffer ed., 2013) [hereinafter Shaffer, *Transnational*].

I. NORMATIVELY EVALUATING IP PROTECTION

From a normative perspective, there is no singular optimal level of intellectual property protection either globally or nationally. Without transnational legal ordering, the level that a nation chooses will vary based on the values and priorities that it seeks to advance. In part, these choices will reflect its level of development and its comparative advantage in innovation and imitation. Different forms of intellectual property protection are important for the creation and diffusion of knowledge for economic development. Yet the proper level of intellectual property protection is an extremely difficult and contested empirical question.³ Too little protection can undercut incentives for creative and innovative activity, and thus result in a reduction of social welfare. Too much protection can obstruct innovation and raise costs for consumers. Thus too much protection may reduce both the production of knowledge and the ability of the public to use it. Intellectual property protection may jeopardize the pursuit of other social goals as well, such as access to medicines. Policy makers must navigate this tension and balance the different policy goals that reflect divergent values and priorities. In short, determining the appropriate scope and level of IP protection raises both empirical issues and value choices.

The debates over pharmaceutical patent protection and the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) raise at least five potentially competing normative priorities with profound distributive implications. These are: monopoly incentives to induce innovation; free trade; economic development, public health; and the right to life and human dignity.⁴ We discuss each in turn.

Knowledge has some public goods attributes. Once knowledge enters the public domain it is no longer excludable, and one's consumption of it does not diminish its availability. And yet, among the main challenges that intellectual property policy confronts is how to generate this knowledge, both efficiently and equitably. States have granted temporary monopoly privileges such as patents in order to provide incentives to innovate. The offering of such legal protection removes knowledge from the public domain for a defined time period.⁵

A legal order of liberalized trade also provides benefits. While it is true that liberalized trade produces both winners and losers and may give rise to distributional conflicts, one can make a normative case that trade liberalization results in a wider variety of products being made available at lower prices. Liberalized trade rewards efficient production and exchange. A liberal trade legal order also helps to provide predictability to encourage long-term investment and increased productivity. It further helps countries to avoid the kind of tit-for-tat protectionist measures that gave rise to the drastic reduction in global trade during the 1930s and had devastating economic and political consequences. A stable and predictable legal order of liberalized trade can help countries avoid the temptation of engaging in trade discrimination during financial crises.⁶

³ See, e.g., KEITH MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* (2000).

⁴ For an exploration of this issue in the context of WTO dispute settlement, see Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? The Case of TRIPS and Pharmaceutical Patent Protection*, 7 J. INT'L ECON. L. 459 (2004).

⁵ Knowledge can be subject to some excludability, as through trade secrets, so that it is not a pure public good. See, e.g., Joseph E. Stiglitz, *Knowledge as a Global Public Good*, in *GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY* 306–25 (Inge Kaul, Isabelle Grunberg & Marc Stern eds., 1999) [hereinafter *GLOBAL PUBLIC GOODS*] (labelling knowledge an “impure public good”).

⁶ See, e.g., Nancy Birdsall & Robert Lawrence, *Deep Integration and Trade Agreements: Good for Developing Countries*, in *GLOBAL PUBLIC GOODS*, *supra* note 5, at 128, 133.

A legal order can also prioritize economic development goals in which poorer countries may “free ride” on the innovations of others, benefitting from imitating their products and making them available for their citizens at reduced prices. Imitation and reverse engineering are core mechanisms of this strategy.⁷ Through this process, these countries can develop new industries that eventually can become competitive innovators, as happened with Japan and Korea, and now appears to be occurring with China. At a later time, these countries may switch their policies toward granting greater intellectual property protection to further innovation.

Public health has been viewed as a public good since all individuals benefit from the global curtailment and eradication of diseases and they do not diminish that good when they benefit from it.⁸ Incentives for innovation, such as patents, can contribute to the development of drugs and treatments to combat disease. Although ideally everyone could benefit equally from effective advances in medicine, in practice these goods have not been equally available to everyone, in large part because of their cost.

Finally from a human rights perspective, the availability of disease-eradicating medicines can be viewed as an integral component of the human right to life and dignity. The normative priority of the human right to life and dignity can compete or conflict with other important values. In particular, sharp tensions between human rights and property rights produce political, social, and economic controversies over pharmaceutical patent protection, as well as issues regarding the funding of medicines compared to other policy initiatives in a world of scarcity. “Rights” language, whether applied to human rights or property rights, implies a sense of entitlement in which the right trumps other policy goals in terms of hierarchy.

The recognition and enforcement of patent rights under TRIPS and other IP treaties can generate incentives for the production of knowledge and new drugs for public health and the protection of human life. But the HIV/AIDS pandemic underscored how the protection of pharmaceutical patent rights may also undermine the benefits of liberalized trade by restricting consumer access through monopoly pricing power and staving off generic drug competition. These policies can reduce public health options for containing diseases, and raise human rights concerns insofar as lack of access leads to unnecessary and preventable deaths.

Societies inevitably must make choices among conflicting normative priorities.⁹ The key institutional question is: who decides the appropriate balancing among policy goals?¹⁰ Choices between liberalized trade, patent protection, economic development, public health, and human rights reflect different values, priorities, perspectives, and generate considerable uncertainty. Policymakers must make institutional choices despite these tradeoffs. The rise of different transnational legal orders in different substantive domains help frame approaches to these normative and institutional questions.

II. THE RISE OF TRANSNATIONAL LEGAL ORDERS

⁷ SUSAN K. SELL, POWER AND IDEAS: NORTH-SOUTH POLITICS OF INTELLECTUAL PROPERTY AND ANTITRUST (1998).

⁸ See, e.g., Todd Sandler & Daniel G. Arce, *A Conceptual Framework for Understanding Global and Transnational Goods for Health*, 23 FISCAL STUD. 195 (2002).

⁹ See Gregory Shaffer, *International Law and Global Public Goods in a Legal Pluralist World*, EUROPEAN J. INT’L L., Vol. 31, No. 3, 669 (2012).

¹⁰ Gregory Shaffer, *Comparative Institutional Analysis and a New Legal Realism*, 2013 Wisconsin Law Review (forthcoming 2013).

Social orders increasingly are legalized transnationally, reflecting processes of economic and cultural globalization.¹¹ As a result, issues that formerly were viewed as national in scope have been transformed to have transnational (and sometimes global) dimensions.¹² Whether the social order concerns protections for intellectual property rights or public health, removal of barriers to trade or observance of human rights, the ordering of responses to these issues inside the state and across national frontiers increasingly involves legal norms that transcend national boundaries. We can define a transnational legal order (TLO) as a *collection of formalized legal norms and associated organizations and actors that authoritatively order behavior that spans national jurisdictions*.¹³

The concept of the creation of TLOs addresses the social and political construction of problems and their resolution. The construction of a problem is not a “natural” one, but involves actors with particular perceptions, including of their own interests, which advance particular imaginings of solutions to the problem to create a new order. They increasingly do so by working to create and institutionalize a legal order that is transnational in scope. Different transnational legal orders emerge that vary in terms of geographic scope and legal scope. TLOs can vary geographically, ranging from bilateral, regional, plurilateral, multilateral, to global agreements. Such range is illustrated by law applying to the European Union, to North America under the North American Free Trade Agreement (NAFTA), to parts of South America under the Andean Pact, to countries spanning the Pacific under the proposed Trans-Pacific Partnership Agreement, to countries spanning the globe under the WTO and the United Nations (UN). They also vary by substantive legal focus, such as over trade, investment, finance, environmental protection, intellectual property, public health, and human rights. These TLOs, of varying legal and geographic scope operate simultaneously, sometimes incognizant of each other, sometimes in competition with each other, and sometimes in antagonistic interaction with each other. They can thus be seen as varying along two dimensions: (1) the degree of settlement of the transnational legal norms, and (2) the extent of issue alignment among existing TLOs.¹⁴

The politics of international trade and IP law in relation to pharmaceutical patents increasingly involves the interaction of such transnational legal orders. In particular, it involves the interaction of TLOs focused on trade and intellectual property protection, and TLOs focused on human rights. These transnational legal orders involve recursive interaction between transnational legal norm-making and national implementation. They may feature conflicts among TLOs not only transnationally but also within nation states.

The issue of access to medicines, in particular, has been characterized by a high degree of contestation and a significant lack of alignment among international institutions over the last decade. The result has been significant tension among TLOs that previously were distinct and segregated, those of IP, trade, and the human right to health. As Laurence Helfer shows, one can see the interaction of these TLOs in terms of three time periods. In the first period, the TLOs were separate, did not interact, and their norms were relatively open-ended and unsettled transnationally. In the second period, an IP-trade TLO became predominant and its norms appeared to be relatively

¹¹ See Shaffer, *Transnational*, *supra* note 2.

¹² Shaffer, *supra* note 9.

¹³ “Associated organizations and actors” is construed broadly to include any organization or social formation, including networks, and actors may refer both to collective actors and to individuals whose activities and careers cross national boundaries. See TRANSNATIONAL LEGAL ORDERS, *supra* note 2; Shaffer, *Transnational*, *supra* note 2.

¹⁴ TRANSNATIONAL LEGAL ORDERS, *supra* note 2.

settled transnationally. In the third period, the IP TLO on pharmaceutical patents became unsettled in light of developments in a parallel TLO on the economic and social right to health care.¹⁵

Before the mid-1990s, the IP and economic and social rights TLOs were entirely distinct and relatively unsettled. Under the IP TLO, there was considerable debate within the World Intellectual Property Organization (WIPO) as to what form of special and differential treatment should be applied to developing countries, and there were few substantive requirements for patents other than application of non-discrimination norms. Similarly, under the UN International Covenant on Economic, Social and Cultural Rights (ICESCR), the scope of an economic and social right to health was contested among states and civil society actors. Yet, although there was contestation within these TLOs, there was no interaction between them. States were thus largely unconstrained in adapting the IP and right to health legal norms that they desired, including regarding access to medicines.

From the mid-1990s until around 2000, in light of the incorporation of IP into the WTO package of agreements, and the negotiation of new bilateral and plurilateral agreements containing TRIPS-plus provisions,¹⁶ countries around the world adopted new IP laws, including for the patenting of pharmaceutical products. There appeared to be settlement as to the applicable legal norms in this domain, which many observers and civil society actors decried. As a result, countries were considerably more constrained in providing inexpensive drugs to patients pursuant to a right to health.

Since around 2000, a new transnational legal order for the economic and social right of access to medicines has become institutionalized. It has done so as a result of a number of factors, and in particular the resistance of states, non-state actors, and international human rights and health organizations to the IP TLO. The salience of the AIDS epidemic where improved access to medicines could save millions of lives helped to precipitate the emergence of this rival TLO. Powerful business interests supported by their home states nonetheless continued to push for greater IP protection, including through bilateral and plurilateral agreements, leading to considerable normative dissensus and contestation, as well as competing constraints for developing countries from these rival transnational legal orders.

III. THE CONSTRUCTION OF THE TLO FOR INTELLECTUAL PROPERTY

Law is often viewed as producing social order out of conflict. But in studying law, we also need to assess how law reflects power. Law, in this sense, is Janus-faced, involving both the creation of normative order and the reflection of power. Legal realist scholars have long noted this aspect of law, but it has often been elided in legal scholarship.¹⁷ As the political scientist Michael Barnett writes:

Power and legitimacy [such as legal legitimacy] . . . are not conflicting concepts but rather are complementary ones. The powerful, too, want their actions to be

¹⁵ See Laurence Helfer, *Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines*, in TRANSNATIONAL LEGAL ORDERS, *supra* note 2. See also LAURENCE R. HELFER & GRAEME W. AUSTIN, HUMAN RIGHTS AND INTELLECTUAL PROPERTY: MAPPING THE GLOBAL INTERFACE (2011).

¹⁶ “TRIPS-plus” refers to requirements that exceed the minimum standards mandated by TRIPS.

¹⁷ See Hanoch Dagan, *The Realist Conception of Law*, U. TORONTO L.J., Vol. 57, No. 3, 607 (2007); Victoria Nourse & Gregory Shaffer, *Varieties of New Legal Realism: Can a New World Order Prompt a New Legal Theory?*, 95 CORNELL L. REV. 62 (2009).

viewed as legitimate, if only to maintain their power and further their interests. Even the powerful, in this view, cannot act in an expedient and narrowly self-interested manner and must observe international society's underlying rules and norms.¹⁸

The United States (U.S.) and the European Union (EU) use a variety of means to shape IP rules transnationally. They use the carrot of granting access to their valuable markets, and the stick of threatening to withdraw such access, in order to pressure countries to raise IP standards. They have the material resources to engage in negotiations in multiple fora to advance their interests, and are the protagonists in creating institutions that shape and constrain what can be discussed within them. They have the knowledge resources to shape understandings, including through the provision of technical assistance and capacity building which frame issues in particular ways. For example, representatives of pharmaceutical trade associations work with U.S. and EU officials to draft “model” laws and to teach as “faculty” in workshops organized by WIPO on intellectual property law and its enforcement.¹⁹

The very concept of “intellectual property” is a social and political construction. Alternative organizing concepts could be used and institutionalized through law, such as “access to knowledge,” or “knowledge for development,” but the concept of “intellectual property” has been globalized. The concept is, for example, at odds with many traditional and indigenous approaches to knowledge and ideas, and countries have varied over time in the extent of intellectual property protection available in light of their stage of development. The original signatories to the Berne and Paris Conventions, respectively, for patent and copyright protection were primarily developed countries.²⁰ Over time, countries have adopted IP laws that mirrored those of the former colonizer, or tailored IP laws to reflect perceptions of domestic interests.²¹ For example, a number of developing countries would not issue patents on pharmaceutical products and agricultural chemicals.²² In fact, before 1970, the United States was among a small minority of countries that offered patents on pharmaceutical products.²³

Much has been written about the strategies of the powerful that led to the creation of the TRIPS Agreement.²⁴ In a strategic move, the United States integrated IP into trade policies during

¹⁸ Michael N. Barnett, *Bringing in the New World Order: Liberalism, Legitimacy, and the United Nations*, 49 *WORLD POL.* 526, 544 (1997).

¹⁹ See CAROLYN DEERE, *THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES* (2009).

²⁰ Brazil, Ecuador, and El Salvador, and Guatemala, for example, were the only developing country signatories to the 1883 International Convention for the Protection of Industrial Property Paris Convention (the Paris Convention). *Id.* at 37.

²¹ See Ruth L. Okediji, *The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System*, 7 *SING. J. INT'L & COMP. L.* 316, 326–37 (2011); DEERE, *supra* note 19, at 37–38 (contrasting Latin American adaptation of IP rules for national purposes with African countries copying the laws of the colonial metropole).

²² By the 1970s, India's patent laws allowed patents on the methods and processes related to medicines, but not on the medicines themselves. Brazil did not permit patents on pharmaceutical processes and products from 1971 to 1996. DEERE, *supra* note 19, at 40.

²³ *Id.*

²⁴ See, e.g., PETER DRAHOS WITH JOHN BRAITHWAITE, *INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?* (2003) [hereinafter *INFORMATION FEUDALISM*]; CHRISTOPHER MAY & SUSAN SELL, *INTELLECTUAL PROPERTY RIGHTS: A CRITICAL HISTORY* (Lynne Rienner ed., 2005); SUSAN SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* (2003).

the 1980s, using the threat of withdrawing market access to constrain the ability of developing countries to resist demands for greater IP protection. The U.S. used, and continues to use, its Special 301 procedure under which countries are placed on watch lists of varying priority regarding their IP protections.²⁵ From 1985-1995, at least eighteen countries reformed national laws to strengthen patent protection due to other measures by the U.S. and EU.²⁶ Working closely with private trade associations, these strategies eventually facilitated the inclusion of the TRIPS Agreement as part of the WTO's single package of agreements.²⁷ A country could not benefit from WTO market access opportunities unless it also agreed to be bound by the TRIPS Agreement's IP requirements.

A. *The TRIPS Agreement and its Flexibilities*

The TRIPS Agreement set forth unprecedented strong mandatory, minimum standards of IP rules, and applied them to countries regardless of level of development, although with different deadlines for implementation which have been extended for least developed countries.²⁸ The Agreement obliges WTO members to implement these minimum standards for most categories of IP. For patents, it requires protection for all fields of technology for a minimum of twenty years.²⁹ It also requires states to ensure that private IP rights holders can take "effective action" against IP infringement, and help enforce IP rights through border measures and criminal law.³⁰ The liberal trade economist Jagdish Bhagwati thus writes that the TRIPS Agreement "positions the WTO primarily as a collector of intellectual property-related rents on behalf of multinational corporations."³¹ The financial burden of the agreement's implementation and enforcement is considerable. World Bank economists have estimated that the agreement has cost less developed countries \$60 billion a year.³²

²⁵ Office of the United States Trade Representative, April 1, 2013. "2012 Special 301 Report," www.ustr.gov/sites/default/files/2012_Special_301_Report_0.pdf.

²⁶ A number of US and EU domestic laws allowed for the coercion of developing countries. The Generalized System of Preferences Renewal Act (1984), for example, authorized the US president to withdraw tariff concessions from developing countries with weak IP protection. At the time, 140 countries received US GSP benefits. DRAHOS with BRAITHWAITE, at 88.

²⁷ World Trade Organization, 1994. Agreement on Trade-Related Aspects of Intellectual Property Rights. www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

²⁸ Deadlines for implementation are varied and have been revised; developing countries were granted a five-year transition period until January 2000. Least-developed countries were initially expected to implement TRIPS by 2006, a deadline which was later extended to 2013 after requesting an extension. See DEERE, *supra* note 19, at 67–69 tbl.3.1. Negotiations for a further extension for the LDCs are currently underway. William New, ip-watch, May 24, 2013, "At WTO, LDC fight for extension of TRIPS transition continues," www.ip-watch.org/2013/05/24/ldc-fight-for-extension-of-trips-transition-continues/

²⁹ The 1883 International Convention for the Protection of Industrial Property (the Paris Convention) is silent on the question of patent duration. DEERE, *supra* note 19, at 66.

³⁰ World Trade Organization, TRIPS, Article 41.

³¹ Jagdish Bhagwati, *What It Will Take to Get Developing Countries into a New Round of Multilateral Trade Negotiations*, INST. FOR AGRIC. & TRADE POL., http://www.iatp.org/files/What_It_Will_Take_to_Get_Developing_Countries_.htm (last visited Mar. 15, 2013).

³² See J. Michael Finger, *Introduction and Overview*, in POOR PEOPLE'S KNOWLEDGE: PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 4 (J. Michael Finger & Philip Schuler eds., 2004). See also WORLD BANK, GLOBAL ECONOMIC PROSPECTS AND THE DEVELOPING COUNTRIES 136 (2002) ("Bangladesh anticipated one-time costs of administrative TRIPS compliance (drafting legislation) amounting to \$250,000, and over \$1.1 million in annual costs for judicial work, equipment, and enforcement efforts.").

Paradoxically, although the TRIPS Agreement imposes significant obligations on states to protect the holders of IP rights, commentators now commonly refer to the flexibilities in its provisions to counter U.S. and EU demands for ever greater IP requirements. Although the most stringent at the time it was signed, the TRIPS Agreement provides for interpretive options, such as what constitutes novelty and an inventive step for purposes of granting a patent. Among the most important of the exceptions for patents for developing countries are: the right of parallel importation; the right to grant compulsory licenses; and ‘Bolar’ exceptions for generic drug companies to prepare a drug under patent for marketing authorization once the patent expires.³³

The TRIPS Agreement restricts the use of compulsory licensing to certain specified conditions, and in particular for predominant use for only the domestic market.³⁴ The explosion of the AIDS crisis and international protests against the effect of pharmaceutical patents on public health placed pressure on the WTO to facilitate the use of compulsory licenses and other TRIPS “flexibilities.” In 2001, WTO members negotiated the Doha Declaration on Public Health³⁵ and they adopted a waiver in August 2003 that enables any member country to import pharmaceutical products under a compulsory license (although the conditions of the waiver are still contested for being too stringent).³⁶ This decision could assist those developing countries that lack the domestic manufacturing capacity to produce pharmaceuticals themselves under a compulsory license. A number of developing countries have since issued compulsory licenses, mostly related to public

³³ WTO, TRIPS, Articles 6, 8.1, 8.2, 30, and 31. Carlos Correa, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES, (The South Center: Geneva, 2000), pp. 70-77; 93-100. Available at: apps.who.int/medicine/docs/pdf/h2963e/h2963e.pdf

³⁴ Article 6 of the 2001 Doha Declaration underlined the fact that TRIPS Article 31(f) might limit the ability of countries with insufficient manufacturing capabilities to import cheaper generics, as the products manufactured under compulsory licenses must be “predominantly” for the domestic market. World Trade Organization, DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, WT/MIN(01)/DEC/W/2. 14

November 2001 available at: www.who.int/medicines/areas/policy/tripshealth.pdf. v See also Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 45–47 (2001).

³⁵ DOHA DECLARATION.

³⁶ This waiver is subject to the terms of the “30 August Decision.” See DEERE, *supra* note 19, at 82. Additionally, on December 6, 2005, the General Council adopted a decision to amend TRIPS in an attempt to solve problems posed by Article 31(f); however, the amendment will not become part of the Agreement until two thirds of WTO Members ratify it. See Press Release, World Trade Org., Members OK Amendment to Make Health Flexibility Permanent (Dec. 6, 2005), available at http://www.wto.org/english/news_e/pres05_e/pr426_e. The original deadline was December 2007, which was later extended to December 2009, and then to December 2011. See *Amendment of the TRIPS Agreement: Decision of 6 December 2005*, WORLD TRADE ORG. (Dec. 8, 2005), http://www.wto.org/english/tratop_e/trips_e/wt1641_e.htm; *Amendment of the TRIPS Agreement – Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement: Decision of 18 December 2007*, WORLD TRADE ORG. (Dec. 21, 2007), http://www.wto.org/english/tratop_e/trips_e/wt-1-711_e.pdf; *Amendment of the TRIPS Agreement – Second Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement: Decision of 17 December 2009*, WORLD TRADE ORG. (Dec. 18, 2009), http://www.wto.org/english/tratop_e/trips_e/wt-1-785_e.pdf. As of December 2011, forty one countries had ratified the amendment. See *WTO Members Accepting Amendment of the TRIPS Agreement*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last updated Nov. 5, 2012). “Countries wanting to import under the ‘paragraph 6’ system to have to notify the WTO in two ways. They have to announce once that they intend to make use of the system, and then they have to supply information each time they use it.” See *Notifications by importing WTO Members*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm (last visited Mar. 15, 2013) (listing Rwanda as a state that has imported pursuant to paragraph 6).

health or government use.³⁷ Perhaps even more importantly, some larger developing countries have used the threat of compulsory licenses to gain leverage in negotiation with patent holders to lower prices.³⁸

The ‘Bolar’ exception (named after the *U.S. Roche v. Bolar* case) permits generic drug producers to make use of patented materials during the patent term for the purpose of acquiring marketing approval and obtaining registration of a generic version of a branded drug. This exception helps to expedite bringing generic versions to market upon expiration of the patent.³⁹ Because it facilitates a more rapid entry of lower cost generic drugs, the Bolar exception can lower prices for both government health agencies and individual consumers. A WTO panel in the *Canada- Patent Protection of Pharmaceutical Products* case interpreted Article 30 of the TRIPs Agreement to permit such exceptions.⁴⁰ Developing countries, however, so far have not widely adopted Bolar-type exceptions, particularly because many lack a generic industry. A 2006 survey of 106 developing countries showed that less than 10 had adopted explicit Bolar-type provisions.⁴¹

In contrast, a much greater number of developing countries have permitted parallel imports of pharmaceutical products. Pharmaceutical companies provide opportunities for parallel imports whenever they practice price discrimination across diverse markets. A patent holder may charge “x” for a drug in one territorial market, and “x+100” for that same drug in another territorial market. Parallel importing provides a country with the opportunity to import a drug from the territorial market that offers the “x” price, rather than the “x+100” price, thereby containing costs. Such practices create an incentive for developing countries to import patented products from lower-priced markets. A 2006 sample of fifty-four developing countries showed that thirty-three permitted parallel imports. The countries varied, however, as to whether they recognized “exhaustion” of intellectual property rights upon first sale in the world or only in a region.⁴² TRIPs Article 6 permits countries to choose their preferred exhaustion system. Under a national or domestic exhaustion regime, when an IPR owner sells a good in a foreign market, she retains her right to prevent that genuine good from entering the domestic market where the IP right has not been “exhausted.” In other words, she has a right to prevent parallel importation. Generally,

³⁷ These countries include: Brazil, Ghana, Guinea, Indonesia, Malaysia (three times), Mozambique, Rwanda, Swaziland, Taiwan, Thailand (four times), Zambia, and Zimbabwe. DEERE, *supra* note 19, at 83. Importantly, developed countries have also referenced government use as a basis to interfere with patent rights for public health purposes. See Jerome H. Reichman with Catherine Hasenzahl, “Non-voluntary licensing of patented inventions: Historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the USA”, Issue Paper 5, June 2003: ICSTD/UNCTAD Project on IPRs and Sustainable Development. Available at: ictsd.net/downloads/2008/06/cs_reichman_hasenzahl.pdf

³⁸ See Frederick M. Abbott & Jerome H. Reichman, *The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT’L ECON. L. 921, 951 (2007) (“[T]he Brazilian government has used the threat of compulsory licenses to pressure foreign multinational patent holders to significantly lower the prices charged for [antiretroviral treatments]”).

³⁹ See generally, DEERE, *supra* note 19, at 81. See also, Jerome H. Reichman, *Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow?*, 46 HOUS. L. REV. 1115, 1138 (2009) (describing a Chinese Bolar exception “which permits generic producers to reverse-engineer patented medicines to conduct clinical trials prior to the expiration of the patent”).

⁴⁰ See *Canada – Patent Protection of Pharmaceutical Products: Report of the Panel*, WORLD TRADE ORG. (Mar. 17, 2000), http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf; see also DEERE, *supra* note 19, at 81.

⁴¹ DEERE, *supra* note 19, at 79–81. For example, “Argentina’s patent law states that any third party may use a product or process protected by patent prior to its expiration ‘to obtain the information required for the approval of a product or process by the competent authority so that it may be marketed following the patent expiration.’” *Id.*

⁴² DEERE, *supra* note 19, at 75.

international exhaustion regimes, in contrast to national ones, should expand access to medicines at a lower price because they facilitate parallel importation and deny the patent holder the right to block such imports because a first sale of the good anywhere in the world exhausts the domestic IP right.⁴³

B. The Proliferation of Bilateral and Plurilateral Agreements after TRIPS

For leading industrialized countries such as the United States, the TRIPS Agreement represented only a foundation on which further IP protection could be built. They considered the TRIPS standards to be a floor, constituting absolute minimum standards, whereas many developing countries considered them to be a ceiling above which they would not have to go. At the conclusion of the TRIPS negotiations, a leading U.S. advocate proclaimed that, “we got 95% of what we wanted.”⁴⁴

In subsequent developments, the 5% that TRIPS proponents failed to achieve has prominently featured in U.S. and EU bilateral and plurilateral agreements. These agreements have eliminated many of the flexibilities provided in the TRIPS Agreement.⁴⁵ For example, many of them prohibit the practice of parallel importation of cheaper patented drugs and restrict the conditions under which countries may issue compulsory licenses. These provisions are examples of the exact features that U.S.- and OECD-based pharmaceutical firms sought, but failed to obtain, in the TRIPS negotiations. These new agreements are invariably TRIPS-plus agreements, because they expand requirements from the base that the TRIPS Agreement set, and TRIPS-minus agreements, in that they eliminate many TRIPS flexibilities.⁴⁶ As a result, these bilateral, regional, and plurilateral IP agreements reduce access to lower cost products and may jeopardize generic competition.

With respect to essential medicines, TRIPS-minus provisions *limit* a number of pertinent flexibilities under the TRIPS Agreement, such as parallel importation, and compulsory licenses. To restrict parallel importation, TRIPS-minus provisions may provide the patent owner with an exclusive right to prohibit parallel importing contractually, thus curtailing a country’s ability to access more affordable patented drugs,⁴⁷ as under the U.S. FTAs with Australia, Morocco and Singapore.⁴⁸ The granting of compulsory licenses may be limited to narrowly specified conditions,

⁴³ Carsten Fink, *Comment: Competition Law as a Means of Containing Intellectual Property Rights*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 771 (Keith Maskus & Jerome Reichman eds., 2005).

⁴⁴ SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 48 (2003).

⁴⁵ Susan K. Sell, *TRIPS Was Never Enough: Vertical Form Shifting, FTAs, ACTA, AND TPP*, 18 J. INTELL. PROP. L. 447, 448 (2011). Deere discusses a number of other tools used to push developing countries to implement stronger IP protection, including bilateral investment treaties, Special 301 threats, diplomatic threats, and industry pressure, such as direct lobbying by the pharmaceutical sector in developing countries. See DEERE, *supra* note 19, at 154–64. The WTO website indicates that, “[a]s of 15 November 2011, some 505 RTAs (counting goods and services notifications separately) have been notified to the GATT/WTO.” *Regional Trade Agreements*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/region_e/region_e.htm (last visited Mar. 15, 2013).

⁴⁶ See, e.g., Sell, *supra* note 40, at 448.

⁴⁷ Id. at 453–54.

⁴⁸ See DEERE, *supra* note 19, at 338–40 (listing the US FTAs with Singapore, Morocco, and Australia as containing provisions where “patent holders may limit parallel imports of pharmaceutical products through licensing contracts.”).

considerably more restrictive than under the TRIPs Agreement.⁴⁹ The U.S. FTAs with Australia, Jordan, Singapore and Vietnam, for example, contain provisions that limit compulsory licenses to situations such as national emergencies, public non-commercial use, and as an antitrust remedy.⁵⁰

The TRIPS-plus provisions include expanded data-exclusivity requirements, patent linkage for marketing approvals, and lengthier patent terms.⁵¹ Some FTAs have included more stringent data-exclusivity requirements designed to force generic manufacturers to generate their own test data, as opposed to being able to rely on the findings of the brand name companies.⁵² The aim is to further delay generic competition and thus prolong the payment of higher prices to U.S. and EU rights holders. The U.S. has FTAs with provisions that expand test data protection for pharmaceutical products with at least thirteen developing countries, including Vietnam, Jordan, Chile, Singapore, Morocco, Australia, Bahrain, and the countries of the Dominican Republic-Central American Free Trade Agreement (DR-CAFTA): that is, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic.⁵³ These data exclusivity provisions significantly extend TRIPs Article 39.3, which requires WTO members to protect undisclosed test data against unfair competition.⁵⁴

Many FTAs also require that the registration of medicines by health authorities be linked to patent protection. As a consequence, governmental authorities cannot register a drug that remains under patent protection. The treaties require regulatory authorities to notify the patent holder if a generic competitor attempts to register a generic version of a drug. This enrolls regulatory authorities into the patent enforcement process, mimicking the U.S. Hatch-Waxman regime. Free Trade Agreements that contain provisions prohibiting marketing approval of a generic drug during the patent term, unless authorized by the patent owner, include the U.S. FTAs with Singapore, Chile, Morocco, Australia, Bahrain, and the countries of the DR-CAFTA.⁵⁵

In combination, many U.S. FTAs prohibit generic producers from challenging a patent until after it has been granted. U.S. proposals for the Trans-Pacific Partnership negotiations would

⁴⁹ Sell discusses the detrimental effect of the interplay between TRIPS-Plus provisions. For example, the ability of a state to issue compulsory licenses is affected by data exclusivity provisions and drug registration/patent linkage provisions. As a result, “prospective licensees are unlikely to replicate test data, and government cannot normally wait until a new set of test data has been developed.” Sell, *supra* note 40, at 454.

⁵⁰ See DEERE, *supra* note 19, at 338–40.

⁵¹ See Carlos M. Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, 84 BULL. WORLD HEALTH ORG. 399, 401 (2006); see also Sell, *supra* note 40, at 452–55.

⁵² For example TRIPS-Plus data exclusivity requirements are included in U.S. FTAs with Morocco, Bahrain, Singapore, Australia, and DR-CAFTA. See Carsten Fink and Patrick Reichenmiller, “Tightening TRIPS: Intellectual Property Provisions of U.S. Free Trade Agreements”, Richard Newfarmer, ed., TRADE, DOHA, and DEVELOPMENT: A WINDOW INTO THE ISSUES (The World Bank: Washington D.C., 2006): 291.

⁵³ See DEERE, *supra* note 19, at 338–40; Sell, *supra* note 40, at 453.

⁵⁴ See Sell, *supra* note 40, at 453.

⁵⁵ See DEERE, *supra* note 19, at 338–40. TRIPS-Plus U.S. FTAs include: The United States – Chile Free Trade Agreement, www.ustr.gov/trade-agreements/free-trade-agreements/chile-fta/final-text; The United States – Singapore Free Trade Agreement, www.ustr.gov/trade-agreements/singapore-fta/final-text; The United States – Morocco Free Trade Agreement, www.ustr.gov/trade-agreements/morocco-fta/final-text; The United States – Australia Free Trade Agreement, www.ustr.gov/trade-agreements/australia-fta/final-text; The United States – Bahrain Free Trade Agreement, www.ustr.gov/trade-agreements/bahrain-fta/final-text; the Dominican Republic – Central America - United States Free Trade Agreement (CAFTA-DR), www.cafta-dr-dominican-republic-central-america-fta/final-text.

expressly forbid pre-grant opposition.⁵⁶ Pre-grant opposition provisions in national laws permit generic producers to contest the patent application as it is filed. Without pre-grant opposition, generic producers wishing to challenge the validity of a drug patent have to wait until the patent has been granted and may have to engage in a costly and time-consuming judicial process. These provisions thus effectively block a generic company from obtaining marketing authorization from health authorities during the period that a patent is contested, again creating delays for generic companies and stalling competition.⁵⁷

In addition, a number of FTAs expand the patent term to make up for delays in the application process. They thus may significantly extend the 20-year period of patent protection provided under the TRIPs Agreement. The US. has FTAs with Vietnam, Jordan, Singapore, Chile, Morocco, Australia, Bahrain, and the DR-CAFTA which all contain provisions that provide patent term extensions for delays caused by regulatory approval processes.⁵⁸

The bilateral TRIPS-plus agreements are complemented by a unique “certification” process pursuant to which the U.S. Executive must certify to the U.S. Congress that the foreign country has modified its laws in compliance with the agreement in order for the agreement to take effect.⁵⁹ This certification process, in practice, requires the foreign country to show its draft legislation to the U.S. executive and receive its approval. The U.S. typically demands changes in such legislation, triggering a new, one-sided negotiation over that country’s implementing legislation. The aim of the U.S. executive is, once more, to reduce any flexible interpretations of the agreement’s requirements. In contrast, and asymmetrically, under U.S. law, the bilateral agreement will have no effect if it conflicts with any existing or subsequent U.S. law.⁶⁰

These TRIPS-plus agreements are part of a U.S. strategy to divide developing countries. Those countries that have already increased IP protections under an FTA with the U.S. have nothing to lose from their being multilateralized (and perhaps much to gain as other developing countries and their constituencies will then have to pay increased royalties and license fees to U.S. companies as well). Over time, as developing country holdouts become isolated, a tipping point could be reached through which the more stringent legal requirements become multilateralized.⁶¹

The U.S. so far has been unsuccessful in negotiating enhanced patent protections in multilateral fora since the TRIPs Agreement. Thus the U.S. has pursued not only bilateral FTAs, but also plurilateral agreements. In particular, it initially failed in its efforts to negotiate a

⁵⁶ *Draft: Trans-Pacific Partnership—Intellectual Property Rights Chapter*, KNOWLEDGE ECOLOGY INT’L (Feb. 10, 2011), <http://www.keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>. For discussion, see Sean Flynn, Brook Baker, Margot Kaminski & Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT’L L. REV. 106 (2012).

⁵⁷ See DEERE, *supra* note 19, at 338.

⁵⁸ See *id.* at 338–40; see also Correa, *supra* note 46, at 401.

⁵⁹ For example, the U.S. Congress passed an implementation bill in the United States–Central American–Dominican Republic Free Trade Agreement that requires the President to certify that the signatories have complied with the FTA provisions before its entry into force. Dominican Republic–Central American–United States Free Trade Agreement Implementation Act, Publ. L. 109-53, 109th Cong., 1st sess. (2005), Section 101, “Approval and Entry into Force of the Agreement”; see also: “Bush secures CAFTA vote in last hours with renewed textile pledge”, *Inside U.S. Trade* July 29 (2005), (World Trade Online).

⁶⁰ Frederick Abbott, “Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law”, UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper No. 12, February 2006; available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1912621, 3-5.

⁶¹ Peter Drahos, *Bits and Bips*, 4 J. WORLD INTELL. PROP. 791 (2001).

Substantive Patent Law Treaty (SPLT) under the auspices of WIPO.⁶² The U.S. then led efforts with Japan to strengthen IP enforcement through a new Anti-Counterfeiting Trade Agreement (ACTA), which the USTR calls “the highest-standard plurilateral agreement ever achieved concerning the enforcement of intellectual property rights.”⁶³ Signed by eight countries on October 1, 2011,⁶⁴ non-signatories may be affected since the U.S. undoubtedly will press for countries to adopt its provisions as a condition for new FTAs.⁶⁵ Indeed, the Office of the United States Trade Representative (USTR) maintains that “it looks forward to partnering with developing countries through ACTA, and cooperating with ACTA partners to provide technical assistance to developing countries.”⁶⁶

Many commentators have noted the unbalanced nature of ACTA, finding that it favors rights-holders.⁶⁷ Unlike the WTO Doha negotiating text⁶⁸ and the WIPO Development Agenda,⁶⁹ ACTA includes no development dimension. It lacks language concerning limitations and exceptions for fair use of copyrights, and early drafts of ACTA would have endorsed in-transit seizures of generic drugs.⁷⁰ It creates a new ACTA Committee to oversee IP enforcement under its terms. The U.S. now views ACTA as the new (raised) floor for IP enforcement.

ACTA constitutes a “club” agreement in which only industrialized countries interested in strong IP protection were invited to participate.⁷¹ Argentina, Brazil, India and China were thus

⁶² See, e.g., Sell, *supra* note 40, at 455 (“In intellectual property norm setting, developing countries successfully rebuffed the U.S. and European efforts to pursue a TRIPS-plus Substantive Patent Law Treaty (SPLT) at WIPO.”). After painstaking negotiations to resume formal discussion, in late 2010 the Standing Committee on the Law of Patents agreed to begin work on multilateral agreements on exceptions and limitations and patent quality. William New and Kaitlin Mara, “WIPO Returns to Substantive Patent Law Talks after 5 years with Balance”, Intellectual Property Watch, 10/16/2010. Available at: <http://www.ip-watch.org/2010/10/16/wipo-returns-to-substantive-patent-law-talks-after-5-years-with-balance/print>; Kimberlee Weatherall, “Three Lessons from ACTA and its Political Aftermath”, 35 Suffolk Transnat’l L. Rev. 575 (2012).

⁶³ *Anti-Counterfeiting Trade Agreement (ACTA)*, OFFICE OF THE U.S. TRADE REP., <http://www.ustr.gov/acta> (last visited Mar. 15, 2013).

⁶⁴ The signatories were the U.S., Australia, Canada, Korea, Japan, New Zealand, Morocco, and Singapore. *Id.*

⁶⁵ Sell, *supra* note 40, at 456 (“Inevitably, TRIPS-plus ACTA provisions will reappear in bilateral and regional trade agreements going forward in an effort to raise global standards of protection.”).

⁶⁶ *Trade Facts: Anti-Counterfeiting Trade Agreement*, OFFICE OF THE U.S. TRADE REP. (Aug. 4, 2008), available at http://www.ustr.gov/sites/default/files/uploads/factsheets/2008/asset_upload_file760_15084.pdf.

⁶⁷ See Sell, *supra* note 40, at 457; Sean Flynn, “Learning from ACTA: Toward a Positive Agenda for TPP”, (March 3, 2012). Available at: <http://www.infojustice.org/archives/8650>; Margot E. Kaminski, *An Overview and the Evolution of the Anti-Counterfeiting Trade Agreement*, 21 ALB. L.J. SCI. & TECH. 385, 394–95 (2011); J. Janewa Oseitutu, “Value Divergence in Global Intellectual Property Law”, 87 Ind. L.J., 1639, 1667–69 (2012); Andrew Rens, “Enforcement Theater: The Enforcement Agenda and the Institutionalization of Enforcement Theater in the Anti-Counterfeiting Trade Agreement”, 35 Suffolk Transnat’l L. Rev. 553, 556 (2012).

⁶⁸ WT/MIN (05)/DEC 22 December 2005 “Doha Work Programme Ministerial Declaration (adopted 12/18/2005) available at: www.wto.org/english/thewto_e/minist_e/min05_e/final_text_e.htm

⁶⁹ WIPO Doc. A/43/16 Annex A. (September 2007)

⁷⁰ Margot E. Kaminski, *An Overview and the Evolution of the Anti-Counterfeiting Trade Agreement*, 21 ALB. L.J. SCI. & TECH. 385, 394–95 (2011) (“The only time ACTA mentions limitations or exceptions is in its discussion of technological circumvention measures, stating that “appropriate” limitations or exceptions may be maintained or adopted by parties in providing for remedies for the circumvention of technological measures.”); Weatherall, 2012, 577.

⁷¹ Daniel Gervais, “International Decision”, 103 Am. J. Int’l L. 549, 555 (2009); Peter K. Yu, *ACTA and Its Complex Politics*, 3 WIPO J. 1 (Nov. 2011); Peter K. Yu, *TRIPS and Its Achilles’ Heel*, 18 J. INTELL. PROP. L. 479, 513 (2011). On club goods see Richard Cornes and Todd Sandler, *THE THEORY OF EXTERNALITIES, PUBLIC GOODS, AND CLUB GOODS* (Cambridge: Cambridge University Press, 1996).

excluded. The draft texts were also kept from the public so that there was less opportunity to shape debates. The final agreement, moreover, was not even being presented to the U.S. Congress for ratification, but rather went into effect as a so-called sole “Executive Agreement” on the grounds that it is a trade agreement, and not an IP agreement.⁷² However, it is a trade agreement in name only, and not in substance.⁷³ Had it been negotiated as an IP agreement under WIPO’s auspices, the treaty would have had to be presented to the Senate requiring a 2/3rds supra-majority approval under the Treaty presentment clause of the U.S. constitution. The future of ACTA, nonetheless, remains uncertain after the European Parliament overwhelmingly voted against it. Hundreds of thousands of Europeans took to the streets to protest ACTA in February 2012 and the European Union has suspended ratification.⁷⁴

The U.S. is now actively negotiating to join another plurilateral agreement, the Trans-Pacific Partnership (TPP) Agreement. Leaked negotiating texts indicate that the U.S. aims to introduce more TRIPs-Plus provisions.⁷⁵ In these negotiations, the U.S. now looks to ACTA and the 2011 U.S.-Korea FTA as providing the new “gold standard” for IP protection and enforcement.⁷⁶ In sum, industrialized countries continue to work with the pharmaceutical and entertainment industries to build an enhanced IP transnational legal order.

IV. THE EMERGENCE OF A COUNTERVAILING TLO FOR ECONOMIC AND SOCIAL RIGHTS

Implementing the TRIPs Agreement has been more of a challenge than the U.S. and Europe initially contemplated.⁷⁷ It has been so, in large part, because a countervailing process of transnational legal ordering has emerged with a different normative frame, one with a human rights focus.⁷⁸ Developing countries, non-state actors, and UN-based organizations have advanced this frame at the international and national levels both to counter the push for ever stronger IP protections, and to spur recognition and application of a right to health in public policy more generally. As the right to health becomes institutionalized nationally and transnationally, it too can be viewed as a TLO. It interacts with and rivals the TLO for IP protection when the two overlap in addressing an issue, such as access to life-saving medicines.

At the international level, developing countries have found support from the World Health Organization (WHO) Assembly, the UN Committee on Economic, Social and Cultural Rights, the UN High Commissioner on Human Rights (UNHCHR), the UN Special Rapporteur on the Right to Health, and the Joint UN Programme on HIV/AIDS. The WHO Constitution establishes that

⁷² Jack Goldsmith & Lawrence Lessig, *Anti-Counterfeiting Agreement Raises Constitutional Concerns*, WASH. POST, Mar. 26, 2010, <http://www.washingtonpost.com/wp-dyn/content/article/2010/03/25/AR2010032502403.html> (discussing the Obama administration’s assertion that ACTA will be adopted as a sole executive agreement).

⁷³ Sell, *supra* note 40, at 456 (noting ACTA is an IP treaty, a fact counterintuitive in light of its name).

⁷⁴ Sean Flynn, *Learning from ACTA: Toward a Positive Agenda for TPP*, INFOJUSTICE.ORG (Mar. 3, 2012), <http://www.infojustice.org/archives/8650>; Susan K. Sell, *Revenge of the “Nerds”: Collective Action Against Intellectual Property Maximalism in the Global Information Age*, INT’L STUDIES REV., Vol. 15, No. 1 (2013).

⁷⁵ For a detailed analysis, see Flynn, Baker, Kaminski & Koo, *supra* note 50.

⁷⁶ U.S. TPP IPR Proposal Offers Middle Ground Between ‘May 10’ Korea FTA, INSIDE U.S. TRADE (Oct. 27, 2011), <http://insidetradetrade.com/Inside-US-Trade/Inside-U.S.-Trade-10/28/2011/us-tpp-ipr-proposal-offers-middle-ground-between-may-10-korea-fta/menu-id-710.html>.

⁷⁷ See, e.g., Yu, *TRIPS and Its Achilles’ Heel*, *supra* note 63 (discussing the particular difficulty TRIPS enforcement provisions have posed).

⁷⁸ See Lisa Forman, “Rights” and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines?, 10 HEALTH & HUM. RTS. 37 (2008); Helfer, *supra* note 15.

“the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.”⁷⁹ The right to health also is incorporated in multiple human rights instruments, including the 1948 Universal Declaration on Human Rights, the International Covenant on Economic Social and Cultural Rights, and the United Nations Human Rights Council.⁸⁰ The UNHCHR identified access to essential medicines as “a vital component of fulfilling the right to health.”⁸¹ The UN Millennium Development Goals (MDG) include access to essential medicines; the MDG Gap Task Force Report 2012 advised that “developing countries should carefully assess possible adverse impacts on access to medicines when adopting Trips-Plus provisions.”⁸²

Such rights advocacy helped to build alternative normative framings and pressure for the amendment and interpretation of the TRIPS Agreement in light of social welfare concerns, as reflected in the negotiation of the Doha Declaration on TRIPS and Public Health in 2001. Egypt, Brazil, and Argentina, supported in parallel by powerful campaigns by non-governmental organizations (NGOs), proposed and succeeded in establishing the WIPO Development Agenda.⁸³ The WIPO Development Agenda has been viewed as “a call for restraint on the part of developed countries in their crusade for ever-stronger IP protection.”⁸⁴ After six years of debate, WIPO adopted a series of recommendations related to the Development Agenda in 2007, and temporarily suspended negotiations for a new Substantive Patent Law Treaty that industrialized countries had promoted.⁸⁵ Even though critics contend that WIPO remains part of a transnational legal culture focused on IP protection as defined predominantly by industrialized country legal systems, WIPO’s Development Agenda reflects a move to a more development-friendly approach to IP, endorsing access to technology and benefit-sharing.⁸⁶

Institutionalizing the human right to health has gained momentum at the regional and national levels as well. Laurence Helfer and Karen Alter have analyzed the Andean Community’s successful regional pro-access to medicines decisions in the Andean Tribunal.⁸⁷ They demonstrate

⁷⁹ WORLD HEALTH ORG., WORLD INTELLECTUAL PROPERTY ORG. & WORLD TRADE ORG., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE 40 (2013) [hereinafter PROMOTING ACCESS] (quoting the Constitution of the WHO).

⁸⁰ *Id.* at 40–41.

⁸¹ *Id.* at 42.

⁸² *Id.* at 43.

⁸³ DEERE, *supra* note 19, at 128. WIPO Doc. A/43/16 Annex A. (September 2007)

⁸⁴ DEERE, *supra* note 19, at 128. On various ways to frame an understanding of the WIPO Development Agenda, see Neil Netanel, ed. THE DEVELOPMENT AGENDA: GLOBAL INTELLECTUAL PROPERTY AND DEVELOPING COUNTRIES (N.Y.: Oxford University Press, 2009).

⁸⁵ *Id.* at 132. However, as of this writing, negotiations on a Substantive Patent Law Treaty have been renewed by WIPO. William New and Kaitlin Mara, “WIPO Returns to Substantive Patent Law Talks after 5 years with Balance”, Intellectual Property Watch, 10/16/2010. Available at: <http://www.ip-watch.org/2010/10/16/wipo-returns-to-substantive-patent-law-talks-after-5-years-with-balance/print>

⁸⁶ See, e.g., Sell, *supra* note 40, at 450; Peter K. Yu, *A Tale of Two Development Agendas*, 35 OHIO N.U. L. REV. 456, 515–22 (2009) (describing the Development Agenda’s evolution into an “agenda on pro development reform of the international intellectual Property system”). For more cautious assessments see Ruth Okediji, “History Lessons for the WIPO Development Agenda”, in Netanel (2009): 137-161; and Keith Maskus, “The WIPO Development Agenda: A Cautionary Note”, in Netanel (2009): 163-174.

⁸⁷ Laurence Helfer & Karen Alter, *The Influence of the Andean Intellectual Property Regime on Access to Medicines in Latin America*, in BALANCING WEALTH AND HEALTH; GLOBAL ADMINISTRATIVE LAW AND THE BATTLE OVER INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN LATIN AMERICA (Rochelle Dreyfuss & Cesar Rodriguez-Garavito eds., 2013).

that Andean governments *required* the adoption of TRIPs flexibilities in implementation. The Andean Tribunal has been able to combat TRIPS-Plus provisions by enforcing bans on pipeline patents, second-use patents, and placing limits on data exclusivity.⁸⁸

The development of a rival economic and social rights frame, most importantly, is reflected at the national level in the growth of new transnational constitutional law movements.⁸⁹ Although there is a small body of literature on the role of constitutionalism in international law,⁹⁰ it is this bottom-up transnational constitutional movement that is the key development, representing a sweep of judicialization and rights adjudication around the world.⁹¹ This movement diffuses constitutional law norms across national jurisdictions that can be used to interpret international law commitments, such as those under the TRIPS Agreement and the ICESCR. As a joint report of the WHO, WIPO and the WTO notes, “[b]y 2009, 135 countries had incorporated aspects of the right to health in their national constitutions.”⁹²

Brazil, India, and South Africa have enjoyed some notable success in implementing provisions facilitating access to medicines and the use of TRIPs flexibilities. They all successfully have warded off legal challenges from originator drug firms and their government sponsors.⁹³ India, for example, defended itself against the Swiss pharmaceutical firm Novartis’ challenge to India’s right to implement flexibilities to prevent evergreening.⁹⁴ In April 2013 The Indian Supreme Court upheld the Indian Patent Office’s decision to deny Novartis a patent on its drug Gleevec.⁹⁵ India and Brazil also lodged complaints at the WTO against the European Union and the Netherlands, in May 2010, for seizing generic drugs in transit. In its complaint, India invoked relevant TRIPs provisions as well as the Doha Ministerial Declaration on TRIPS and Public Health

⁸⁸ Helfer and Alter.

⁸⁹ See, e.g., VICKI JACKSON, *CONSTITUTIONAL ENGAGEMENT IN A TRANSNATIONAL ERA* (2009); Tom Ginsburg, *Locking in Democracy: Constitutions, Commitment and International Law*, 38 N.Y.U. J. INT’L L. & POL. 707 (2006).

⁹⁰ JEFFREY L. DUNOFF & JOEL P. TRACHTMAN, *RULING THE WORLD?: CONSTITUTIONALISM, INTERNATIONAL LAW, AND GLOBAL GOVERNANCE* (2009); JAN KLABBERS ET AL., *THE CONSTITUTIONALIZATION OF INTERNATIONAL LAW* (2009).

⁹¹ See Hirschl, *The Judicialization of Politics*, in *THE OXFORD HANDBOOK OF LAW AND POLITICS* 126–27 (Keith E. Whittington, R. Daniel Kelemen & Gregory A. Caldeira eds., 2008); Tom Ginsburg & Mila Veerstedt, *The Global Spread of Constitutional Review: An Empirical Assessment*, *Journal of Law, Economics and Organization* (forthcoming 2014). As Ginsburg and Veerstedt write, “[b]y our account, some 38% of all constitutional systems had constitutional review in 1951; by 2011, 72% of the world’s constitutions gave courts the power to supervise implementation of the constitution and set aside legislation for incompatibility . . . Arguably, this trend is one of the most important phenomena in late 20th and early 21st century government.” *Id.* For a political science analysis of diffusion from below see, Ann Towns, *Norms and Social Hierarchies: Understanding International Policy Diffusion “From Below”*, INT’L ORG., Vol. 66, No. 2, 179–209 (2012).

⁹² PROMOTING ACCESS, *supra* note 71, at 40.;

⁹³ See, e.g., HELFER & AUSTIN, *supra* note 15; Smita Narula, *The Rights-Based Approach to Intellectual Property and Access to Medicines: Parameters and Pitfalls* (N.Y.U. Public Law and Legal Theory Working Papers, Working Paper No. 299, 2011), available at http://lsr.nellco.org/nyu_plltwp/299.

⁹⁴ See, e.g., Sandeep Rathod, *Evergreening: A Status Check in Selected Countries*, 7 J. Generic Medicines 227 (2010)

⁹⁵ After a seven year legal battle, the Indian Supreme Court upheld a decision of the Indian Patent Office to refuse to grant a patent on the Swiss pharmaceutical company Novartis’ Gleevec. Under Indian patent law, section 3(d) requires that patents only be granted on new and innovative compounds that have demonstrated increased therapeutic efficacy. This law aims to curtail the pharmaceutical firms’ practice of evergreening. See Ellen ‘t Hoen, “A Victory for Global Public Health in the Indian Supreme Court”, *JOURNAL OF PUBLIC HEALTH POLICY* (2013), 1-5.

and Article 12(1) of the ICESCR, “which recognizes the right of all persons to the enjoyment of the highest attainable standard of physical and mental health.”⁹⁶ India and Brazil obtained a favorable settlement as a result.⁹⁷

Smaller countries such as Ecuador also have been champions of promoting access to health. For example, a coalition of local generic drug producers, social, environmental and indigenous organizations enjoyed the strong support of Ecuador’s President Correa who rejected a proposed U.S.-Ecuador FTA. In doing so, they framed intellectual property rights as “an urgent health issue.”⁹⁸

Around the world, national courts have become bolder in overseeing human rights protections, including economic and social rights, such as the right to health. National courts in Argentina, Colombia, Costa Rica, Ecuador, El Salvador, Peru, South Africa, Kenya, and Venezuela have recognized HIV/AIDS patients’ rights to access to medicines.⁹⁹ As Laurence Helfer points out, “a 2006 study identified seventy-one cases from twelve countries invoking a right of access to medicines, with a success rate of 83 percent.”¹⁰⁰ This national move in developing countries of incorporating a human rights frame can also contribute, and in a number of countries already has contributed, to interpreting and shaping the definition of IP rights at the national level.

V. STRATEGIES FOR DEVELOPING COUNTRIES

The development of a rival human rights transnational legal order has created pressure to shape patent law in developing countries for social ends. Toward this end, developing countries can adopt pragmatic strategies to shape and tailor IP legal norms and practices. This chapter concludes by raising five complementary strategies, two concerning substantive matters and three institutional ones.¹⁰¹

A. Substantive strategies

⁹⁶ Lisa Forman, *An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law*, J. WORLD INTELL. PROP., Vol. 14, No. 2, 168 (2011) (quoting Indian complaint).

⁹⁷ Whether the settlement goes far enough is still a matter of debate. See Brook K. Baker, *Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough* (Am. Univ. Washington Coll. Law, PIJIP Research Paper no. 2012-02, Dec. 2012), available at <http://digitalcommons.wcl.american.edu/research/24/>.

⁹⁸ Antoni Verger & Barbara van Paassen, *Human Development vis-à-vis Free Trade: Understanding Developing Countries’ Positions in Trade Negotiations on Education and Intellectual Property Rights*, 2012 REV. OF INT’L POL. ECON. 22.

⁹⁹ Helfer, *Pharmaceutical Patents*, *supra* note 15.; Patricia Asero Ochieng et. al., Petition No. 409 of 2009, Judgment, High Court of Kenya, April 20, 2012, <http://www.aidslawproject.org/wp-content/uploads/2012/04/Judgment-Petition-No-409-of-2009-Anti-counterfeit-case.pdf> The Kenyan High Court struck down a U.S.-sponsored anti-counterfeiting law. The Court cited the right to health and determined that the law would have curbed access to generic medicines.

¹⁰⁰ *Id.*

¹⁰¹ These strategies complement those proposed by others for the implementation of intellectual property regimes within developing countries, such as Professor Carlos Correa, Rochelle Dreyfuss, César Rodríguez-Garavito, and Amy Kapczynski. See, e.g., Frederick Abbott, *The TRIPS-Legality of Measures Taken to Address Public Health Crises: Responding to USTR-State-Industry Positions that Undermine the WTO*, in THE POLITICAL ECONOMY OF INTERNATIONAL TRADE LAW (Daniel Kennedy & James Southwick eds., 2002); CARLOS CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS (2000).

A number of developing countries and their stakeholders have adopted two complementary strategies to shape IP norms. On the one hand, they have participated in the development of a rival TLO that can affect the interpretation and application of IP law, that of economic and social rights. On the other hand, they may apply long-established U.S. and EU exceptions to IP protections in new ways to address broader social goals, strategically building from the foreign to meet local needs.

1. Developing alternative normative frames for the interpretation of international IP norms.

As John Braithwaite and Peter Drahos contend in their book *Global Business Regulation*, less powerful stakeholders in global debates fare better if they invest resources in developing principle-based normative frames. These frames can then be combined with technical expertise to apply them. Otherwise, such expertise will tend to work within normative frames created by powerful actors, such as the U.S. and EU, and diffused through technical assistance programs, whether through WIPO, WTO, bilateral or private sector programs. The U.S., for example, arguably has the strongest protections of free speech in the world under the First Amendment of the U.S. Constitution, which it does not compromise in applying policies in overlapping policy domains. Developing countries can do the same using the normative frames of human rights, consumer protection, access to medicines, and access to knowledge in applying IP law. As is already evident in the right to health context, these frames can be transnationalized through the support of allied civil society groups and international institutions, furthering the development of a rival TLO that can be used for local ends.

2. Citing U.S. and EU precedents while transforming them for national purposes.

As the French child psychologist Jean Piaget writes, “to comprehend is to invent.”¹⁰² Developing countries are required to implement international IP law that they have signed and ratified, which sets forth particular concepts, standards and rules. They can do so, however, in light of their development needs by inventing while implementing, by adapting while adopting. The U.S. and EU legal systems for IP include exceptions which reflect U.S. and EU social goals. Developing countries can strategically cite these exceptions conceptually, but apply them in new ways, thereby building from the foreign in a manner that advances the local. In this way, developing countries can help to foil U.S. and EU pressures by noting that they are applying exceptions recognized in U.S. and EU law itself, and applied by their courts,¹⁰³ even if U.S. and EU courts in practice would apply the exceptions differently. For example, Indian courts have limited the granting of injunctive relief to curtail access to generic medicines, creatively citing U.S. jurisprudence for support. In a 2008 case, *Roche v. Cipla*, the Indian court determined that it would apply the normal Indian standards for granting a preliminary injunction, which are more limited than the standards demanded by IP rights holders. Interestingly, the Indian court creatively cited a US case, *eBay v. MercExchange*, and a non-precedential U.S. Federal Circuit decision that noted public health concerns, to affirm the denial of an injunction in a case involving a drug-eluting

¹⁰² See JEAN PIAGET, OÙ VA L'ÉDUCATION? COMPRENDRE, C'EST INVENTER (1973). Roberto Unger appears to have adapted this concept slightly while attributing it to Piaget. See ROBERTO MANGABEIRA UNGER, DEMOCRACY REALIZED 96 (2000) (“To imitate, wrote Piaget, is to invent.”).

¹⁰³ Jerome Reichman, “Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow?” HOUST L. REV. 46(4): 1115-1185 (2009).

stent.¹⁰⁴ The Indian court concluded that harm to third parties would be irreparable and denied a preliminary injunction, even though it appears that U.S. courts would have regularly granted it under U.S. case law.¹⁰⁵

Additional opportunities may exist for using U.S. precedents and practices in the area of antitrust/competition law that have sought to balance protecting innovation while trying to constrain health care costs. The U.S. Federal Trade Commission (FTC) has fined brand name companies that pursue strategies of product launches that “serve no purpose other than to undermine the ability of a generic to compete.”¹⁰⁶ The FTC is more likely to pursue a case in which the plaintiff can demonstrate: “(1) reduced consumer choice; (2) additional conduct aimed at preventing generic substitution, and (3) little or no demonstrable medical benefit from substitution.”¹⁰⁷ Such strategies could support efforts to prevent evergreening and other market manipulations to stave off generic competition. While hardly a panacea, adopting and implementing strong competition laws to reduce IP-related abuses of monopoly positions is a strategy that has been advocated and implemented in a number of countries, such as South Africa.¹⁰⁸

B. Institutional strategies

Institutional strategies complement substantive ones. Developing countries have implemented a number of institutional strategies to advance their positions and thwart pressure on them. They have invested in developing local technical expertise that can build links regionally and transnationally.

1. Developing Local Expertise.

Developing countries need to develop not only normative frames for addressing the trade-human rights-IP nexus; they also need technical expertise to apply it. In this way, they become entrepreneurs and not simply adapters of U.S. and EU legal norms that are institutionalized through international law and technical assistance implementation programs. This local IP expertise will need to be broad-based, embedded within government institutions, and include representatives of generic producers of pharmaceuticals, academics, and civil society.¹⁰⁹ In this way, developing

¹⁰⁴ EBAY INC. ET. AL. V. MERCEXCHANGE L.L.C. NO. 05-130 2005 available at: www.supremecourt.gov/opinions/05pdf/05-130.pdf

¹⁰⁵ Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571, 1607 n. 212 (2009) (citing F. Hoffmann-La Roche Ltd. v. Cipla Ltd. (2008) 642 I.A., available at <http://www.i-mak.org/storage/F%20Hoffmann%20La%20Roche%20v%20Cipla%20Ltd%202008.pdf>).

¹⁰⁶ Seth Silber & Kara Kuritz, *Product Switching in the Pharmaceutical Industry: Ripe for Antitrust Scrutiny?* J. GENERIC MEDICINES, Vol. 7, No. 2, 129 (2010) (quoting FTC Chairman Jon Leibowitz).

¹⁰⁷ *Id.* at 127.

¹⁰⁸ See Carsten Fink, *Comment I: Competition Law as a means of Containing Intellectual Property Rights*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 772 (Keith E. Maskus & Jerome H. Reichman eds., 2005); Heinz Klug, *Access to Medicines and the Transformation of the South African State*, in TRANSNATIONAL LEGAL ORDERING AND STATE CHANGE (Gregory Shaffer, ed. 2013).

¹⁰⁹ Brazil has built considerable expertise, for example, in WTO law. See Gregory Shaffer, *The Trials of Winning at the WTO: What Lies Behind Brazil's Success*, 41 CORNELL INT'L L.J. 383 (2008). See also BATTLING WEALTH AND HEALTH: GLOBAL ADMINISTRATIVE LAW AND THE BATTLE OVER INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN LATIN AMERICA (Rochelle Dreyfuss & César Rodríguez-Garavito eds., forthcoming) (focusing on this need and examples within the Latin American context); GREGORY SHAFFER & JAMES NEDUMPARA, *INDIA AND THE*

countries can better institutionalize alternative frames for addressing the IP- trade-human rights nexus at the national level.

Governments need to create strong institutions with professional expertise. Patent offices, for example, must make critical determinations in approving patents, as must courts in reviewing challenges to them. Peter Drahos has written extensively about the development of expertise in developing country patent offices in order for them to make independent decisions and not simply follow analyses made in the U.S. and European Patent Office (EPO).¹¹⁰ The Indian legal system, as well as a number of Latin American systems, for example, provides for important substantive and procedural innovations,¹¹¹ but these provisions will only have meaning if institutions apply them in practice. Institutions are most likely to implement them in practice if they are pressed to do so by legal advocates working with the generic pharmaceutical sector and civil society, supported by academics.¹¹²

2. Pooling resources.

One way that expertise can be built and diffused is by pooling resources through regional, transnational, and international alliances specializing in trade-related intellectual property issues.¹¹³ The Andean Pact provides an example of how such expertise can be institutionalized.¹¹⁴ Regional centers can provide a forum for the sharing of experiences and the identification of best practices. These centers can work with academics, or be tied to academic institutions. UNCTAD's development-oriented initiatives can serve as a node in this network.¹¹⁵ However, regional institutions can be captured if they are not developed in a bottom-up manner, as Carolyn Deere demonstrates in her study of the French West African organization for intellectual property, OAPI (Organisation Africaine de la Propriété Intellectuelle).¹¹⁶ Thus, broad-based initiatives that include health activists and generic pharmaceutical producers are, once more, central.

3. Coordinating with Allies in Industrialized Countries.

Finally, developing countries will need to continue to, coordinate with private parties and government authorities in the United States and Europe to undercut industry pressure in the formation of U.S. and EU negotiating positions and strategies. International negotiations involve a two-level game in which national constituencies compete in the formation of national positions

WTO (2013).

¹¹⁰ See, e.g., Peter Drahos, "Trust Me": *Patent Offices in Developing Countries*, 34 AM. J.L. & MED. 151 (2008).

¹¹¹ See, e.g., Paola Bergallo & Agustina Ramón Michel, *The Recursivity of Global Lawmaking in the Fight for an Argentine Policy on Drug Patents*, in BATTLING WEALTH AND HEALTH, *supra* note 97; Kapczynski, *supra* note 93, at 1571 (addressing Indian innovations in (1) the substantive evaluation of patents in terms of what constitutes novelty; (2) the substantive evaluation of patents in terms of what constitutes an inventive step; (3) the inclusion of broad standing rights to challenge a patent before it is issued through an administrative process; (4) limits on the grant of injunctive relief in favor of rights holders; and (5) the enhancement of rights to challenge patents under competition law).

¹¹² BATTLING WEALTH AND HEALTH, *supra* note 97.

¹¹³ See also Peter Drahos, *When the Weak Bargain with the Strong: Negotiations in the World Trade Organization*, 8 INT'L NEGOTIATION 79 (2003).

¹¹⁴ Laurence R. Helfer et al., *Islands of Effective International Adjudication: Constructing an Intellectual Property Rule of Law in the Andean Community*, 103 AM. J. INT'L L. 1 (2009).

¹¹⁵ DEERE, *supra* note 19, at 137–40.

¹¹⁶ *Id.*

and those national positions are then advanced in international negotiations.¹¹⁷ Developing countries can work with U.S. and European political allies to alter the U.S. and European domestic political calculus. If developing countries cannot neutralize the clout of large pharmaceutical firms in the formation of U.S. and European positions, then developing countries will face the full brunt of U.S. and European pressure in the negotiation and enforcement of pharmaceutical patent rights.

In a world of asymmetric power, developing countries enhance the prospects of their success if other U.S. and European constituencies offset the pharmaceutical industry's pressure on U.S. and European trade authorities to aggressively advance industry interests. Domestic and international non-governmental advocates, such as ACT UP, Doctors Without Borders, and Oxfam, have, directly and indirectly, been allies. They raise fundamental moral issues that are picked up in the media and that help to hold U.S. and EU political leaders accountable. They also harness the public's self-interest over the cost of prescription drugs and public officials' struggles to finance health care commitments within the United States and Europe themselves, potentially "destabilizing the consensus that U.S. business elites had built around TRIPS."¹¹⁸

This strategy has worked in a number of cases. The United States backed off from challenging South Africa's and Brazil's patent laws primarily in the context of U.S. domestic political pressures. AIDS activists gathered at Vice President Gore's presidential campaign stops holding placards for the nightly news and chanting "Gore's greed kills" to press the administration to change its policy on South Africa.¹¹⁹ The Bush administration withdrew the United States' claim against Brazil's compulsory licensing provisions under Brazil's patent law following similar protests.¹²⁰ United States Trade Representative Robert Zoellick again deflected U.S. pharmaceutical industry pressures in agreeing to the Declaration on the TRIPS Agreement and Public Health at Doha.¹²¹ U.S. negotiators were similarly pressed by a Democratic Congress to alter its negotiating positions in the FTAs with Columbia and Panama, ultimately concluded in 2011, to retain more flexibility for providing access to medicines.¹²² In short, when TRIPS issues become politicized domestically within the United States and Europe, developing countries retain greater leeway to develop intellectual property policies to fit their own needs.

¹¹⁷ See, e.g., DOUBLE-EDGED DIPLOMACY: INTERNATIONAL BARGAINING AND DOMESTIC POLITICS (Peter B. Evans, Harold K. Jacobson & Robert D. Putnam eds., 1993); Robert Putnam, *Diplomacy and Domestic Politics: The Logic of Two-level Games*, 42 INT'L ORG. 427 (1988). For an application to the US and EU contexts regarding trade, see GREGORY SHAFFER, DEFENDING INTERESTS: PUBLIC-PRIVATE PARTNERSHIPS IN WTO LITIGATION (2003).

¹¹⁸ JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION 576 (2001).

¹¹⁹ See Doug Ireland, *AIDS Drugs for Africa*, NATION, Oct. 4, 1999, at 5; Steven Meyers, *South Africa and U.S. End Dispute Over Drugs*, N.Y. TIMES, Sept. 18, 1999, at A8. Vice-President Gore was co-chairman of the U.S.-South Africa Bi-National Commission on pharmaceutical issues.

¹²⁰ See, e.g., U.S., *Brazil End WTO Case on Patents, Split on Bilateral Process*, 19 INSIDE U.S. TRADE 1, 2 (2001). Doctors Without Borders and Oxfam launched campaigns in the United States and Europe against US policies. See, e.g., *Drug Companies vs. Brazil: The Threat to Public Health*, OXFAM (May 1, 2001), available at <http://policy-practice.oxfam.org.uk/publications/drug-companies-vs-brazil-the-threat-to-public-health-114469>.

¹²¹ See also Gary Yerkey & Daniel Pruzin, *Agreement on TRIPS/Public Health Reached at WTO Ministerial in Doha*, 18 INT'L TRADE REP. 1817 (2001).

¹²² U.S. *TPP Environment Proposal Follows 'May 10,' But May Have Different Effects*, INSIDE U.S. TRADE, Nov. 18, 2011 ("The May 10 deal was negotiated between House Democrats and the Bush administration and strengthened labor rights and environmental protections in trade deals with Colombia, Panama and Peru, while also offering these countries additional flexibilities in the area of intellectual property rights in order to promote access to medicines."). Jamie Love at Knowledge Ecology International in the U.S., for example, has been relentless in the struggle for access to medicines and knowledge both domestically and transnationally. See, e.g., James Love, Director, KNOWLEDGE ECOLOGY INT'L, <http://keionline.org/jamie> (last visited Mar. 16, 2013) (including a biography and selected publications of James Love).

CONCLUSION

The construction of transnational legal orders provides normative ordering that addresses issues perceived to be problems that are transnational in scope. It thereby constrains and facilitates domestic law and practice. Developing countries can benefit from transnational legal ordering, but such ordering also can reflect the particular interests of powerful countries and constituencies within them. As regards the transnational legal ordering of trade and IP, constituencies within developing countries increasingly demand that their countries retain the flexibility to implement IP protection in a manner that respects human rights and development concerns.

Paradoxically, these countries profit from, and are also constrained by, a rival legal order that is also transnational in scope — that of the economic and social right to health. On the one hand, a number of developing countries have adopted strategies to deploy this rival TLO to advance their goals. Countries such as India and Brazil, for example, have attempted to adapt patent law in innovative ways, in part to meet the demands of constituencies within them to further a human right to health care. On the other hand, such constituencies have pressed the government to provide health services on human rights grounds that the government otherwise would have foregone, whether because of budgetary priorities or otherwise. Today, national law is made in transnational context, and national policies are being adapted accordingly. To understand and participate effectively in legal processes, one increasingly needs to think transnationally.