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Pharmaceutical Patents and the Human Right to Health

The Contested Evolution of the Transnational Legal Order on Access to Medicines

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I. INTRODUCTION

This chapter analyzes the origins, evolution, and impact of the TLO on access to medicines (A2M). This TLO is currently characterized by a low level of normative settlement and institutional alignment (the "low institutionalization" cell of Figure 1.3 in Halliday & Shaffer, Chapter 1). Disputes over the regulation of A2M are occurring in multiple transnational, national, and local venues, including the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), the UN Human Rights Council (UNHRC), the World Health Organization (WHO), bilateral treaty negotiations, national parliaments, constitutional courts, and domestic administrative agencies. Competing groups of states and non-state actors shift horizontally and vertically among these forums in an effort to develop competing legal rules over the propriety of granting intellectual property (IP) protection to newly developed life-saving drugs.

On one side of this contested terrain are multinational pharmaceutical companies and the industrialized countries in which they are based, which argue that strong patent protection is essential to incentivizing medical research and development. On the other side are public interest NGOs and developing country negotiators (including those from Brazil, India, South Africa, and several nations in Latin America), which invoke the human right to health to justify restricting pharmaceutical patents, facilitating the manufacture of cheaper generic copies, and maximizing the distribution of life-saving medicines to millions of the world's poor. Squeezed in the middle are many national governments, which confront a shrinking domestic policy space hemmed in by a thicket of overlapping treaty commitments, diminishing health budgets, and national court judgments ordering the provision of essential medicines to the patients who demand them.

This chapter applies the TLOs framework (Halliday & Shaffer, Chapter 1) to explain the origins of these controversies and their consequences. The chapter argues that the current state of affairs arose from a clash between two previously discrete TLOs – one relating to IP protection (specifically, patent protection for new drugs) and the other concerning the right to health (in particular, a right of access to essential medicines, including patented medicines). The collision between these unrelated TLOs occurred diachronically in three distinct phases.

In Phase 1, which occurred prior to the mid-1990s, the IP and right to health TLOs each existed in relatively stable but distinct policy spaces. Within each TLO, legal norms were highly aligned but unsettled, placing each TLO in the upper left quadrant of Figure 1.3 (in Halliday & Shaffer, Chapter 1). Section II of this chapter identifies the facilitating circumstances and precipitating conditions that led to the formation of each TLO, the degree of alignment among the relevant international institutions, and the interactions among key actors over the development of legal norms. It also describes the wide discretion that national and subnational actors enjoyed regarding how to regulate A2M.

Phase 2, which occurred roughly between the mid-1990s and 2000, involved a rapid expansion of the IP TLO, in particular, of the legal and geographic scope of pharmaceutical patents. This expansion resulted from the incorporation of IP into the WTO as embodied in the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) and the subsequent negotiation of regional and bilateral treaties that require "TRIPS Plus" IP standards. Section III of this chapter describes the formation, institutionalization, and domestic effects of these developments. It argues that the regulation of A2M during this period was characterized by a high degree of normative settlement and low levels of alignment (the lower right quadrant of Figure 1.3 in Halliday & Shaffer, Chapter 1), a configuration that reflected the ability of industrialized nations that favored strong patent protection for new drugs to impose their policy preferences on developing countries.

Section IV of the chapter analyzes Phase 3 – a period from approximately 2000 to the present – the most salient features of which were a backlash against pharmaceutical patents and a campaign by developing countries and civil society groups to increase A2M. The facilitating conditions for these events were an increase in the legalization and justiciability of the human right to health in international and national law. High-profile litigation by proponents of strong patents provided the precipitating events for this backlash. Specifically, the United States and pharmaceutical firms attempted aggressively to enforce pharmaceutical patents in Brazil and South Africa, ignoring the implications of both countries' efforts to combat the global HIV/AIDS pandemic. These enforcement efforts triggered a coordinated public relations and international advocacy response by key NGOs and developing country governments.

The result, at the international level, was a modest weakening of patent protection in the form of a WTO Ministerial Declaration on TRIPS and Public Health and an amendment of TRIPS. Galvanized by these developments, both proponents and opponents of IP shifted their advocacy strategies to different venues. Industrialized countries focused on bilateral and plurilateral treaty negotiations (including the Anti-Counterfeiting Trade Agreement (ACTA) and the Trans-Pacific Partnership (TPP)), and NGOs and patients invoked the right to health in national court litigation, especially in developing countries, to compel governments to broaden access to patented drugs. As a result of these competing efforts, contestations over A2M now occur simultaneously and sequentially in multilateral, regional, bilateral, and domestic forums, creating a TLO that is both weakly aligned and unsettled (the lower left cell of Figure 1.3 in Halliday & Shaffer, Chapter 1). For many governments, the unfortunate consequence is a marked diminution in the domestic policy space available to regulate A2M. Section V concludes by summarizing the chapter's contributions to the study of TLOs.

II. PHASE 1: DISTINCT TLOS FOR INTELLECTUAL PROPERTY AND HUMAN RIGHTS

This section analyzes the two distinct TLOs – one for IP and the other for the right to health – that governed A2M prior to the mid-1990s. After describing the facilitating circumstances and precipitating conditions that led to the formation of each TLO, it analyzes the degree of institutional alignment and normative settlement in each issue area, focusing on the legal and geographic scope of the relevant norms and the contestations among key actors at the transnational, national, and local levels. Section II concludes with an assessment of the combined impact of the two TLOs on the domestic regulatory space relating to A2M.

A. *The Intellectual Property TLO Prior to the Mid-1990s*

This section reviews the origins and evolution of the IP TLO, with a focus on patents and pharmaceuticals. It summarizes decades of legal and policy developments that commentators have analyzed in detail elsewhere (Sell 1998; Correa 2000; Watal 2001; Sell 2003; Helfer 2004).

1. Facilitating Circumstances and Precipitating Conditions

Patents are exclusive economic rights awarded to inventors for limited time periods that prevent others from making, using, importing, or selling the patented inventions. In return for granting these rights, patent applicants must disclose the

invention in a manner that enables others to put it into practice. Other prerequisites for patentability are novelty (a new characteristic not found in the "prior art"), non-obviousness (an "inventive step" not obvious to one skilled in the field), and utility or industrial applicability (Ho 2011).

Patents enable inventors to recoup the costs of their research and development and to earn a profit by charging consumers monopoly prices. From the public's vantage point, the patent system assumes that the short-term costs of higher prices are offset by the additional inventions that protection encourages over the long term. Stated in economic terms, the core justification for a patent system is the belief that patents improve dynamic efficiency (by stimulating innovation and technological progress) at the expense of static efficiency (resulting from the costs of monopoly pricing) (UK Commission on Intellectual Property Rights 2002).

National patent laws are exclusively territorial in scope. As a result, inventors lobbied for an international legal regime to protect their innovations in other jurisdictions. The Paris Convention for the Protection of Industrial Property, adopted in 1883 and revised periodically over the following century, harmonizes procedures relating to priority, registration, and licensing, and it requires national treatment for foreign patent owners. The treaty's substantive standards of protection, however, are extremely modest (Sell 2003: 108–109; Hestermeyer 2007: 35–37).

England and the United States first recognized patents for new medicines in the late 1700s. The laws of both countries distinguish between "product" and "process" patents for new drugs. A product patent grants the owner exclusive rights over the chemical compound itself; a process patent covers only the means by which that compound is made and allows others to produce the same drug using a different method. Many other countries, however, expressly excluded pharmaceuticals from one or both types of patent protection. For example, most developing nations and many industrialized countries did not recognize product patents for new drugs until well into the second half of the twentieth century. This omission was not inadvertent but rather reflected a conscious choice to promote the production, importation, and distribution of cheaper generic medicines. In reflection of this reality, the Paris Convention did not require signatory nations to recognize either product or process patents for medicines (Correa 2007: 271; Hestermeyer 2007: 28, 37).

Not surprisingly, the pharmaceutical industry strongly opposed the lack of full patent protection for new drugs. It framed its objection in economic and moral terms. The unfettered copying of patented medicines was, the industry complained, a competitive disadvantage for industrialized economies and a deplorable form of modern-day "piracy." These arguments resonated with industrialized country governments, which recognized the strategic importance of intangible knowledge goods for economic growth and international trade (Sell 1998; Deere 2009).

2. Institutionalization: Venues, Actors, and Norms

In the 1980s, the pharmaceutical industry launched a campaign for stronger IP rights. The campaign unfolded in two primary venues. At the national level, the industry lobbied the United States (and, to a lesser extent, the European Community) to threaten sanctions against countries that failed to protect those rights. Internationally, it opposed an effort by developing nations to roll back patent provisions of the Paris Convention.

The "Special 301" procedure adopted by the United States is perhaps the most well-known example of the national strategy. Section 301 of the Trade Act of 1974 authorized the U.S. Trade Representative to investigate countries with weak IP protection and threaten retaliatory trade sanctions against them. The United States deployed Special 301 against more than a dozen countries between the 1970s and early 1990s, successfully pressuring governments to enact IP reforms that benefitted foreign IP industries, including U.S.-based pharmaceutical companies (Katzenberger & Kur 1996; Puckett & Reynolds 1996).

In the framework provided by Halliday and Shaffer, Special 301 increased the geographic scope and normative unsettlement of the legal rules governing patent medicines at the national and local levels. As a result of U.S. pressure, laws on the books in targeted developing countries more closely reflected U.S. policy preferences. But law in action – specifically, the application of those laws by domestic patent examiners – was a different matter. Empirical studies of this period revealed continued lack of patent enforcement in many developing nations (Buscaglia & Guerrero-Cusumano 1995). In addition, the economic coercion that the United States deployed resulted in the adoption of legal norms that developing states either openly resisted or accepted only grudgingly.

Internationally, normative contestations played out in the early 1980s at a fractious diplomatic conference convened to consider revisions to the Paris Convention. WIPO was the most logical international organization to host these negotiations. The specialized UN agency was established in the late 1960s to "promot[e] creative intellectual activity and facilitat[e] the transfer of technology … to developing countries in order to accelerate economic, social and cultural development" (UN-WIPO Agreement 1967, Article 1) and to "promote the protection of intellectual property throughout the world" (WIPO Convention 1967, Article 3(i)). WIPO's Secretariat achieved these arguably disparate goals by administering IP treaties, providing technical assistance and policy advice to domestic IP administrative agencies, and hosting multilateral conferences for member states. No other international organization rivaled WIPO in the performance of these tasks, with the result that the IP TLO of the 1970s and 1980s was characterized by a high degree of issue area alignment.

The opening salvo in the WIPO patent wars occurred in 1980, when India and the Andean Pact countries introduced a proposal to give preferential treatment for the Paris Convention's developing country members, a revision that would have diluted the treaty's patent rules, including those relating to pharmaceuticals. The United States and other industrialized nations strongly opposed any efforts to weaken the treaty, and they introduced their own counterproposals to expand patent rights. The competing groups fought pitched diplomatic battles on and off for several years. When the dust settled in 1985, the United States and its allies had fought the developing countries to a standstill. The conference ended in a deadlock, without any revision of the Paris Convention (Sell 1998: 107–130).

The failed negotiations led the United States and the European Community to conclude that they could not satisfy the IP industries' demands for stronger patent protection in WIPO by revising the IP treaties within that organization's purview. Dissatisfaction with WIPO was a catalyst for radically restructuring the institutional alignment of the IP TLO, an issue that is analyzed in Section III.

B. The Human Rights TLO Prior to the Mid-1990s

This section provides a thumbnail sketch of the evolution of the international human rights regime, emphasizing developments relevant to the right to health analyzed at greater length elsewhere (Henkin et al. 2009; Helfer & Austin 2011).

1. Facilitating Circumstances and Precipitating Conditions

World War II provided the impetus for creating an international legal regime to protect the fundamental rights of all human beings. Confronted with irrefutable evidence of mass atrocities, the victors of that conflict resolved to change international law's presumption that abuses committed by a nation-state against its citizens within its borders was the concern of that state alone. During the ensuing decades, the human rights TLO developed in two principle ways – the articulation and refinement of a catalog of individual liberties and the creation of new international institutions.

States achieved the first objective by adopting numerous non-binding declarations and treaties to protect a wide array of civil, political, economic, social, and cultural rights. Many of the rights in these international instruments were later incorporated into national constitutions, legislation, and judicial decisions, providing a layer of domestic legal protection and remedies for violations. Human rights advocates were keenly aware, however, that governments are often unwilling or unable to police their own conduct. They thus supported the creation of international tribunals and review bodies to monitor whether governments were in fact respecting these rights.

Not surprisingly, many states were reluctant to submit themselves to external scrutiny and resisted proposals to create a global human rights court or centralized monitoring mechanism. Instead, the international institutions in the human rights TLO evolved in a piecemeal fashion, resulting in a dizzying array of courts, tribunals, commissions, committees, working groups, and Special Rapporteurs. Within the UN human rights system alone, the number of international review and monitoring mechanisms is staggering. It includes the Human Rights Council (which, prior to 2006, was known as the Commission on Human Rights); the Council's Advisory Committee (until 2006, the Sub-Commission on the Promotion and Protection of Human Rights); the High Commissioner for Human Rights; scores of Special Rapporteurs and working groups; and more than a dozen treaty bodies (Henkin et al. 2009).

These trends – normative expansion and institutional fragmentation – also characterized the evolution of the right to health. International recognition of this right dates back to the Universal Declaration of Human Rights, Article 25 of which states that everyone has "the right to a standard of living adequate for the health and well-being of himself and his family, including … medical care." The Preamble of the WHO Constitution similarly proclaims that "[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being."

The right to health has been reaffirmed in numerous global and regional human rights instruments (Marks 2006) and has been incorporated into two-thirds of national constitutions (Kinney & Clark 2004). The most prominent treaty is the International Covenant on Economic, Social and Cultural Rights (ICESCR), which "recognize[s] the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," including "those necessary for … [t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases" (ICESCR, Article 12). Adopted in 1966, the ICESCR entered into force ten years later. As of 1995, more than 130 countries had ratified the treaty.

2. Institutionalization: Venues, Actors, and Norms

Notwithstanding the widespread international acceptance of the right to health in principle, state and non-state actors continued to debate the content of the right at the national and local levels. ICESCR was drafted to attract ratifications from socialist states, developing nations, and industrialized countries. Such widespread appeal could only be achieved, however, by adopting vague norms that papered over deep-seated ideological divisions among these groups of countries (Henkin et al. 2009: 219).

Further underscoring these differences was the programmatic and promotional nature of the right to health. As the ICESCR states in a famously ambiguous

passage, each state party is required to "take steps … to the maximum of its available resources, with a view to achieving progressively the full realization of" economic, social, and cultural rights (ICESCR, Article 2.1). For many commentators, the incremental, resource-dependent nature of progressive realization robbed the right to health of any meaningful substantive content, provided insufficient guidance to states, and cast doubt on the justiciability of health rights by national courts (Fidler 1999: 188; Toebes 1999: 661–662; Meier & Mori 2005: 114). In the human rights TLO's early years, these normative challenges went mostly unanswered.

Beginning in the late 1980s, however, one international body responded to these criticisms. The Committee on Economic, Social and Cultural Rights (the ICESCR Committee) – a group of human rights experts that reviews state party reports on implementation of the ICESCR and issues recommendations concerning its interpretation – began to issue "general comments" that clarified and expanded economic, social, and cultural rights in novel ways. The committee developed a "violations approach" that distinguishes "core obligations" – minimum essential levels of each right that all states parties must immediately implement – from other aspects of rights that may be achieved progressively (General Comment No. 3 1990; Chapman 1998). The committee also articulated a distinctive tripartite framework of obligations to respect, protect, and fulfill. According to this framework, obligations to respect require states to refrain from interfering with protected rights. Obligations to protect "require states to prevent interference by third parties (particularly nonstate actors)." And obligations to fulfill "involve the duty … to adopt appropriate legislative, administrative, budgetary, judicial, promotional, and other measures aimed at the full realization of the rights in question" (Dennis & Stewart 2004: 491).

Through its general comments and review of state party reports, the ICESCR Committee became an international focal point for the normative development of economic, social, and cultural rights. The legal frameworks developed by the committee increased the institutional alignment of the human rights TLO, but they also modestly decreased its normative settlement, as states sometimes sparred with the committee over how to interpret and apply particular rights. These developments did not, however, alter the diverse geographic scope of economic, social, and cultural rights. A number of countries – including, most notably, the United States – refrained from ratifying the ICESCR and thus remained outside of the committee's normative orbit. And even with the committee's jurisprudential enhancements, economic, social, and cultural rights remained highly resource- and context-dependent, with the result that the content of rights varied widely depending on a country's level of economic development.

C. The Combined Impact of Distinct TLOs for Intellectual Property and for Human Rights on Access to Medicines

The previous sections describe the evolution of two distinct TLOs, one relating to IP and the other relating to human rights. During this period, which lasted until the mid-1990s, the international regulation of A2M was minimal and unobtrusive. Every state could decide whether or not to ratify the two key multilateral treaties – the Paris Convention and the ICESCR – whose preeminence signaled the high degree of institutional alignment within each TLO. Moreover, those states that did join could rightfully argue that these treaties did not impose onerous requirements regarding either patent protection for new drugs or the human right to health, nor did they contain robust international enforcement mechanisms to monitor potential violations.

As a result of this international regulatory lassitude, each nation enjoyed broad discretion to decide which domestic laws and policies best promoted its national welfare relating to A2M. Industrialized states that prioritized innovation by domestic pharmaceutical firms added process and product patents to their national IP statutes. In contrast, poorer developing countries were free to eschew such protection and instead adopt policies to increase the availability of cheaper medicines manufactured by generic drug companies at home or abroad.

Toward the end of this period, however, normative contestations increased in both TLOs. Within IP, industrialized and developing countries clashed at WIPO over the scope and content of patent protection rules, and the United States threatened to impose unilateral trade sanctions to pressure developing countries to recognize and expand the protection of pharmaceutical patents. Within human rights, nations that had ratified the ICECSR with the understanding that economic and social rights (including the right to health) were ambiguous and aspirational found themselves reporting to a committee of UN experts – the ICESCR Committee – which had developed a more precise violations approach and a tripartite framework of legal obligations.

Importantly, these normative contestations occurred exclusively *within* each TLO; they did not spill over the boundary *between* the two TLOs. Stated differently, the regulation of A2M was "partitioned" between the two TLOs, with "different subsets of [the] underlying issue" governed by distinct legal norms (Halliday & Shaffer, Chapter 1: 33) that allowed considerable discretion to national governments. Figure 9.1 provides a graphical illustration of this alignment.

The absence of *inter*-TLO conflicts may seem surprising, given that actors in both TLOs claimed the authority to regulate A2M. What explains this lack of engagement? During the second half of the twentieth century, the most pressing concerns

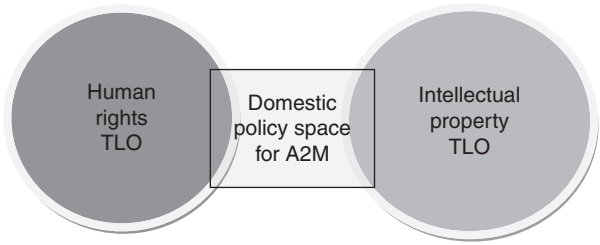

FIGURE 9.1. Two distinct TLOs for human rights and intellectual property.

in the human rights TLO were the elaboration and codification of legal norms and the creation of new international monitoring mechanisms (Helfer 1999: 296–301). In the IP TLO, in contrast, the post-war era's central focus was the gradual expansion of protected subject matter through multilateral treaty revisions that were then transposed to the national and local levels. Both sets of activities focused internally on building the core components of each legal order. More importantly, the states and non-state actors in each TLO interacted infrequently, if at all, and they did not view the other legal order as threatening their own TLO's sphere of influence or its opportunities for expansion (Helfer 2007: 280).

III. PHASE 2: THE EXPANSION OF THE IP TLO RELATING TO PHARMACEUTICAL PATENTS

The isolation between the two legal orders ended in the mid-1990s with a marked expansion of the IP TLO, in particular its international rules relating to product and process patents for new drugs. This expansion resulted from a deliberate and politically astute strategy by industrialized nations and their pharmaceutical industries to make strong IP protection rules a mandatory component of the world trading system. These actors achieved a major victory in 1994 with the adoption of the TRIPS Agreement, a multilateral IP treaty linked to the newly established WTO, whose detailed patent rules are far more demanding than those required by the Paris Convention.

In addition to raising substantive IP protection standards, this strategy radically increased the geographic scope and enforcement mechanisms of the IP TLO. As a condition of joining the WTO, every nation – including many developing countries that previously had denied patents for new drugs – was required to accept TRIPS and to participate in the WTO dispute settlement system. In the years immediately following the adoption of TRIPS, industrialized countries and pharmaceutical firms pushed for even further expansion of the IP TLO, demanding strict domestic implementation of IP rights, filing WTO complaints against countries that violated

TRIPS' patent rules, and negotiating regional and bilateral treaties that required pharmaceutical patent protections that exceeded even TRIPS' demanding standards (Sell 2003).

This section first identifies the facilitating circumstances and precipitating conditions that led to a dramatic "regime shift" from the WIPO to the WTO (Helfer 2004). As a consequence of this shift, the transnational regulation of A2M moved from the upper left to the lower right quadrant of Figure 1.3 (in Halliday & Shaffer, Chapter 1) due to an increase in normative settlement and a decrease in institutional alignment. This reconfiguration reflected the success of industrialized nations in imposing their desire for pharmaceutical patent protection on other countries, an imposition that narrowed the domestic policy space available to those countries to provide inexpensive drugs to consumers. As the section III.C reveals, however, the exercise of this hegemonic power was unstable and ultimately provoked a backlash in the human rights TLO over A2M.

A. *Facilitating Circumstances and Precipitating Conditions*

Two factors motivated the United States and the European Community to shift IP rulemaking from the WIPO, where it had been centered for decades, to the General Agreement on Tariffs and Trade (GATT), the principal treaty of the world trading system. The first factor related to dissatisfaction with the outcome of the Paris Convention negotiations hosted by the WIPO in the mid-1980s. The second focused on institutional features of the GATT that facilitated adoption of more stringent IP protection standards and enforcement mechanisms that these states favored. The end of the Cold War, the resulting rise of U.S. hegemony, and the shift to deregulated market-based economies facilitated the success of this endeavor.

As described in Section II, industrialized nations successfully fended off efforts by WIPO's developing country members to weaken international patent rules. The acrimonious failure of the Paris Convention diplomatic conference in the mid-1980s preserved existing treaty bargains, but it also convinced industrialized countries that it would be futile to launch any new initiatives to expand IP protection at WIPO. Instead, the United States (later joined by the European Community, Canada, and Japan) included IP protection as part of the mandate for the Uruguay Round of negotiations in GATT, which ultimately led to the creation of the WTO.

Three institutional features of the GATT/WTO made it a superior venue in which to negotiate stronger IP protection standards and enforcement mechanisms. First, as the nation and the region with the largest domestic markets, the United States and the European Community enjoyed far greater leverage in the GATT/WTO than they did in WIPO. GATT/WTO negotiations also operate on the principle of consensus, which the United States and the European Community used

strategically to force disclosure of weaker states' preferences, block proposals those states favored, and advance their own initiatives (Braithwaite & Drahos 2000: 570; Steinberg 2002: 350–367).

Second, the ability to link IP to trade expanded the zone of agreement among nations with divergent interests. Developing countries voluntarily accepted (or were coerced to accept) a grand bargain whose terms included greater access to the markets of industrialized nations in exchange for incorporating IP protection rules and enforcement mechanisms into the global trading system (Petersmann 1996–1997: 442; Drahos 2002: 769–770).

Third, GATT dispute settlement was far more effective than the adjudication mechanisms associated with WIPO conventions, mechanisms that were cumbersome in theory and never used in practice (Cordray 1994). More importantly, the Uruguay Round negotiators agreed to substantially overhaul GATT dispute settlement, establishing a system of mandatory adjudication that included binding ad hoc panels, a standing Appellate Body, and the threat of retaliatory sanctions to induce compliance by states found to have violated global trade rules.

By the spring of 1994, the United States and its industrialized country allies had achieved their primary objective – an agreement on "trade-related aspects of intellectual property rights" that incorporated strong IP rules into the world trading system. The next section describes the consequences for developing countries of this shift from the WIPO to TRIPS.

B. Increased Normative Settlement and Decreased Institutional Alignment

TRIPS effectuated nothing short of a revolution in the IP TLO. It increased substantive IP protection rules in several preexisting conventions negotiated within WIPO and incorporated them into a single comprehensive multilateral agreement. These standards applied to the entire WTO membership, including developing countries that had never joined the Paris Convention or that in practice had a tenuous or equivocal commitment to protecting IP in their domestic laws.

Of particular importance for A2M, TRIPS required that patents and the exclusive rights that accompany them be made available for inventions in "all fields of technology" if they are "new, involve an inventive step and are capable of industrial application" (TRIPS, Article 27.1). The breadth of this language and the treaty's negotiating history reveal that patent rights extended both to pharmaceutical products and to the processes for manufacturing those products (Gervais 2003: 218–219). These provisions significantly expanded the patentability of new drugs. As discussed in Section II, Phase 1 of the evolution of the A2M TLO (which lasted until the mid-1990s) was characterized by a widespread diversity of national practices, with many countries eschewing pharmaceutical patent protection on public health grounds.

Under TRIPS, however, "so long as an invention meets the technical requirements of patentability, a patent must be granted for an inventive product, including a pharmaceutical compound, even if it would negatively impact the accessibility of drugs" (Ho 2007: 1476).

In addition to expanding substantive patent rules, TRIPS also increased opportunities to enforce patent rights at the local, national, and international levels. For IP owners, the treaty enhanced domestic enforcement by requiring all WTO members to restructure their judicial and administrative systems relating to IP rights. For states, TRIPS provided two new international institutions: a TRIPS Council, an interstate body that reviews national implementation measures and highlights potential areas of non-compliance; and a Dispute Settlement Body with the power to adjudicate complaints and penalize treaty violators. Faced with the prospect of robust enforcement at all three levels of the IP TLO, WTO members devoted significant time and resources to implementing the treaty in their national legal systems (Helfer 2004: 23).

TRIPS' negotiators recognized that the overhaul of domestic IP laws and enforcement measures would be complicated and time consuming. To ease the transition, the treaty provided a period of up to ten years during which developing and least-developed countries were not required to extend full patent rights to pharmaceutical products (TRIPS, Articles 65, 70; Gervais 2003: 349, 365–366). It also included provisions – such as compulsory licenses, exceptions to exclusive rights, and parallel importation rules – that allowed all WTO members a modicum of flexibility to balance pharmaceutical patent protection against other social and economic goals.

These transition and flexibility provisions tempered TRIPS' hard edges. But those edges were quickly sharpened again by bilateral and regional trade pacts that the United States and the European Community negotiated with developing countries. These treaties are known as "TRIPS Plus" agreements because they contain IP protection rules that are more stringent than those of TRIPS, compel developing states fully to implement TRIPS before its transition periods expire, or require those countries to join or adhere to other multilateral IP agreements (GRAIN 2001). By negotiating treaties with developing nations bilaterally or in small groups, the United States and European Community used their greater negotiating leverage to ratchet up IP rights and to "push … harmonization forward at a pace that is greater than is apparently possible within the framework of the WTO" (OECD 2001: 112). They also successfully "integrated the patent offices of many developing countries … into a system of global governance" that is closely modeled on the patent systems of industrialized nations (Drahos 2010: 318).

As the foregoing discussion reveals, the negotiation of TRIPS and TRIPS Plus treaties caused a marked expansion of the IP TLO. These developments did not,

however, eclipse WIPO as a forum for IP norm development. On the contrary, they engendered a "competitive alignment," by which "different organizations and actors" in the TLO operated "within a common frame but … attempt[ed] to predominate in providing the relevant legal norms" (Halliday & Shaffer, Chapter 1: 34). Over time, a "division of labor" developed between the two organizations (Ibid.: 17). The WTO emphasized IP enforcement and dispute settlement, whereas WIPO focused on creating new IP norms, administering existing treaties, and providing technical assistance to developing states. This two-track system facilitated further expansion of the IP TLO. In the area of patents, for example, the WIPO served as a forum for the negotiation of two multilateral agreements – the Patent Law Treaty (PLT) and the Substantive Patent Law Treaty (SPLT) – which extended TRIPS by harmonizing patent application procedures and expanding the rights of patent owners.

C. The Impact of Increased Pharmaceutical Patent Protection and IP Enforcement Mechanisms on Access to Medicines

The developments described in Section IIIB increased normative settlement and the lack of institutional alignment within the IP TLO in three ways: by expanding the protection of pharmaceutical patents, extending that protection to the entire WTO membership, and creating multiple venues for negotiating new IP norms. At the national and local levels, these events substantially reduced the policy freedom that governments had previously enjoyed to regulate A2M. The rejection of product and process patents – and the lower prices for the new drugs that accompanied them – was no longer possible for any state that wanted to participate in the global trade regime. Nor could a state commit to TRIPS in principle and then ignore it in practice, because the treaty's enforcement requirements and dispute settlement mechanisms made shirking TRIPS a far more costly strategy. By the century's end, therefore, it appeared that industrialized countries and multinational pharmaceutical firms had triumphed in their campaign to expand mandatory patent protection for new drugs. Figure 9.2 provides a graphical illustration of this phenomenon.

Yet contrary to the predictions of some commentators, the expansion of the IP TLO did not generate a global settlement consensus in favor of higher IP protection. Instead, it increased the tensions between the IP TLO and other TLOs, including human rights, on whose turf IP rules were now impinging. These tensions had both substantive and procedural dimensions. Substantively, TRIPS and TRIPS Plus treaties required the recognition of IP over knowledge goods, including life-saving medicines, which in other TLOs were treated (if sometimes only implicitly) as beyond private ownership on public health, moral, or cultural grounds. Procedurally, tensions were engendered by IP treaties' more stringent enforcement mechanisms as compared to those of human rights agreements. These enforcement

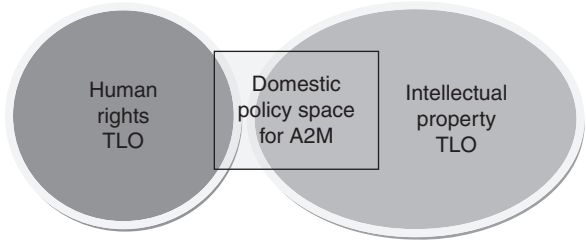

FIGURE 9.2. Patent protection for new drugs and the expansion of the intellectual property TLO.

disparities created an imbalance, whereby adherence to the latter agreements could be subordinated to compliance with the former in areas where the two sets of treaties overlapped (Helfer 2004: 26–27).

Industrialized countries and IP industries exacerbated the fears of this subordination by filing complaints in the WTO and in national courts that ignored countervailing health policies in favor of maximalist conceptions of IP protection. The result, as Section IV explains, was a growing belief – shared by many developing country governments, civil society groups, activists, and scholars – that TRIPS and its progeny were coerced agreements that should be resisted rather than embraced (Govaere & Demaret 2001; Harris 2006).

IV. PHASE 3: THE BACKLASH AGAINST PHARMACEUTICAL PATENTS AND THE INCREASED LEGALIZATION AND JUSTICIABILITY OF THE HUMAN RIGHT TO HEALTH

The backlash against the IP TLO, which began approximately in 2000, has several distinct but mutually reinforcing elements. International human rights experts and monitoring bodies devoted significant attention to concretizing the right to health and to highlighting the negative consequences of TRIPS for the realization of that right. A consortium of public health NGOs and developing countries then invoked these norms to launch campaigns against pharmaceutical patent protection at the transnational, national, and local levels. These campaigns thwarted high-profile litigation against Brazil and South Africa that sought to enforce patent rights over life-saving antiretroviral medications for HIV/AIDS. In the WTO, A2M proponents pushed for a Declaration on TRIPS and Public Health and an amendment to TRIPS that expressly recognized the need to adjust the protection of pharmaceutical patents in light of public health needs.

These campaigns, and the concretization of the human right to health on which they were premised, halted the drive to expand IP protection in the WTO and

WIPO, the key multilateral venues of the IP TLO. They did not, however, expand or preserve the policy discretion of governments to regulate A2M. In fact, that discretion decreased as a result of competing strategies adopted by coalitions that favored or opposed strong patent rules for new drugs.

First, in response to complaints from individuals and public interest NGOs, national judges became increasingly bold in adjudicating complaints invoking the right to health. Courts in several developing countries ordered health ministries to provide patented drugs to patients, sometimes with little regard for their cost or their impact on broader health outcomes. Second, industrialized countries, recognizing the inhospitable environment in the WTO and WIPO, shifted to plurilateral and bilateral negotiating venues. Capitalizing on their greater negotiating leverage in these forums, industrialized states challenged attempts by developing nations to invoke the flexibilities in TRIPS (such as compulsory licenses on pharmaceutical patents) and launched new treaty initiatives (such as the ACTA and TPP) to reverse the effects of the WTO public health declaration adopted earlier in the decade (Drezner 2007: 176–203).

As a result of these developments, contestations over the right to health and pharmaceutical patents now occur in numerous venues at the multilateral, plurilateral, regional, domestic, and local levels, placing the A2M TLO in the lower left quadrant of Figure 1.3 (in Halliday & Shaffer, Chapter 1). These contestations have squeezed many governments between highly legalized IP protection and right to health rules, leaving little policy space for domestic regulations that accommodate both sets of rules.

A. *Facilitating Circumstances*

The rapid normative evolution of the right to health has its origins in two key documents in the human rights TLO: (1) a General Comment on the right to health by the ICESCR Committee, and (2) a resolution on IP and human rights by the UN Sub-Commission on the Promotion and Protection of Human Rights. These two documents, both adopted in August 2000, triggered a norm cascade (Lutz & Sikkink 2001) of resolutions, reports, and recommendations in the UN human rights system that identified significant conflicts between IP treaties and the right to health and extended that right to include access to live-saving medicines.

The General Comment is a detailed analysis of the legal obligations that, in the view of the ICESCR Committee, are implicit in state parties' recognition of "the right of everyone to the enjoyment of the highest attainable standard of … health" (ICESCR, Article 12). As applied to A2M, this right includes four elements: the availability of medication in sufficient quantity, the physical and economic accessibility of medication without discrimination, the acceptability of medication in

light of cultural and ethical norms, and the provision of medication of an appropriate quality (General Comment No. 14 2000; see also Hestermeyer 2007: 105). The General Comment also analyzes the tripartite "respect, protect, and ensure" framework described in Section II. To "respect" the right to health, states parties must refrain from denying or interfering with access to essential medicines. To "protect" that right, states must prevent third parties, including private actors, from interfering with such access. And to "fulfill" that right, states are required to adopt appropriate legislative, administrative, and budgetary measures to facilitate access (General Comment No. 14 2000: paras. 33–38).

In recognition of the progressive nature of the right to health, the General Comment does not require immediate access to all medications. Rather, it identifies the "core obligation" of states parties as the provision of "essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs" (Ibid.: para. 43(d)). As part of that program, WHO maintains and updates a Model List of medicines that are intended to "address the priority health care requirements of a given population." The most recent version of the list includes more than 350 drugs for treating infectious diseases, including HIV/AIDS, malaria, and tuberculosis, chronic diseases such as hypertension and diabetes, and reproductive health (WHO 2010).

The UN Sub-Commission's attention to access to medicines originated in a statement by a consortium of NGOs that forcefully asserted "the primacy of human rights obligations over the commercial and profit-driven motives upon which agreements such as TRIPS are based" (Weissbrodt & Schoff 2003). The consortium's views shaped the Sub-Commission's subsequent resolution on Intellectual Property Rights and Human Rights (Resolution 2000/7). The resolution asserted that "actual or potential conflicts exist between the implementation of [TRIPS] and the realization of economic, social and cultural rights," including "restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health" (Ibid.: Preamble, para. 11). To resolve these conflicts, the Sub-Commission urged states, intergovernmental organizations, and NGOs to recognize that human rights have "primacy … over economic policies and agreements" (Ibid.: para. 3).

A rapid evolution of the human right to health occurred in the decade following the adoption of General Comment No. 14 and Resolution 2000/7. The mounting opposition to TRIPS and TRIPS Plus treaties conjoined with other factors – including concern over the spread of global pandemics, such as HIV/AIDS, malaria, and tuberculosis, and the growing number of life-saving drugs covered by patents – to engender repeated assertions that the right to health encompasses a right of access to life-saving medicines and that this right has primacy over IP protection.

Statements endorsing one or both of these principles spread quickly across the human rights TLO. Among the most noteworthy were: declarations by the UN

General Assembly in 2001 and 2006; resolutions of the Commission on Human Rights in 2001, 2002, 2003, and 2005; a 2001 study by the UN High Commissioner for Human Rights; several reports of Special Rapporteurs on the right to health; Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines adopted in 2008; a 2001 Statement on Human Rights and Intellectual Property by the ICESCR Committee; a 2003 general comment by the UN Committee on the Rights of the Child; and a 2008 resolution of the African Commission on Human and Peoples' Rights (Helfer & Austin 2011: 113–114). Supportive commentators analyzed and extended these statements, bolstering the claim that international law had evolved to include a right of access to life-saving medications, regardless of whether they were protected by patents (Lazzarini 2003; Yamin 2003; see also Helfer 2003).

B. Precipitating Conditions

The A2M norm cascade provided a tool for actors in the human rights TLO to counter the rapid expansion of pharmaceutical patents in the IP TLO. As a formal matter, the norms generated by this cascade were non-binding and thus did not conflict with the legally binding obligations of TRIPS or TRIPS Plus treaties. However, as the number and specificity of the statements endorsing a right of access to life-saving medicines increased, it became progressively more difficult for industrialized countries and pharmaceutical firms to challenge their legitimacy. Developing countries and right to health NGOs also invoked these norms in international and national venues to reorient a legal discourse that privileged the private ownership of IP over human rights and other social values (Forman 2008). At first, proponents of greater A2M used the right to health as a shield to oppose litigation against Brazil and South Africa that was seeking to enforce pharmaceutical patents for HIV/AIDS drugs. But these actors soon switched to an affirmative strategy, invoking the right as a sword to bring about legal change in the WTO.

In 2000, the United States, in response to demands from its domestic pharmaceutical industry, filed a WTO complaint against Brazil to challenge a provision of that country's 1996 industrial property law requiring "local working" of foreign patents. The law authorized the government to issue compulsory licenses for patents not manufactured in Brazil within three years of receiving patent protection. Beginning in the early 1990s, the government used the threat of such licenses to negotiate with pharmaceutical firms for deep discounts on patented antiretroviral drugs, which it then distributed to patients at very low prices. Human rights and public health NGOs responded to the WTO suit by publicizing Brazil's striking success in reducing HIV/AIDS deaths. After several months of intense pressure, the United States withdrew its complaint again Brazil in June 2001 (Sell 2003: 137; Bird & Cahoy 2008).

A second critical juncture in the A2M campaign occurred in South Africa, a country with one of the world's highest HIV/AIDS infection rates. Between 1997 and 2001, the United States and pharmaceutical companies threatened trade sanctions and litigation in an attempt to block South Africa from enforcing the Medicines and Related Substances Control Amendment Act, a 1997 statute that authorized the parallel importation of patented drugs and created a transparent pricing mechanism that included generic medicines (Klug 2008; Muriu 2009).

After the adoption of the Act, a consortium of forty pharmaceutical companies filed a lawsuit in the High Court of Pretoria, arguing that the statute violated TRIPS and the right to property protected by South Africa's post-apartheid constitution. The government opposed these claims, but it did not raise human rights or public health arguments. That changed in 2001, when the Treatment Action Campaign (TAC) – a South African A2M advocacy group – joined the litigation as an amicus curiae. In addition to filing affidavits that illuminated the legal and factual flaws in the pharmaceutical companies' claims, TAC invoked the rights to life and health protected by the South African Constitution and by treaties that the country had ratified, as well as the international soft-law statements cited in Part IVA, which endorsed a right of access to life-saving medicines. The NGO argued that these rights should be given priority over IP protection and provided the legal authority to uphold the Medicines Act (Heywood 2001; Muriu 2009).

The TAC also mobilized outside of the courtroom, collaborating with NGOs and activists in other parts of the world to oppose efforts by the United States and the pharmaceutical industry to enforce drug patents for HIV/AIDS. Civil society activism during a U.S. presidential election cycle convinced the Clinton Administration in mid-1999 to withdraw the threat of trade sanctions against South Africa (Sell 2001–2002). The same campaign also induced the pharmaceutical firms to drop their challenge to the Medicines Act. In April 2001, the drug companies unconditionally withdrew their lawsuit in response to what one NGO leader described as "strong international public outrage over the companies' legal challenge of a developing country's medicines law and the companies' weak legal position" ('t Hoen 2005: 206).

The victories in Brazil and South Africa emboldened access to medicines advocates to push for reforms in the WTO. In the same month as the South African litigation ended, a coalition of fifty-eight developing countries called on the TRIPS Council to hold a special session devoted to public health issues ('t Hoen 2002: 38). In a document distributed prior to the June 2001 session of the Council, the coalition cited resolutions and statements adopted in the UN human rights system to support a proposal clarifying that TRIPS does not interfere with national policies that promote A2M. This proposal served as the template for the Declaration on TRIPS and Public Health, which was adopted at the November 2001 Ministerial Conference that launched the Doha Round of WTO trade negotiations (Helfer 2004: 65–66).

Among the declaration's most noteworthy provisions were affirmations of WTO members' rights "to protect public health and, in particular, to promote access to medicines for all" and "to use, to the full, the provisions in the TRIPS Agreement which provide flexibility for this purpose," including compulsory licenses issued in response to national health emergencies (Declaration on TRIPS and Public Health 2001: para. 4). The declaration also allowed least-developed countries to defer IP protection of pharmaceutical products for an additional ten years, until 2016. And it promised to find a mechanism for countries that lacked sufficient domestic pharmaceutical manufacturing capacity to import generic drugs from other WTO countries (Abbott 2002). In response to the latter provision, the TRIPS Council waived the domestic use requirement for compulsory licenses in 2003. In 2005, the Council made the waiver permanent, adopting an amendment to TRIPS – to date, the only formal revision of that treaty – that will enter into force if and when it is ratified by two-thirds of WTO member states (Abbott 2005).

C. The Domestic Adjudication of the Right to Health, the Spread of Bilateral and Plurilateral IP Treaties, and the Further Diminution of Domestic Policy Space

Many NGOs and commentators initially hailed the 2001 Public Health Declaration as a major breakthrough for A2M and a harbinger of broader efforts to dial back IP protection standards (Sell 2001–2002; Lohr 2002). Subsequent assessments were less sanguine, however, especially as the legal and practical complexities of the 2003 waiver and the 2005 amendment became apparent (Abbott & Reichman 2007). Yet even critics acknowledged that the Public Health Declaration emboldened governments to invoke the flexibilities in TRIPS in their domestic laws.

There is considerable evidence to support this conclusion. For the first few years after TRIPS entered into force in 1995, no state issued compulsory licenses for patented HIV/AIDS drugs. Beginning in 2002, however, both developing and middle-income nations began to issue such licenses, including Brazil (2007), Cameroon (2005), Ghana (2005), Indonesia (2004), Malaysia (2004), Mozambique (2004), Rwanda (2007), Thailand (2007), Zambia (2004), and Zimbabwe (2002). As a result, the price of antiretroviral medications in these countries has fallen sharply (Ho 2007).

Viewed in isolation, this empirical pattern suggests that the 2001 Public Health Declaration – and the concretization of the human right to health that inspired it – expanded the discretion of governments to regulate A2M. In reality, however, the domestic regulatory space has contracted, rather than expanded, over the past decade. The reasons are twofold: burgeoning litigation in national courts invoking a right of right access to patented medicines and renewed efforts by the United States

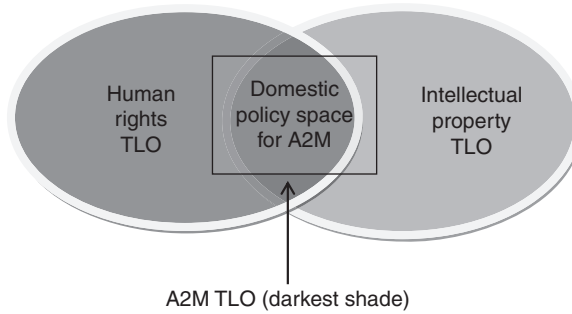

FIGURE 9.3. The diminution of domestic policy discretion and the creation of an access to medicines TLO.

and the European Community to circumvent the Public Health Declaration by negotiating bilateral and plurilateral TRIPS Plus treaties. Figure 9.3 illustrates the diminution of domestic policy discretion.

As noted in Section IIB2, many commentators in the 1980s and 1990s were highly skeptical of the justiciability of the human right to health. Their concerns centered on the ambiguous content of the right and the inability of domestic judges to make the financial and administrative decisions that litigation of health rights necessarily entailed. However, after the detailed exegesis of the right to health by the ICESCR Committee and the numerous statements by UN human rights bodies endorsing a right of access to medicines, national courts in developing countries began to tackle the challenges of adjudicating these rights in response to complaints by individuals and NGOs. The trend was especially pronounced in Latin America, a region "characterized by rights-rich constitutions, high social exclusion, and systemic failures of representation by the political branches of government" (Yamin & Parra-Vera 2009: 149).

In an early and influential case, more than 150 HIV-infected individuals filed a complaint against the Venezuelan Ministry of Health and Social Action alleging that the failure to provide antiretroviral drugs violated multiple rights guaranteed by the Venezuelan constitution and by international law. In a landmark decision, the Supreme Court of Venezuela ruled for the plaintiffs (*Cruz del Valle Bermúdez v. Ministerio de Sanidad y Asistencia Social* 1999). The court rejected the defense of insufficient resources and ordered the health ministry to seek the budget allocations needed to provide antiretroviral medications to all HIV-infected individuals in the country. The order was both comprehensive and highly specific, requiring the ministry to:

- take measures necessary to ensure an uninterrupted supply of antiretroviral drugs;
- cover all tests necessary for the use of antiretroviral drugs;

- provide medications necessary for treating opportunistic infections;
- develop a policy of comprehensive medical assistance for people living with HIV/AIDS eligible for social assistance; and
- undertake research on HIV/AIDS to develop programs and infrastructure to prevent HIV transmission and care for those infected.

In the decade following the *Bermúdez* decision, domestic adjudication of A2M claims increased sharply, pushed forward by advocates who relied on the interpretations of the right to health articulated by the ICESCR Committee and other UN human rights bodies. National judges responded favorably to these claims, with high courts in Argentina, Colombia, Costa Rica, Ecuador, El Salvador, Kenya, Peru, and South Africa recognizing that HIV/AIDS patients have a right to receive antiretroviral medicines (Byrne 2009; Yamin & Gloppen 2011; O'Neil Institute 2013). A 2006 study identified seventy-one cases from twelve countries invoking a right of access to medicines, with a success rate of 83 percent (Hogerzeil et al. 2006).

Litigation before regional human rights bodies has reinforced this trend. In 2001, the Inter-American Commission on Human Rights declared admissible a complaint challenging El Salvador's failure to provide antiretroviral drugs to HIV/AIDS patients. The government quickly settled the case after a Salvadorian court ruled in the plaintiffs' favor, a decision that "contributed to treatment activism throughout the region, complementing high-profile cases before a number of domestic courts" (UNAIDS 2006: 71). In 2008, the African Commission on Human and Peoples' Rights adopted a Resolution on Access to Health and Needed Medicines in Africa that closely tracks the tripartite framework of the ICESCR Committee.

Yet even as a growing number of national courts were enforcing a right of A2M, the United States and the European Community were stepping up efforts to tighten IP rules for pharmaceutical patents in regional, plurilateral, and bilateral trade agreements. Many of these treaties undercut the Declaration on TRIPS and Public Health by adopting provisions to restrict the very same flexibility mechanisms that the declaration had previously reaffirmed ('t Hoen 2009: 70–71, 74–75), including the following:

- *Patent linkage*. Prohibits public health authorities from granting approval to market lower-cost generic drugs during the patent term without the consent of the patent holder;
- *Data exclusivity*. Prohibits the use of pharmaceutical test data for regulatory purposes, delaying the approval of generic medicines;
- *Patent extension*. Lengthens the term of pharmaceutical patent protections beyond the twenty years required by TRIPS to offset regulatory delays in approving new drugs;
- *Second use patents*. Requires the recognition of pharmaceutical patents for new uses of existing chemical substances;

- *Compulsory license restrictions*. Limits the grounds for authorizing local drug companies to manufacture and distribute generic medicines, provided that they pay reasonable royalties to patent owners;
- *Prohibitions of parallel importation*. Prevents the importation of generic medicines manufactured in other countries.

In addition to negotiating treaties that enhanced the protection of pharmaceutical patents, the United States and the European Community also launched plurilateral treaty initiatives to augment the criminal and civil enforcement of IP rights. Among the most notorious of these initiatives is ACTA, whose signatories include Australia, Canada, Japan, Mexico, Morocco, New Zealand, Singapore, South Korea, and Switzerland. According to EC officials, ACTA seeks nothing less than "to create a new global gold standard on IPR enforcement" (European Commission 2007). The treaty has engendered strong opposition from civil society groups not only because its enforcement rules exceed those in TRIPS but also because its draft texts were kept secret until the agreement was all but finalized in late 2010 (Geist 2010). ACTA applies to all types of IP, but A2M advocates are especially concerned that the treaty will hamper trade in pharmaceuticals by enabling patent owners to seize generic drugs in transit between countries that are not parties to the treaty (Grosse Ruse-Khan 2011; Yu 2012).

These developments have had two consequences in the A2M TLO. The first, which relates to the TLO's formal legal rules, has been to constrict the autonomy of national governments to decide how best to meet the health needs of their populations. On the one hand, the expansion of pharmaceutical patents has sharply limited opportunities to import, approve, manufacture, and distribute generic drugs to the patients who need them. On the other hand, domestic courts have invoked right to health clauses in national constitutions and human rights treaties to compel governments to provide such medicines, in some instances without regard to cost. A few commentators have called for a further diminution of government discretion, arguing that "states must use TRIPS flexibilities to fulfill their duties under the right to health, and that they must negotiate less restrictive intellectual property rights in bilateral free-trade agreements" (Forman 2007: 345).

A second consequence relates to law in action versus law on the books. The influence of formal legal rules is often dependent on their application in practice by key actors. In the IP system, the front-line decision makers include officials in domestic IP administrative agencies who review patent applications from pharmaceutical companies. Studies of these agencies in India and Central and South America reveal that agency officials have considerable latitude to apply national IP laws in ways that limit the number of pharmaceutical patents granted in a given jurisdiction (Helfer et al. 2009; Kapczynski 2009; Dreyfuss & Rodríguez-Garavito 2014;). Over

the past few years, however, developing countries have come under pressure from industrialized nations to reduce or eliminate the discretion of agency officials. The patent linkage and data exclusivity rules discussed earlier in this section are the most common manifestations of this trend. Another recent example concerns the controversies relating to the power of Brazil's National Health Surveillance Agency (ANVISA) to review drug patents granted by the National Institute of Industrial Property (INPI), the Brazilian administrative body responsible for patent examinations and registrations (Center for Strategic Studies and Debates 2013: ch. 8).

V. CONCLUSION

By charting the evolution of IP and human rights rules governing access to medicines, this chapter makes three contributions to the study of TLOs. First, the chapter questions the conventional wisdom that the A2M issue area is characterized by high legalization of IP protection (obligatory and precise rules governing pharmaceutical patents with strong adjudication and enforcement mechanisms) and low legalization of the human right to health (hortatory and vague norms with few opportunities for adjudication or enforcement). The chapter further demonstrates that the legalization of the right to health in general and A2M in particular has increased sharply over the past decade, primarily in reaction to a previous period of rapid expansion of pharmaceutical patent protection rules. The result is a TLO characterized by ongoing high-profile clashes over competing legal rules in a broad and diverse array of venues.

Second, the chapter analyzes the mechanisms and strategies used by different groups of countries and coalitions of non-state actors to develop competing legal norms relating to the intersection of the human rights and IP TLOs. These include: (1) expanding the number of multilateral, regional, plurilateral, and bilateral venues in which treaties and soft-law norms are adopted; (2) opportunistically shifting negotiations among these venues; and (3) regulating how different countries implement international rules in their domestic legal orders.

These mechanisms and strategies highlight several insights of the TLO framework. First, they show that studies of normative settlement and institutional alignment are incomplete unless they consider interactions at the transnational, national, and local levels (Halliday & Shaffer, Chapter 1). Second, they suggest that scholars must pay careful attention to "defining the boundaries of TLOs and changes in their boundaries over time" (Ibid.: 20). And third, they demonstrate that the formation of a new TLO in response to competitive interactions between two formerly discrete TLOs can engender rapid unsettlement and a misalignment of norms and institutions that had been stable and uncontested for an extended period of time (Ibid.).

Third, this chapter highlights that the diachronic processes of normative contestation between and within TLOs can engender negative consequences – in particular,

by reducing the policy discretion of governments as norms that are ambiguous and limited in scope become more precise, expansive, and enforceable. Other scholars have argued that the "strategic inconsistency" of international rules within "regime complexes" increases discretion by allowing national governments to pick and choose which international rules to follow (Raustiala & Victor 2004: 301–305). This chapter suggests a contrary conclusion that future studies of TLOs may wish to explore: that highly contested international rules constrain, rather than expand, the policy space available to governments when those rules are transposed into national and sub-national legal systems and can be invoked and enforced by competing groups of domestic actors.

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