Lisa Forman, BA, LLB, MA, SJD, is a Canadian Institutes of Health Research (CIHR) postdoctoral fellow with the Comparative Program on Health and Society (CPHS), Munk Centre for International Studies, University of Toronto.

Please address correspondence to the author at lisa.forman@utoronto.ca or at the Munk Centre for International Studies, 1 Devonshire Place, Toronto, ON M5S 2K1, Canada.

Competing interests: None declared.

* This article is drawn from research funded through CIHR and CPHS and is based on a working paper published in *Munk Centre for International Studies Briefings Volume Four: Comparative Program on Health and Society and Lupina Foundation Working Paper Series 2006/2007*.

"RIGHTS" AND WRONGS: WHAT UTILITY FOR THE RIGHT TO HEALTH IN REFORMING TRADE RULES ON MEDICINES?*

Lisa Forman

ABSTRACT

This paper explores the legal and normative potential of the right to health to mitigate the restrictive impact of trade-related intellectual property rules on access to medicines, as evidenced by the global outcomes of the seminal pharmaceutical company litigation in South Africa in 2001. I argue that the litigation and resulting public furor provoked a paradigm shift in global approaches to AIDS treatment in sub-Saharan Africa. I argue further that this outcome illustrates how human rights in concert with social action were able to effectively challenge dominant claims about the necessity of stringent trade-related intellectual property rights in poor countries, and ergo, to raise the priority of public health needs in related decision-making. I explore the causal role of rights in achieving these outcomes through the analytical lens provided by international legal compliance theories, and in particular, the model of normative emergence proposed by Martha Finnemore and Kathryn Sikkink. I suggest that the AIDS medicines experience offers strategic guidance for realizing the right to health's transformative potential with regard to essential medicines more generally.

INTRODUCTION

What role, if any, could the right to health play in reforming trade-related intellectual property rights and assuring greater accountability from corporate and state actors regarding global access to medicines? This question is not simply a product of the wishful thinking of human rights academics. In the past eight years, rights-based advocacy, litigation, and discourse have significantly shifted government policies, corporate pricing, and even trade rules related to AIDS medicines. These outcomes are of no small significance given the ongoing ravages of a global drug gap, perpetuated and exacerbated by trade-related intellectual property rules that restrict governmental capacities to access more affordable medicines.[1] I suggest that the AIDS medicine experience and the seminal corporate litigation in South Africa in 2001, in particular, point to the transformative potential of the right to health to raise the priority of public health needs in trade-related intellectual property rights, and to advance access to critical health interventions in resource-poor settings.

This article focuses on the South African corporate litigation as a defining moment in global approaches to treatment access in sub-Saharan Africa. I do not suggest that the litigation was the end point of this struggle: since 2001 there have been considerable advances in AIDS treatment access both globally and within South Africa. Nor do I purport to introduce new empirical data about a seven-year-old instance of litigation well addressed in academic and activist literature.[2] Instead, I explore the litigation's apparent function in provoking a new global paradigm on AIDS treatment in sub-Saharan Africa and its implications for the efficacy of rights-based strategies for essential medicines more generally. I adopt the analytical lens provided by international legal compliance theo-

ries in exploring the role of rights in achieving these changes and argue that the AIDS medicines experience provides empirical evidence of these theories, particularly the model of normative emergence proposed by Martha Finnemore and Kathryn Sikkink. The article proceeds by illustrating how trade rules restrict access to medicines, expanding on why the right to health may be a powerful tool for mitigating these restrictions and exploring the contribution of international legal compliance theories to this analysis. I then turn to explore the AIDS medicines experience and the South African litigation, in particular. I conclude by examining the broader implications of this experience.

TRIPS, PATENTS, AND ACCESS TO AFFORDABLE MEDICINES

The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was introduced when the WTO was formed, as part of the package of agreements that all acceding countries must implement. TRIPS globalized pharmaceutical patents for the first time, requiring all WTO members to provide 20-year, exclusive patent protection on pharmaceuticals.[3] This was an unprecedented legal requirement in many countries that had not patented drugs or had far less stringent patent rules for medicines. For example, before TRIPS, over 40 countries did not patent drugs; many (like India) only patented processes and not products, and many others had patents for less than 20 years.[4] TRIPS does permit limits to patents in order to enable governments to meet public health needs, including (but not limited to) parallel imports (whereby countries import cheaper patented medicines) and compulsory licensing (whereby countries manufacture or import generics under strict conditions).[5] The use of these mechanisms, however, has been highly contested and constrained by corporate and government pressures through litigation and unilateral trade sanctions. At the same time, countries are being persuaded and coerced into adopting far stronger intellectual property rules in bilateral and regional free trade agreements (FTA) that makes TRIPS even more restrictive and generally make it more difficult for generic medicines to enter the market.[6]

The primary impact of TRIPS has been to drive up drug prices in countries introducing drug patents, since patents give their holders the exclusive right to sell these medicines for particular periods, thereby excluding the price-reducing impact of generic competition.[7] However, TRIPS is also restricting global access to generic alternatives by phasing out generic manufacture unless authorized under TRIPS. These restrictions will particularly affect countries dependent on generic exports. While TRIPS was amended in 2005 (pursuant to a 2003 WTO agreement) to allow under strict conditions the export of medicines produced under licence, this provision has been used only once.[8] Several factors account for this limited usage, including persistent corporate and governmental threats of legal or economic sanctions and the complexity, cost, and limited duration and scope of the rules themselves.[9]

I do not suggest that access to medicines is primarily determined by drug prices: as the World Health Organization (WHO) indicates, affordable pricing is only one determinant of access.[10] Nonetheless, as indicated above, patents are a primary factor in determining price, and price can be a primary determinant of drug access. The impact of patents on price is illustrated by the fact that drug prices fall sharply (coming much closer to marginal production costs) when patents expire and generic entry enables market competition.[11] Moreover, the influence of pricing is disproportionate in many poor countries, where the majority of individual drug expenditure is out-of-pocket and medicine procurement is often the greatest public expenditure on health.[12] Pricing can also influence the availability of sustainable financing both within and outside a state, since a very expensive drug is not likely to be purchased in any great quantity, or at all, by poor governments, nor likely to receive international funding.[13] The impact of pricing on public- and international-sector financing of medicines underscores the fact that high drug prices may keep medicines for common diseases like cancer and diabetes well out of reach of those who most need them.

Questions about drug prices are closely linked to arguments about the necessity of patenting for assuring rewards and incentives for drug developers. While pharmaceutical patents play important roles in financing the pharmaceutical industry and stimulating research and development, drug patents in poor countries produce very limited profits; in 2005, patented drug sales in Africa and the Indian sub-continent *combined* amounted to only 2.3% of global sales. In contrast, drug consumption in North America, Europe, and Japan alone contributed to over 85% of the global

pharmaceutical market.[14] Whatever the extent of reward accruing from developing regions, it manifestly does not ensure drug innovations for the primary disease burdens prevalent in such countries; as Trouiller et al. found, for example, only 0.1% of new chemical entities produced between 1975 and 1999 were for tropical diseases and tuberculosis.[15] While corporate attention to drug development for neglected diseases has increased in the past eight years, Moran attributes this increase not to commercial incentives but rather to pharmaceutical industry efforts to minimize reputational damage resulting from the failure to address developing country needs.[16]

In this light, it is not surprising that there is growing consensus that in poor countries, "patents are not a relevant factor or effective in stimulating research and development and bringing new products to market."[17] If patents in poor countries are not necessary to sustain the innovation of new medicines, this raises valid questions about the justifications for requiring them, particularly considering the human costs of limited drug access in poor countries.[18]

THE LEGAL, NORMATIVE, AND DISCURSIVE POWER OF RIGHTS

The human right to health provides a different account of government duties on medicines that significantly re-prioritizes public needs for medicines. The provision of essential medicines is seen to place a core duty on governments that cannot be traded for private property interests or domestic economic growth. The right's potential is therefore to provide a means of achieving a more public-health-oriented formulation, implementation, and interpretation of trade rules by domestic courts, governments, and the WTO alike, and perhaps even a mechanism to assist efforts to amend the TRIPS agreement itself. These are admittedly strong claims for a right often criticized as indeterminate and lacking universality and enforceability, and for a body of law widely perceived to be ineffective.[19] I argue, however, that while critics who dispute the universality and efficacy of rights may touch on some truths about their weaknesses, the right to health and international law may, nonetheless, hold a transformative, albeit contingent, legal and moral power.

To some extent, this power is implicit in the tremendous growth of the international human rights system itself. Over the past 60 years, human rights have exploded into existence in international law and have been expanded in more than 100 human rights instruments and countless UN resolutions, declarations, conferences, and programs of action. A large international human rights system has developed at the UN, as have regional systems in Africa, Europe, and the Americas. There has been a similar growth in constitutionalism over this time period: since 1945, about 50% of UN members (92 countries) have introduced forms of rights into their constitutional systems, with enforceable rights a recurrent feature.[20]

Certainly, not all human rights are equally regarded, and within liberal democracies, social rights, such as the right to health, have often faced considerable legal and political resistance and neglect. Yet the growing legal force of the right to health in international and domestic law is noticeably eroding suggestions that this right lacks legality, determinacy, and enforceability. The right to health is now extensively codified in international and regional instruments.[21] Furthermore, many of these instruments are now widely ratified.[22] At the same time, expert interpretations have advanced understanding of the scope of individual entitlements under this right and the correlative duties that it places on states. It is notable, therefore, that the UN Committee on Economic, Social and Cultural Rights has indicated that states hold minimum core duties to provide essential medicines, which are not subject to progressive realization.[23] These normative developments are increasingly reflected in domestic law: health rights now appear in two-thirds of all constitutions.[24] Domestic courts are increasingly willing to enforce the right to health, either indirectly through civil rights to life and equality, as in India and Canada, or as a direct justiciable right, as in South Africa and several Latin American countries.[25] There is also a growing jurisprudence in which access to medicines has been successfully claimed under human rights protections.[26] Where state implementation of these decisions is effective (as in South Africa), they can lead to considerable public-health benefits.[27] The right to health is therefore no longer appropriately characterized as an ineffectual manifesto right; it is a widely recognized legal right with tangible force and effect in claiming access to health care and medicines.[28]

THE NORMATIVE POWER OF THE RIGHT TO HEALTH

The force of the right to health is not constituted

only by its technical legal standing in any given country, and the remainder of this paper will focus on the more normative power of rights and law. This argument is intended to directly address one of the most common perceptions about international law and, in particular, international human rights law: namely that, while international human rights law promotes beautiful rhetorical aspirations, since it lacks a central enforcement body, a world police, and a world court, it is weak, unenforceable, and largely ineffective.[29] There is certainly some truth to these criticisms — human rights law has been shockingly ineffective in preventing even egregious violations. This observation has been powerfully illustrated since the Second World War by the failure to prevent genocide in Cambodia, Rwanda, and currently, Sudan. There can be little doubt that ratification of international treaties is no guarantee of their fulfillment.

Critiques of the efficacy of international law, however, often fail to recognize the more transformative ways in which human rights have entered our collective consciousness, not simply as commitments in law, but as ideas and collective understandings with the potential to transform basic social and political priorities and shift real-world outcomes. As Judith Shklar suggests, this is to recognize that civilization advances when what is commonly perceived as misfortune becomes considered injustice instead.[30] Ideas can considerably alter what is considered appropriate and legitimate, and certainly, the demise of slavery, apartheid, and colonialism, as well as the extension of women's suffrage, provide powerful examples of how ideas can produce real-world changes.

Slavery, in particular, provides a fascinating illustration of the power of ideas and norms to shift collective understandings. Until 200 years ago, the dominant socio-political perspective on slavery was that it was a legitimate form of property and labor, and it was only through the assiduous efforts of a global abolitionist movement that slavery was abolished. This is a remarkable outcome given that instances of slavery have been recorded throughout human history. Today, there is not a single country in the world where slavery is not outlawed (albeit that the practice persists illegally), and the dominant perception is that it is evil and a shocking violation of human rights.[31] While there is debate about whether the demise of slavery was due to economic rather than moral causes, the role of moral norms is hard to discount.[32] This is particularly so given illustrations that slavery was profitable up until it was abolished.[33]

This collective shift against slavery reflects one of the most covertly transformative aspects of human rights, which is its core idea that all persons, irrespective of their race, geographical location, gender, or sexual orientation, are possessed of inherent human dignity and equal worth, and that this value places reasonable limits on economic interests and property claims, as well as on domestic and global governance. This is not to suggest that ideas alone can produce transformative outcomes. What is common to slavery, women's suffrage, and anti-colonialism is that these changes were accompanied and enabled by extensive social action.[34] This relationship is reflected in the recognition of international legal theorists that social movements are central not just to advancing rights claims but also to creating them.[35] In this conception, subaltern legal and political struggles are increasingly understood to hold a rights "creationist" and "juris-generative" potential that may drive the development of international law from below.[36] The social genesis of many human rights norms not only points to a critical contingency for the force of rights, but also effectively contradicts the critique of human rights as a Western "civilizing" gambit imposed on an unwilling global South from above.[37]

A fundamental component of the force of rights lies in their nature, not simply as morality but as law. To some extent, this argument recognizes the normative function of law itself, which is, in large part, central to socio-political regulation. Consider, for example, how intimately concepts such as the rule-of-law are linked to conceptions of good governance, and how the existence of law itself is linked to order. In this view, the absence of law is seen as lawlessness and the breeding ground for *Lord of the Flies*-like predation.[38] Law as a language for rights claims may hook into these meanings, so that advancing claims based on international law can add considerably to their perceived legitimacy, appropriateness, and, indeed, necessity.[39] I do not suggest, however, that all law provides effective or appropriate rules; law is as easily an instrument for repression as it is for emancipation. However, whatever its tenor, law provides many of the rules by which societies are regulated and may, therefore, provide an important source of

socio-political power, as well as an important site of resistance. This power is perversely illustrated by the effective adoption of rights-talk and international law by corporations to advance the global protection of their interests; indeed, TRIPS itself is recognized as a victory of corporate lobbying advanced via the industry's extraordinary economic power, which enables them to prescribe self-serving laws and policies.[40]

If rights can counter this one-sided participation in law and policy formation on medicines and enable marginalized and subaltern groups without economic power to influence policy and law, they may provide social power and empowerment, as well as the promise of political accountability. Courts play an important role in empowering rights, since in legal fora, judges can either give teeth to the substantive justice potential of rights or reduce them to formal rules that entrench the status quo. No amount of prescriptive rules can eradicate this penumbra of uncertainty.[41] Thus, the legal force of these rights may be contingent on judicial willingness to give them force and effect, and achieving this force may be difficult, given ideological objections to recognizing and enforcing health rights that persist in some jurisdictions.

I am not therefore advocating rights as guarantees of justice. Rights are inherently indeterminate, and their application to various problems must be worked afresh in contexts that textual formulations are likely to address only abstractly. Yet, while they are not guarantees of justice, they may well ensure systemic trends toward justice, and in the case of health, they may ensure a commitment to equity in health policy, free from contingent politics. This point is exemplified in Patricia Williams' suggestion that rights are to law as conscious commitments are to the psyche, a metaphor that suggests both the strengths of rights and conscious commitments, as well as their potential weaknesses.[42] Individual conscious commitments (for example, New Year's resolutions) do not necessarily translate into concrete action and tangible outcomes. The implication is that, like us, governments may need some external assistance and added incentives to fulfill their commitments.

As the discussion on slavery implies, part of the normative power of rights lies in their potential to reconfigure broader conceptions of appropriate behavior and, indeed, what is considered as right and wrong conduct. This is partially illustrated by the intimately interconnected meanings of the words "rights" and "right": what we understand to be right is not just what we consider appropriate, but also what we consider to be correct and true. To this extent, using the language of rights may overlap beliefs and truths in ways not consciously obvious. This overlap is apparent in the multiple meanings of the word "belief," which does not simply refer to what should be ("I believe in rights"), but also to what "is" ("I believe in God; I don't believe in fairies").

Michel Foucault has powerfully advanced the idea that truth may be both shifting and contingent, arguing that "truth" is not inherent, but is "a thing of this world . . . and that [e]ach society has its regime of truth, its 'general politics' of truth — that is, the types of discourses it accepts and makes function as true."[43] Thus, Foucault argues, truth is not "the ensemble of truths to be discovered and accepted," but rather:

> the ensemble of rules according to which the true and false are separated and specific effect of power attached to the true, it being understood also that it's not a matter of a battle 'on behalf' of the truth but of a battle about the status of truth and the economic and political role it plays.[44]

To this extent, rights may hold the potential to shift collective conceptions, not simply of what is appropriate, but also of what is true. This effect is particularly apparent in the starkly opposing and competing paradigms of truth relating to trade rules, patents, and AIDS medicines. Until recently, the dominant paradigm — one vigorously promoted by companies and their supporters — was that TRIPS did not permit limitations of patents; that patents could not be limited in any way without destroying the medical innovation system; that poverty, not patents and prices, determined access to medicines; that access to medicines in poor countries was, regardless, irremediable; that African healthcare systems were inadequate for the complex and expensive task of monitoring the efficacy of complicated antiretroviral (ARV) therapies; and that Africans were, in any event, too ignorant to adhere to complicated ARV routines.[45] These arguments significantly influenced

conceptions of the feasibility and wisdom of providing AIDS medicines in Africa and of the moral and legal duties perceived to flow (or not flow) from this "truth."

INTERNATIONAL LEGAL COMPLIANCE THEORIES: WHY AND HOW DO RIGHTS WORK?

This broader conception of the force of rights and law beyond technical legality is assisted considerably by international legal compliance (ILC) theories, which provide competing explanations for how international law may influence state behavior. Rather than debating whether rights and international law do, in fact, work, these theories instead explore how. The two main camps of ILC theories complement and deepen insights about the legal and normative influence of rights and law by focusing on two competing explanations for this influence. Rational choice theorists, such as realists and institutionalists, are skeptical that international norms have direct causal effects and argue that states comply only if doing so furthers self-interested goals like enhanced power or reputational benefits.[46] The central insight of these schools is that countries weigh the costs and benefits of compliance and act accordingly.[47] Interestingly, costs are not just those produced from legal enforcement through courts or treaty penalties but can also come from mechanisms such as negative public opinion or economic sanctions — indeed, any threatened action that offsets the benefits of non-compliance.[48] This is an important insight in relation to the right to health, suggesting that rights and rights strategies can be coercively "enforced," even in the absence of law and legal mechanisms. Rationalist approaches do not, therefore, disprove the normative influence of rights and law on state action, but rather externalize this impact by focusing on the public, economic, or political censure that may indirectly result from changing collective norms.

Normative theorists posit, on the other hand, that norms have a direct causal impact on state behavior.[49] They argue that it is virtually impossible to achieve high levels of compliance over time through coercion, and that what rational actor theories fail to understand is that states comply with international law because they are moral agents, and it is a normative system.[50] The normative theorists propose that states internalize international norms through a variety of mechanisms, either because of "an iterative process of discourse" or a transnational legal process, or because rights reconstitute and construct the identities and interests of social and political agents and, hence, their actions.[51] The latter constructivist theories reaffirm a central tenet of the normative and discursive model of influence discussed above by illustrating how the truth-claims of dominant paradigms are constructed according to the ways in which actors understand, create, and act within public spaces, and by demonstrating that these constructions of reality in turn, "reflect, enact, and reify relations of power."[52] Both the rational choice and normative schools provide valuable insights for assessing how rights may hold either a coercive or persuasive force with regard to medicines and trade rules. Nonetheless, these schools provide explanations that are not mutually exclusive but, rather, complementary.[53] Certainly, as Jeffrey Checkel points out more generally, states may act out of self-interest (or "logics of consequence") and because they have, to some extent, internalized human rights norms ("logics of appropriateness").[54] In any event, it is perhaps less relevant to work out whether coercion or persuasion is the superior process than to assess when either mechanism will apply.[55]

Considerable guidance, in this respect, emerges from theoretical models that focus on process-oriented explanations of how norms emerge, influence actors, and become internalized through mixtures of persuasion and coercion.[56] Each model displays several commonalities and describes a similar process whereby norms are either persuasively or coercively advanced by norm entrepreneurs and transnational networks, leading to the emergence of new rules and their internalization when they are adopted as collective understandings. Moreover, each model identifies transnational actors, either in the form of activist networks or norm entrepreneurs, as key to the emergence of new norms, either through persuasion or public pressure. The remainder of this paper focuses exclusively on the process model advanced by Martha Finnemore and Kathryn Sikkink that combines an account of the legal and normative force of rights and appears to explain the changes that have occurred around AIDS medicines.

Finnemore and Sikkink argue that "norms evolve in a patterned 'life cycle' and that different behavioural logics dominate different segments of the life cycle."[57] This life cycle is composed of a three-stage process of norm emergence, norm acceptance and cascade, and finally, norm internalization.[58] They argue that what

moves an emerging norm into acceptance is when a threshold or tipping point is reached and "a critical mass of relevant state actors adopt [it]."[59] Finnemore and Sikkink indicate that the notion of a tipping point is a pattern independently found in many other disciplines exploring social norms, including American legal theory, sociological research, and international relations theory.[60]

At the first stage in Finnemore and Sikkink's model, norms emerge through persuasion by norm entrepreneurs who reframe state and public perceptions. They are successful when the "new frames resonate with broader public understandings and are adopted as new ways of talking about and understanding issues."[61] The tipping point comes when a critical mass adopts the norm, leading to the second stage, when norms cascade through combined coercion and persuasion. The final stage of normative internalization occurs when norms "acquire a taken-for-granted quality and are no longer a matter of broad public debate." Finnemore and Sikkink suggest that completion of the life cycle is "not an inevitable process" and that "[m]any emergent norms fail to reach a tipping point."[62]

This approach to normative emergence has been critiqued as implying that the emergence of human rights norms is linear and evolutionary.[63] As recent imbroglios in the US over the definition of torture illustrate, even apparently established norms are subject to regression. Moreover, the internalization of norms is not a static process, since evolving norms may become supplanted by other norms undergoing the same process. There are also valid questions about the causality of norms in behavioral change (as debates around the abolition of slavery imply).[64] This critique is answered to some extent by Finnemore, who argues that a basic premise for ascribing causality to norms in any pattern of social change is whether such change has accorded with normative prescriptions, and whether rights have become part of the discursive rationale for change by relevant actors.[65] As the analysis below will show, these touchstones of causality appear in the outcomes of the AIDS medicines struggle. Indeed, I argue that Finnemore and Sikkink's model appears to largely explain the changes that have occurred around AIDS medicines globally and the role played, in particular, by the Pharmaceutical Manufacturers Association (PMA) case in South Africa in 2001.

THE AIDS MEDICINES EXPERIENCE

The PMA case facilitated a tipping point for the emergence of a human right to AIDS medicines and acted as a catalyst for broader legal and political changes around AIDS medicines. I argue that the struggle for AIDS medicines can be seen as an iconic rights experience that, like the US civil rights movement and struggles for women's suffrage, offers important guidance about the kinds of coercive pressure and normative persuasion that could alter broader trade restrictions on medicines. This experience suggests that the right to health may be used to ensure broader access to medicines. It also provides a roadmap showing how rights may be used to mitigate trade restrictions on medicines more generally.

Seven years ago, there was little hope that AIDS medicines could become widely accessible in the developing world. The drugs cost approximately US$15,000 a year. WHO's and UNAIDS's official position was that, given high drug costs and the need for effective prevention, treatment was not a wise use of resources in poorer countries.[66] This shadowed a broader policy consensus that cost-effectiveness demanded a brutal triage in which prevention of HIV/AIDS was funded instead of treatment, an ethically questionable choice in a gross pandemic that had already infected almost 28 million people in sub-Saharan Africa.[67] As a result, there was no international funding for developing countries to purchase drugs, and companies gave extremely limited price concessions. The idea that poor people in Africa should receive expensive state-of-the-art AIDS drugs was viewed as naïve and unrealistic, and arguments for lower-priced medicines were viewed as proposing an unacceptable violation of corporate patents and international trade rules. Generally, access to these drugs in developing countries was around 5% of HIV-positive persons, and in sub-Saharan Africa, the vast epicentre of the global pandemic, access was considerably under 1%.

Yet millions of people were dying from AIDS in sub-Saharan Africa every year, at the same time that antiretroviral medicines had begun to slash AIDS-related illness and death in the West and transform the very nature of the disease. To those on the frontlines of the pandemic, this lack of access primarily on the basis of price did not seem logical, appropriate, or ethically defensible. Rather, it seemed to be a shocking prioritization of property interests over the health and welfare needs of much of the African continent, in service of little more than profit — a global crisis

not just of health but of morality. A dramatic global battle for AIDS medicines ensued, coalescing around moral arguments and human rights claims for medicines and mass actions by social networks of health and human rights activists.[68] This battle challenged drug pricing, legal interpretations of TRIPS, and corporate contestation of TRIPS flexibilities.

The tipping point of this struggle appeared to come in 2001, in the PMA case in South Africa. Between 1997 and 2001, the US and 40 pharmaceutical companies used trade pressures and litigation to prevent the South African government from passing legislation (the "Medicines Act") to gain access to affordable medicines. South Africa, then, as now, had one of the world's largest HIV epidemics. In 2000, the US withdrew its trade pressures after Al Gore was embarrassed by AIDS advocates during his presidential campaign.[69] However, the pharmaceutical companies went to court in South Africa. The industry claimed that South Africa's legislation (and the parallel importing it authorized) breached the TRIPS agreement and South Africa's constitutional property protection.[70] It also argued that the proposed act threatened the industry's incentive to innovate new medicines.[71] In response, the South African government denied that the litigation either posed any serious threats to PMA's intellectual property rights or conflicted with TRIPS and the *Constitution*.[72] It is notable that in the early court documents, there was little focus by either side on HIV/AIDS medicines or human rights arguments.[73] The situation changed in April 2001, when the Treatment Action Campaign (TAC), a South African treatment advocacy group, joined the government's case, and in detailed affidavits set out to show the weakness of corporate arguments about the TRIPS legality of the legislation, and the research- and development-based necessity of opposing it. South Africa's constitutional framework greatly assisted activist claims, particularly because of its entrenchment of a justiciable right to access health-care services, as well as constitutional rules on the limitation of rights that demand strong justifications for any restrictions of core dignity and life interests.[74] Using this framework, TAC brought human rights arguments drawn from international and domestic law, arguing that the right to health provided constitutional authority for the legislation itself and was a legal interest that should be prioritized over corporate property rights.[75] TAC also presented extensive empirical research that undercut corporate claims about the cost of research and development, and its link to innovation, as well as personal testimony from poor people unable to buy medicines to illustrate the human costs of the litigation.[76]

In addition, working with activists around the world, TAC and other South African human rights groups organized an extraordinary level of public action concurrent with the case. On the day the case began, an international day of action was held with demonstrations in 30 cities across the world.[77] A petition opposing the litigation signed by 250 organizations from 35 countries was published in *Business Day*, a national South African newspaper.[78] The international aid group *Médecins Sans Frontières* initiated an international petition that collected 250,000 signatures and persuaded the European Union and Dutch governments to pass resolutions calling for the case to be dropped, followed by the German and French governments.[79] WHO not only stated its support for South Africa's defense of the litigation, but also provided legal assistance.[80] In the days before the hearing, Nelson Mandela, the former South African president, criticized the pharmaceutical companies for charging exorbitant prices on AIDS drugs, attracting considerable media attention.[81] This confluence of activism and media coverage attracted an extraordinary amount of global censure against the corporations, which recognized that they had far more to lose through reputational damage than through any outcomes to which the Medicines Act could possibly lead. In April 2001, the pharmaceutical companies withdrew their case.[82]

The litigation and surrounding media furor precipitated a discernable shift in how the appropriateness of TRIPS and patents in poor countries came to be seen. Even mainstream publications such as the *Washington Post* and *Time* began to question the legitimacy of corporate action to protect patents in developing countries, and, indeed, of the intellectual property system itself.[83] Yet the case appeared to have broader normative effects. Closely following its conclusion, what looks like a norm cascade began, with a sharp upsurge at the UN in international statements on treatment as a human right and on state obligations to provide ARV.[84] This process moved later that year to the WTO in a Declaration on TRIPS and Public Health, issued at the Doha Ministerial Conference. In language redolent of human rights and the right to health, the declaration articulated

that WTO members had "the right to protect public health and, in particular, to promote access to medicines for all"; and "the right" to do so using TRIPS flexibilities such as compulsory licensing and parallel imports.[85]

These rhetorical commitments were matched by considerable policy and price shifts. Due to the combination of pressure, concessions, and the availability of generic alternatives from India (which was not yet bound by TRIPS), drug prices in many low-income countries dropped from US$15,000 to US$148 – $549 per annum.[86] Global funding mechanisms were created, such as the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, the US President's Emergency Plan for AIDS Relief (PEPFAR), and the World Bank Multi-Country HIV/AIDS Program for Africa. In 2002, WHO adopted the goal of placing 3 million people on ARV and, in late 2005, shifted upwards to the goal of achieving universal access to treatment by 2010, a goal similarly adopted by the UN General Assembly and by the G8 as part of a comprehensive plan of assistance for Africa.[87] In 2008, at the 61st World Health Assembly, WHO member states adopted a global strategy and plan of action on public health, innovation, and intellectual property explicitly based on recognizing the right to health and promoting a country's right to use TRIPS flexibilities to the fullest.[88] In six years, access to ARVs in sub-Saharan Africa increased from under 1% to 28%.[89] In 2006 and 2007, AIDS mortality decreased for the first time, partly due to the scaling up of ARV treatment services.[90]

IMPLICATIONS FOR RIGHTS AND TRADE

Rights-based discourse, litigation, and action appear to have played significant roles in shifting policy, price, and perception around AIDS medicines. In the PMA case, discursive arguments and empirical evidence in the litigation, accompanied by mass action and media attention, ensured growing reputational damage for the industry. Without this coercive pressure, the companies were unlikely to have withdrawn the litigation. However, the PMA case also illustrates how social action and rights discourse persuaded a global collective of the legitimacy of the rights claim for medicines and of the immorality of the corporate positions. This not only assured the collective disapproval that became so important to ensuring the corporate withdrawal of its litigation, but also led to a far broader global acceptance of the rights claim and a shift in perspectives on the moral necessity of ensuring access to AIDS medicines in Africa.

TAC members were able to engage the opportunity afforded by the litigation to illustrate counterfactual evidence regarding drug research and development, which not only considerably weakened PMA's challenge, but also undermined broader arguments about the threat to pharmaceutical innovation posed by the potential use of TRIPS flexibilities. The effectiveness of these strategies was to convey to both a court and the public that the litigation in question was a reasonable limitation of corporate profits and posed no real threat to broader medicines access. Certainly, other contemporary events, such as the US complaint against Brazil at the WTO, contributed to growing public pressure.[91] However, as this essay has sought to illustrate, the public attention to the PMA case was distinctive, and the case appeared to act as a turning point in the global (and, indeed, South African) battle for treatment.[92]

The combined force of persuasion and coercion appears to have initiated a process of normative emergence, tipping, and cascade, providing empirical evidence of Finnemore and Sikkink's theoretical model. In the gap that opened up, competing truths about the remediable nature of inaccessible AIDS medicines came to the fore. To return to the WHO framework on access to medicines, in which price is only one of four claimed factors, it is notable that the primary changes precipitating the steep rise in access to AIDS medicines were economic. This correlation suggests that factors like infrastructure (and poverty) are less of a bar to access than is commonly believed, and that political willingness to address other access factors may be fundamentally linked to removing financial barriers. Thus, addressing economic (price) factors may facilitate action on all other access fronts. The AIDS medicines experience further suggests that the multiplicity of variables influencing inaccessible medicines requires multiple strategies, including ensuring the affordability of medicines, rather than simply advancing increased international funding or poverty reduction as the solution, as company representatives have argued.[93] Nonetheless, the figures themselves express caution: at 28% access, over two-thirds of people in need remain without access. There is a persistent need to address other political and infrastructural constraints to access.

In the aftermath of the PMA case and ongoing treatment activism, other arguments have shifted; TRIPS clearly permits exceptions to its patent rules, international consensus is building that patents in poor countries serve no innovative function in motivating the development of drugs for diseases prevalent there, and experience suggests that adherence to ARVs among Africans is proving higher than among North Americans.[94] There is no basis, however, for triumphalism. While the gains are significant, they remain limited; TRIPS has been altered only through a miniscule and complex amendment with unproven utility. Moreover, the carve-out of permissible restrictions of TRIPS rights is limited to AIDS and Africa alone; health needs in other countries and for other drugs are still seen as illegitimate limitations of patent rights. This is exemplified, for example, by controversies over the Thai government's issuing of compulsory licenses in 2006 and 2007 for two antiretroviral drugs sold by Merck and Abbott and a heart medication sold by Bristol Meyers Squibb.[95] Abbott responded by announcing that it would no longer register new drugs for sale in Thailand.[96] The US government threatened trade sanctions by placing Thailand on a priority trade watch list in both 2007 and 2008, citing weakened respect for patents and concerns arising from these compulsory licenses.[97] Litigation and trade pressures on these fronts persist, and stringent patent protection is still sought through bilateral and regional free trade agreements.

With respect to the process explanations of normative influence, these outcomes seem to suggest an emergence and cascade of a right to medicines. However, the broader internalization of this right, which the theoretical models suggest will be the culmination of this process, has not yet occurred. An alternative possibility is that we are watching complementary normative processes, where a human right to AIDS medicines in Africa has, in fact, become internalized, while a more general right to medicines for the poor has not.[98] Either way, even if we view the gains on AIDS medicines as only reflecting tactical concessions, these changes nonetheless indicate that a process of normative diffusion and compliance has begun.[99] There is, however, nothing inevitable about the completion of the process, and much remains to be done if trade rules that proceed beyond tactical concessions and are more attentive to broader public health needs are to be achieved.

CONCLUSION

The AIDS medicines experience suggests that rights in concert with social movement offer a powerful tool for raising the priority of the health needs of the global poor, particularly when these are deemed to conflict with free trade and commercial interests. When assessed against the analytical backdrop of Finnemore and Sikkink's theory of normative emergence, the AIDS medicines experience can be seen to provide a strategic roadmap for advancing the completion of the process of normative diffusion, so that access to medicines as a human right starts to assume a "taken for granted" quality in politics, law, and public opinion. In this context, collective disapprobation of actions that limit access to medicines may become more likely, and political and legal acceptance of limiting patents in the service of access to medicines may follow. To achieve this, trade considerations should become inextricably linked to rights in political considerations and legal adjudication. Violations of the TRIPS agreement should be adjudicated against a broader international law framework in which rights are increasingly accepted as providing competing obligations. Potential strategies include advancing international law argument and reasoning at the WTO's Dispute Resolutions Panel and Appellate Body and influencing policy-makers by advancing a rights framework for assessing the legitimacy of TRIPS and any other bilateral, regional, or multilateral treaties containing intellectual property rights. Rights and international law may, therefore, offer a legal, political, and moral force that can be harnessed to alter existing interpretations and implementation of TRIPS and shift political and social understandings of right and wrong around medicines and trade. The promise of doing so is that TRIPS is increasingly assessed against a rights backdrop and that the health needs of the poor are more appropriately prioritized against private property interests.

ACKNOWLEDGMENTS

I am thankful for helpful comments from Ronald Labonte, Ron Bouchard, Jillian Clare Cohen-Kohler, Zehra Arat, Audrey Chapman, and Catherine Chalin, as well as from participants in the Columbia University Human Rights Seminar 2007 and Health in an Unequal World Network second group meeting, where earlier versions of this paper were presented.

REFERENCES

1. See, for example, L. Forman, "Trade Rules, Intellectual Property and the Right to Health," *Ethics and International Affairs* 21/3 (2007), p. 337.

2. For example, see M. Heywood, "Debunking 'Conglomo-talk:' A Case Study of the *Amicus Curiae* as an Instrument for Advocacy, Investigation and Mobilisation" (paper presented at the conference on Health Law and Human Rights: Exploring the Connections, An International Cross-Disciplinary Conference Honouring Jonathan M. Mann, September 29–October 1, 2001, Philadelphia, PA); D. Barnard, "In the High Court of South Africa, Case No. 4138/98: The Global Politics of Access to Low-Cost AIDS Drugs in Poor Countries," *Kennedy Institute of Ethics Journal* 12/2 (2002), pp. 159–174; E. F. M. 't Hoen,"TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way from Seattle to Doha," *Chicago Journal of International Law* 3/2 (2002), p. 27; and T. Olesen, "'In the Court of Public Opinion': Transnational Problem Construction in the HIV/AIDS Medicine Access Campaign, 1998–2001," *International Sociology* 21/1 (2006), p. 5.

3. *Agreement on Trade-Related Aspects of Intellectual Property Rights,* Annexure 1C to the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco, on April 15, 1994, (TRIPS), Articles 28.1.a and b.

4. World Health Organization (WHO), *Globalization, TRIPS, and Access to Pharmaceuticals*, Policy Perspectives on Medicines Series No. 3 (2001), p. 3; S. Bartelt, "Compulsory Licenses Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health," *Journal of World Intellectual Property* 6/2 (2003), p. 285.

5. TRIPS (see note 3), Articles 6 and 31.

6. L. Forman, "Trading Health for Profit: Bilateral and Regional Free Trade Agreements Affecting Domestic Property Rules on Intellectual Property Rules on Pharmaceuticals," in J. C. Cohen, U. Schuklenk, and P. Illingsworth (eds), *The Power of Pills: Social, Ethical, and Legal Issues in Drug Development, Marketing, and Pricing* (London: Pluto Press, 2006), p. 190.

7. F. M. Abbott, "Study Paper for the British Commission on Intellectual Property Rights on the WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries," (London: Commission on Intellectual Property Rights, 2002), p.5; C. Correa, "Public Health and Intellectual Property Rights," Global Public Policy 2/3 (2002), p. 262; M. G. Bloche, "WTO Deference to National Health Policy: Toward an Interpretive Principle," *Journal of International Economic Law* 5/4 (2002), p. 838.

8. While Canada implemented legislation in 2004 to enable exports under license, this provision remained unutilized until 2007, when Rwanda gave notification of its intent to import medicines from Canada.

9. Forman (see note 1), p. 341.

10. The other three primary variables are rational use of medicines, the existence of adequate infrastructures, and sustainable financing. See WHO, *WHO Medicines Strategy: Countries at the Core 2004–2007* (Geneva: WHO, 2004), p. 24.

11. F. M. Scherer, "The Pharmaceutical Industry," in A. L. Culyer and J. P. Newhouse (eds), *Handbook of Health Economics*, Volume 1. (New York: Elsevier Science B.V., 2000), pp. 1322–1324; R. E. Caves, M. D. Whinston, and M. A. Hurwitz, "Patent Expiration, Entry, and Competition in the US Pharmaceutical Industry," *Brookings Papers on Economic Activity Special Issue: Microeconomics 1991* (Washington: The Brookings Institution, 1991), pp. 1–66.

12. G. Velásquez, Y. Madrid, and J. Quick, "Health Reform and Drug Financing, Selected Topics," *Health Economics and Drugs*, DAP Series no. 6. WHO/DAP/98.3 (Geneva: WHO, 1998); WHO (see note 10), p. 14.

13. These effects were illustrated by the absence of public-sector or international financing of AIDS medicines until their prices were greatly reduced, and by the decision of international organizations to treat malaria using chloroquine despite its growing inefficacy, rather than artemesinin, a far more effective and expensive drug.

14. WHO, *Public Health Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation, and Public Health* (Geneva: WHO, 2006), p. 28.

15. P. Trouiller et al., "Drug Development for

Neglected Diseases: A Deficient Market and a Public Health Policy Failure," *Lancet* 359 (2002), p. 2188.

16. M. Moran, "A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs We Need," *PLoS Medicine* 2/9 (2005), p. 829.

17. WHO and UNAIDS, *Progress on Global Access to HIV Antiretroviral Therapy: A Report on "3 by 5" and Beyond* (Geneva: WHO, 2006), p. 34. See also, United Nations World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHA61.21 (May 24, 2008), para. 7 (recognizing that, while intellectual property rights are an important incentive for developing new health-care products, this "incentive alone does not meet the need for the development of new products to fight disease where the potential paying market is small or uncertain").

18. Forman (see note 6).

19. J. Shand Watson, *Theory and Reality in the International Protection of Human Rights* (Ardsley: Transnational Publishers, 1999); D. Kennedy, "The International Human Rights Movement: Part of the Problem?" *Harvard Human Rights Journal* 15 (2002), p. 101.

20. H. Klug, *Constituting Democracy: Law, Globalism, and South Africa's Political Reconstruction* (Cambridge: Cambridge University Press, 2000), p. 12.

21. See, for example, International Covenant on Economic, Social and Cultural Rights (ICESCR), G.A. Res. 2200 (XXI), UN GAOR, 21st Sess., Supp. No. 16, at 49, UN Doc. No. A/6316 (1966) Article 12.1; Convention on the Rights of the Child (CRC), G.A. Res. 44/25, UN GAOR, 44th Sess., Supp. No. 49, at 166, UN Doc. No. A/44/25 (1989), Article 24.1; Convention on the Elimination of All Forms of Racial Discrimination, G.A. Res. 2106A (XX) (1965), Article 5(e)(iv); Convention on the Elimination of All Forms of Discrimination Against Women, G.A. Res. 34/180, UN GAOR, 34th Sess., Supp. No. 46, at 193, UN Doc. No. A/34/46 (1979), Articles 11.1.f and 12; Council of Europe, The European Social Charter, October 18, 1961, 529 U.N.T.S. 89, Article 11; African Charter on Human and People's Rights, June 27, 1981, O.A.U. Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), Article 16; and Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social, and Cultural Rights (Protocol of San Salvador) (1988), Article 10.

22. For example, 193 states, an effective universality, are party to the Children's Rights Convention (CRC); 185 states have ratified the Convention on the Elimination of Discrimination Against Women (CEDAW); 173 have ratified the Convention on the Elimination of Racial Discrimination (CERD); and 157 have ratified the Covenant on Economic, Social and Cultural Rights (CESCR). UN Office of the High Commissioner for Human Rights, *Ratifications and Reservations* (2008). Available at http://www2.ohchr.org/english/bodies/ratification/index.htm.

23. Committee on Economic, Social and Cultural Rights, General Comment No. 14: The Right to the Highest Attainable Standard of Health. UN Doc. No. E/C.12/2000/4 (2000), paras 42–43.

24. E. D. Kinney and B. A. Clark, "Provisions for Health and Healthcare in the Constitutions of the Countries of the World," *Cornell International Law Journal* 37 (2004), p. 287.

25. See, for example, *Paschim Banga Khet Mazdoor Samity v. State of West Bengal* (1996), 4 S.C.C. 37; *Eldridge v. British Columbia* (Attorney General) (1997), 3 S.C.R. 624; *Minister of Health and Another v. Treatment Action Campaign and Others* (2002), 5 South African Law Report 721 (South African Constitutional Court); *Viceconti v. Ministry of Health and Social Welfare* (1998) (Argentina, Poder Judicial de la Nación, Causa no. 31.777/96, June 2, 1998); *Cruz Bermudez et al. v. Ministerio de Sanidad y Asistencia Social* (Supreme Court of Justice of Venezuela, Case No. 15.789, Decision No. 916, July 15, 1999).

26. See, for example, H. V. Hogerzeil, M. Samson, J. V. Casanovas, and L. Rahmani-Ocora, "Is Access to Essential Medicines as Part of the Fulfillment of the Right to Health Enforceable through the Courts?" *Lancet* 368 (2006), p. 306.

27. For example, in the 2002 Minister of Health decision in South Africa, the Constitutional Court held that the South African government was bound to ensure access to services to prevent mother-to-child transmission of AIDS as part of their constitutional duties under the right to access healthcare services. As a result, the government implemented a national program in over 80% of government clinics. This decision also laid the groundwork for a national AIDS treatment pro-

gram, which was announced in 2003. By October 2006, approximately 165,000–175,000 people were obtaining antiretrovirals through this program. See Republic of South Africa, Ministry of Health, *100% Coverage for Prevention of Mother to Child Transmission of HIV* (March 12, 2007). Available at http://www.doh.gov.za/docs/pr/2007/pr0312a.html; International Treatment Preparedness Coalition (ITPC), *Missing the Target #3: Stagnation in AIDS Treatment Scale Up Puts Millions of Lives at Risk* (November 28, 2006), p. 45.

28. Forman (see note 1), p. 346.

29. Watson (see note 19).

30. J. N. Shklar, *The Faces of Injustice* (New Haven, CT: Yale University Press, 1990), quoted in Harvard Law School Human Rights Program, *Economic and Social Rights and the Right to Health: Session II: Defining the Right to Adequate Health* (Cambridge, MA: Harvard Law School Human Rights Program, 1995), p. 30.

31. To expand, illegal slavery persists, particularly among migrant laborers and women and children in the global sex trafficking industry, and may well involve larger numbers of people than previous centuries of legal slavery. Moreover, in many countries, legal economic slavery is permitted in the form of lesser legal rights for migrant domestic, agricultural, and temporary workers.

32. For example, Adam Smith argued that slavery was grossly inefficient because slaves had no interest but to "eat as much as possible and to labour as little as possible." A. Smith, *The Wealth of Nations* (New York: Norton, 1937), p. 63. For arguments about the contributions of moral norms to abolition, see J. L. Ray, "The Abolition of Slavery and the End of International War," *International Organization* 43/3 (1989), p. 415; C. Brinton, *A History Of Western Morals* (New York: Harcourt, Brace, 1959), pp. 435–436.

33. See, for instance, D. Eltis, *Economic Growth and the Ending of the Transatlantic Slave Trade* (New York: Oxford University Press, 1987), pp. 15 and 28; H. Temperley, "Anti-Slavery as Cultural Imperialism," in C. Bolt and S. Drescher (eds), *Anti-Slavery, Religion and Reform* (Hamden, CT: Anchor Books, 1980), p. 339; and J. L. Ray, "The Abolition of Slavery and the End of International War," *International Organization* 43/3 (1989), p. 415.

34. See, for example, R. Balakrishnan, "International Law and Social Movements: Challenges of Theorizing Resistance," *Columbia Journal of Transnational Law* 41 (2003), p. 401.

35. R. Balakrishnan, *International Law from Below: Development, Social Movements and Third World Resistance* (Cambridge, UK: Cambridge University Press, 2003); U. Baxi, *The Future of Human Rights* (Oxford: Oxford University Press, 2006); B. de Sousa Santos, *Toward a New Legal Common Sense: Law, Globalization, and Emancipation,* 2nd ed. (London: Butterworths Lexis Nexis, 2002); T. Risse-Kappen, *Bringing Transnational Relations Back In: Non-State Actors, Domestic Structure, and International Institution* (Cambridge, UK: Cambridge University Press, 1995).

36. Baxi (see note 35), p. 101; R. B. Siegel, *The Jurisgenerative Role of Social Movements in United States Constitutional Law* (Paper presented at the Latin American Seminar on Constitutional and Political Theory on the Limits of Democracy, June 2004).

37. See, for example, M. Mutua, "Savages, Victims, and Saviours: The Metaphor of Human Rights," *Harvard International Law Journal* 42/1 (2001), pp. 201–245.

38. W. Golding, *Lord of the Flies* (New York: Berkley Publishing Group, 1954).

39. This is not to argue, however, that all such claims will have this power. As Paul Farmer alerts, "[t]he risk of stretching the concept of rights to cover every possible case is that obscene inequalities of risk will be drowned in a rising tide of petty complaint." See P. Farmer, *Pathologies of Power: Health, Human Rights, and the New War on the Poor* (Berkeley and Los Angeles: University of California Press, 2003), p. 231.

40. S. K. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge, UK: Cambridge University Press, 2003), pp. 5–6; R. Weissman, "A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries," *University of Pennsylvania Journal of International Economic Law* 17 (1995), p. 1069.

41. H. L. A. Hart, *Concept of Law* (Broadbridge, UK: Clarendon Press, 1961).

42. P. Williams, *The Alchemy of Race and Rights* (Cambridge, MA: Harvard University Press, 1992), p. 159.

43. J. D. Faubion (ed), *Michel Foucault — Power: Essential Works of Foucault 1954–1984* (New York: New York Press, 1994), p. 131.

44. Ibid., p. 132.

45. For example, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), *TRIPS, Pharmaceutical, and Developing Countries: Implications for Health Care Access, Drug Quality and Drug Development* (Geneva: IFPMA, 2000), p. 14; R. P. Rozek and R. Berkowitz, "The Effects of Patent Protection on the Prices of Pharmaceutical Products: Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?" *The Journal of World Intellectual Property* 1 (1998), pp. 179–243; R. Mallett, (Commission on Intellectual Property Rights, Conference on How Intellectual Property Rights Could Work Better for Developing Countries and Poor People, Transcript, Session 6: Medicines and Vaccines, London: Royal Society, February 21–22, 2002). Available at http://www.iprcommission.org/papers/word/conferences/session6.doc; J. Donnelly, "Natsios Called Racist; Firing Sought," *The Boston Globe* (June 9, 2001).

46. O. Hathaway, "Do Human Rights Treaties Make a Difference?" *Yale Law Journal* 111/8 (2002), p. 1944.

47. A. T. Guzman, "A Compliance-based Theory of International Law," *California Law Review* 90 (2002), p. 1823.

48. G. W. Downs, "Enforcement and the Evolution of Cooperation," *Michigan Journal of International Law* 19 (1998), p. 321.

49. R. O. Keohane, "International Relations and International Law: Two Optics," *Harvard Journal of International Law* 38 (1997), p. 487.

50. O. R. Young, *International Governance: Protecting the Environment in a Stateless Society* (Ithaca, NY: Cornell University Press, 1994), p. 134; B. Kingsbury, "The Concept of Compliance as a Function of Competing Conceptions of International Law" *Michigan Journal of International Law* 19 (1998), p. 349.

51. Regarding the mechanism of "an iterative process of discourse," see A. Chayes and A. Handler Chayes, *The New Sovereignty: Compliance with International Regulatory Agreements* (Cambridge, MA: Harvard University Press, 1995), p. 25; regarding "a transnational legal process," see H. H. Koh, "Why Do Nations Obey International Law?" *Yale Law Journal* 106 (1997), p. 2599; and regarding the third mechanism, see J. T. Checkel, "The Constructivist Turn in International Relations Theory," *World Politics* 50/2 (1998), p. 324.

52. This linkage is explicitly explored in J. F. Keeley, "Toward a Foucauldian Analysis of International Regimes," *International Organization* 44/1 (1990), pp. 83–105. The quote is from M. Finnemore and K. Sikkink, "Taking Stock: The Constructivist Research Program in International Relations and Comparative Politics," *Annual Review of Political Science* 4 (2001), p. 398.

53. Koh (see note 51), p. 2649.

54. J. T. Checkel, "International Norms and Domestic Politics: Bridging the Rationalist-Constructivist Divide," *European Journal of International Relations* 3/4 (1997), p. 475. These competing logics were originally coined by J. G. March and J. P. Olsen, *Rediscovering Institutions* (New York: Free Press, 1989).

55. Checkel (see note 54).

56. See, for example, Koh (see note 51); M. Finnemore and K. Sikkink, "International Norm Dynamics and Political Change," *International Organization* 52/4 (1998), p. 887; T. Risse, S. C. Ropp, and K. Sikkink (eds), *The Power of Human Rights: International Norms and Domestic Change* (Cambridge, UK: Cambridge University Press, 1999).

57. Finnemore and Sikkink (see note 56), p. 888.

58. Ibid., p. 895.

59. Ibid., p. 895.

60. Ibid., see also, M. Gladwell, *The Tipping Point* (New York: Little, Brown, 2000).

61. Finnemore and Sikkink (see note 56), p. 897.

62. Ibid., p. 895.

63. Z. Arat, "Human Rights in Political Party Programs: Inferences from the Case of Turkey" (Paper presented at the International Studies Conference, San Diego, CA, March 22–25, 2006, p. 18; on file with the author).

64. For a similar critique of constructivism more generally, see T. Solomon, "Norms and Human Rights in International Relations," *Political Studies Review* 4 (2006), pp. 44–45, and O. J. Sending, "Constitution, Choice and Change: Problems with the 'Logic of Appropriateness' and Its Use in Constructivist Theory," *European Journal of International Relations* 8 (2002), p. 459–460.

65. M. Finnemore, *National Interests in International Society* (Ithaca and London: Cornell University Press, 1996), pp. 23–24.

66. WHO and UNAIDS, *Guidance Modules on Antiretroviral Treatments: Module 9: Ethical and Societal Issues Relating to Antiretroviral Treatments* WHO/ASD/98.1, UNAIDS/98.7 (Geneva: WHO, 1998), p. 13.

67. For example, E. Marseille, P. B. Hoffman, and J. G. Kahn, "HIV Prevention before HAART in Sub-Saharan Africa," *Lancet* 359/9320 (2002), pp. 1851–1856.

68. See, for example, L. Highleyman, "The Global Epidemic: Affordable Drug Access for Developing Countries," *Bulletin of Experimental Treatments for AIDS* (Summer/Autumn 2001).

69. See P. Bond, "Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S Firms and Politicians," *International Journal of Health Services* 29/4 (1999), pp. 788–798; B. Gellman, "A Conflict of Health and Profits; Gore at Center of Trade Policy Reversal on AIDS Drugs to S. Africa," *Washington Post* (May 21, 2000), p. A01.

70. *The Pharmaceutical Manufacturer's Association and Others v. The President of the Republic of South Africa* (*PMA*) case no. 4183/98, Trans. Prov. Div., Notice in terms of Rule 16A, establishing the constitutional issues raised in the applicant's notice of motion and supporting affidavits, para. 1.b. (PMA case).

71. Ibid., Founding Affidavit, paras. 5 and 8.

72. Ibid., Answering Affidavit, paras. 78(a) and 83(a).

73. The only mention of human rights came in the South African government's argument that South Africa's constitutional right to access health care services obligated passing the legislation. See Ibid., Answering Affidavit, para. 77(c).

74. Republic of South Africa, 1996, *Constitution of the Republic of South Africa,* Act 108. Sections 27(1) and 36.

75. *PMA Case* (see note 70), "TAC Founding Affidavit in Application to be admitted as an *Amicus Curia*, deposed to by Theodora Steele," paras. 11, 15, 16, and 90–98.

76. See, for example, *PMA Case* (see note 70), TAC Replying Affidavit, paras. 35–37, and the Supporting Affidavits by James Packard Love, Nomfundo Dubula, Siphokazi Mthathi, Helen Makebesana, Ntombozuko Khwaza, Thandela Mantshi, Rose Feni, Vernon Ogle, and Judith Ogle.

77. See M. Harvey, "Worldwide Protest Mark First Day of Drug Trial," *WOZA Internet* (March 6, 2001; and Heywood (see note 2), p. 9. Protests were held in countries worldwide, including Canada, the United Kingdom, Brazil, the Philippines, the USA, Britain, Kenya, Thailand, France, Italy, Denmark, Australia, and Germany.

78. Heywood (see note 2), p. 9.

79. C. McGreal, "Shamed and Humiliated — the Drug Firms Back Down," *The Guardian* (April 19, 2001); and Heywood (see note 2), p. 9.

80. Agence France Presse, "WHO Backs South Africa in Anti-AIDS Drug Case" (March 6, 2001).

81. C. Denny, "Mandela Hits Out at AIDS Drug Firms," *The Guardian* (April 16, 2001).

82. *PMA Case* (see note 70), "Joint Statement of Understanding between the Republic of South Africa and the Applicants."

83. *Washington Post*, "Patent Wrongs," Editorial (February 25, 2001); T. Karon, "AIDS Drugs Case Puts Our Ideas About Medicine on Trial," *Time World* (March 5, 2001).

84. United Nations Commission on Human Rights Resolutions 2001/33 (April 23, 2001), 2002/32 (March 6, 2002), 2003/29 (April 22, 2003), 2004/26 (April 16, 2004); UN Commission on Human Rights, *Intellectual Property Rights and Human Rights: Report of the Secretary-General*, UN Doc. No. E/CN.4/Sub.2/2001/12 (2001); UN Commission on Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights: Report of the High Commissioner*, UN Doc. No.E/CN.4/Sub.2/2001/13 (2001); UN Committee

on Economic, Social and Cultural Rights, *Human Rights and Intellectual Property*, UN Doc. No. E/C.12/2001/15 (2001); UN Office of the High Commissioner for Human Rights and UNAIDS, *HIV/AIDS and Human Rights International Guidelines, Revised Guideline 6: Access to Prevention, Treatment, Care and Support, Third International Consultation on HIV/AIDS and Human Rights*, UNAIDS/02.49E, HR/PUB/2002/1 (Geneva: 2002).

85. World Trade Organization, Ministerial Conference fourth session, Doha, November 9–14, 2001, "Declaration on the TRIPS Agreement and Public Health," adopted on November 14, 2001, WT/MIN(01)/DEC/2, para. 4.

86. WHO and UNAIDS (see note 17), p. 30.

87. United Nations General Assembly, 60th Session, *2005 World Summit Outcome*, GA Res. 60/1, UN GAOR, UN Doc. No. A/Res/60/1 (2005), para. 57d; WHO (see note 14); Group of Eight, Gleneagles Summit, Chair's Summary, July 8, 2005.

88. UN World Health Assembly (see note 17), paras. 16 and 35–36, respectively.

89. WHO, UNAIDS, and UNICEF, *Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector, Progress Report* (Geneva: WHO, 2007), p. 5.

90. UNAIDS and WHO, "AIDS Epidemic Update: December 2007," UNAIDS/07.27E / JC1322E (Geneva: WHO/UNAIDS, 2007), pp. 5–6.

91. In 2001, the US lodged a complaint at the WTO against Brazil's intellectual property law for a provision that enabled compulsory licenses to be issued even without local working of the patent in Brazil. Simultaneous global demonstrations against the PMA litigation focused on the US WTO complaint against Brazil with similarly effective results. The US and Brazil settled the complaint on the basis that the clause could remain, as long as Brazil met certain pre-conditions if it used the law.

92. On the progression of South African rights-based AIDS struggles after PMA, see L. Forman, "Ensuring Reasonable Health: Health Rights, the Judiciary and South African HIV/AIDS Policy," *Journal of Law, Medicine and Ethics* 33/4 (2005), p. 711.

93. R. Sykes, "The Reality of Treating HIV and AIDS in Poor Countries," *British Medical Journal* 324/7331 (2002), pp. 214–218.

94. See, for example, WHO (see note 14), p. 34; and UN World Health Assembly (see note 18), para. 7; and E. J. Mills et al., "Adherence to HAART: A Systematic Review of Developed and Developing Nation Patient-Reported Barriers and Facilitators," *PLoS Medicine* 3/11 (November 2006). Available at http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371%2Fjournal.pmed.0030438.

95. Thailand Ministry of Public Health and National Health Security Office, "Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand," February 2007. Available at http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf.

96. N. Zamiska and J. Hookway, "Abbott's Thai Pact May Augur Pricing Shift," *Wall Street Journal* (April 23, 2007), p. A3.

97. Office of the United States Trade Representative, "2007 Special 301 Report," p. 27, and Office of the United States Trade Representative, "2008 Special 301 Report," p. 37.

98. Hestermeyer broadens the nature of the emerging rule beyond the circumscribed bounds of a right to AIDS medicines in Africa, to a customary right to access life-saving medicine in national health emergencies. H. Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford: Oxford University Press, 2007), p. 131.

99. Risse et al. (see note 56), p. 20.