

# A Human Rights Approach to Intellectual Property and Access to Medicines

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## Executive Summary

In this paper, we address whether and how human rights norms and frameworks can be used to improve access to medicines (A2M) by reducing the barriers that intellectual property (IP) laws create to such access. We evaluate the feasibility and usefulness of four human rights-based strategies that our contacts in the A2M community suggested might be particularly productive: (1) the use of human rights arguments in domestic court cases that deal with intellectual property laws, (2) the articulation of norms in the United Nations (UN) human rights system, (3) the use of human rights arguments and frameworks to secure greater pharmaceutical corporate accountability, and (4) the use of health-related rights to build multilateral and regional alliances that can more effectively oppose free trade agreements (FTAs) with TRIPS-plus provisions (TRIPS being Trade-Related Aspects of Intellectual Property Rights). We offer insights and specific short- and long-term action steps for each strategy, including recommendations for further research.

We also offer this brief executive summary of each of the four sections that follow.

**In the first section, we address how, in the past few years, domestic courts have displayed a growing willingness to use human rights laws to reinterpret and even strike down IP laws that impede access to medications.** For example, a court in India concluded that it could not issue injunctions in patent cases where the result would be a substantial increase in the price of medicines, relying in part on the right to life in the Indian constitution. A court in Kenya struck down an “anti-counterfeiting” law as a violation of the right to health in the Kenyan constitution. And a court in Colombia concluded that local health rights required it to enforce price control requirements (if not issue a compulsory license, as activists argued). If the logic of these cases were successfully extended to other countries and other areas of doctrine, domestic human rights protections could serve as a powerful fulcrum to help dislodge harmful intellectual property laws. Judicial articulation of the relationship between the right to health and intellectual property law might also legitimize broader political actions that prioritize the right to health over intellectual property protection. Although such court cases have not always succeeded, and gains have been incremental thus far, this strategy appears to be gaining momentum. *We recommend that activists prioritize the pursuit of human rights arguments in IP-related court cases at the national level. We consider this to be the most promising of the four approaches we have considered, with the greatest likelihood of providing real results for access in the near future.*

**The second section considers how a number of international human rights treaties contain rights that bear on access to medicines.** A variety of UN human rights bodies have already begun to develop law at the intersection of health-related rights and IP. An important general comment, for example, makes it clear that access to medicines is a component of the right to health. Human rights bodies have also recognized that TRIPS can negatively impact access and have urged states to utilize TRIPS flexibilities and avoid TRIPS-plus provisions in FTAs. But existing articulations of these obligations remain somewhat underspecified and are often couched in terms that leave much discretion to states. At least one recent human rights document, however, suggests that states “must” use TRIPS flexibilities, at least in certain circumstances. There is potential to build upon this work, to enunciate more specific obligations,

and to stimulate more focused reviews of state practice. However, processes for achieving these results within the UN system are challenging. Pursuing a system-wide strategy that incorporates all of the political and expert bodies would require tremendous resources with uncertain rewards. *We recommend that A2M activists assess and pursue selected human rights mechanisms that are likely to be the most feasible and productive, especially as applied in specific, strategic moments and country contexts. This may be particularly valuable to help support and disseminate successes at the national level.*

**The third section engages with the question of corporate accountability.**

Pharmaceutical corporations have traditionally rejected the notion that they have *obligations* under the right to health, in part because the international human rights system has not historically considered corporate actors to be directly governed by human rights law. Recent developments, including the emergence of the Working Group on Business & Human Rights, may give A2M activists new tools for campaigns against companies. Some, however, have concerns about the limits of the norms that are being developed in this process, which tend to be modest, for example focusing on transparency. In campaigns, however, human rights language continues to be an important moral resource for targeting corporate conduct. *We recommend further discussion by activists of the benefits and limits of formal human rights work on corporate liability, and that “informal” human rights language be invoked in campaigning to help concretize norms on pharmaceutical companies’ moral and legal obligations.*

**The fourth section notes that activists already utilize human rights arguments to oppose TRIPS-plus provisions in FTAs.** Human rights arguments could be additionally employed at all political levels by activists to generate political will and foster solidarity for the formation of multilateral alliances. Heightened negotiating power resulting from south-south alliances framed around human rights could provide developing countries with the opportunity and strength to oppose TRIPS-plus FTA provisions and stem the proliferation of IP norms that threaten access to medicines. Human rights arguments may provide a useful set of norms to help ensure that resulting alliances remain committed to protecting the right to health. *We recommend that activists continue to invoke human rights as a political tool to encourage south-south alliances, particularly informal ones, and to help generate leverage against regressive FTAs.*

Finally, the paper concludes with several appendices that we hope will be of use to activists working on these issues. *Appendix A* gathers the most important recent domestic court cases in the area and describes their key holdings. *Appendix B* collects and describes the most important international human rights documents and standards relevant to IP and A2M. *Appendix C* offers clarification on the evolution of principles of corporate obligations to respect human rights. (Access to a Dropbox that includes all of the listed resources is also available on request.)

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## Acronyms

<b>A2M</b>	Access to Medicines
<b>ASEAN</b>	Association of Southeast Asian Nations
<b>BRICS</b>	Brazil, Russia, India, China, and South Africa
<b>BSR</b>	Business for Social Responsibility
<b>CEDAW</b>	Convention on the Elimination of All Form of Discrimination Against Women/ Committee on the Elimination of Discrimination Against Women
<b>CRC</b>	Covenant on the Rights of the Child/Committee on the Rights of the Child
<b>CRPD</b>	Convention on the Rights of Persons with Disabilities/Committee on the Rights of Persons with Disabilities
<b>CESCR</b>	Committee on Economic, Social, and Cultural Rights
<b>CSR</b>	Corporate Social Responsibility
<b>FTA</b>	Free Trade Agreement
<b>GATT</b>	General Agreement on Tariffs and Trade
<b>HIV/AIDS</b>	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
<b>HRC</b>	Human Rights Committee (charged with enforcing the ICCPR; not to be confused with the Human Rights Council)
<b>ICCPR</b>	International Covenant on Civil and Political Rights
<b>ICESCR</b>	International Covenant on Economic, Social, and Cultural Rights
<b>IP</b>	Intellectual Property
<b>KEI</b>	Knowledge Ecology International
<b>MSF</b>	Médecins Sans Frontières
<b>NGO</b>	Non-Governmental Organization
<b>OHCHR</b>	Office of the High Commissioner for Human Rights
<b>TAC</b>	Treatment Access Campaign
<b>TRIPS</b>	Trade-Related Aspects of Intellectual Property Rights
<b>TWN</b>	Third World Network
<b>UDHR</b>	Universal Declaration of Human Rights
<b>UN</b>	United Nations
<b>UPR</b>	Universal Periodic Review
<b>WTO</b>	World Trade Organization
<b>3D</b>	3D – Trade, Human Rights, Equitable Economy

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## Introduction

It is well understood that patent protection increases the price of medications and thereby decreases access to them. That many people in middle- and low-income countries cannot afford patented medications is also clear. Existing international law allows countries a variety of strategies to ameliorate the problems that intellectual property (IP) causes for medicines. However, nearly all developing nations fail to make extensive use of Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities. They continue to enforce—and, indeed, to ratchet up—stringent IP protections, despite the consequences of these laws on health. Developed nations put pressure on developing countries, using trade agreements and threats to impose trade sanctions or withhold trade or investment benefits. Fearful of sanctions and desirous of increased tariff liberalization, developing nations often trade away intellectual property provisions with important public health implications for ostensible economic benefits. This bullying dynamic is fueled in many developed and developing countries by elite capture: out of both self interest and ideology, the politically and economically powerful may support such deals as not only in their own interests, but in everyone’s interests. Pharmaceutical companies make their own promises and threats to coax developing nations into strengthening patent protection and use developed country governments to do the same. There are also serious problems with capacity at the local level. Many governments lack the administrative resources to navigate even the relatively simple requirements of compulsory licensing, much less the more resource-intensive work required to examine patents rigorously. All of these factors reinforce each other and have led to a widespread prioritization of IP protection over health-related rights.

### What Leverage Might Human Rights Provide?

**This paper asks whether human rights arguments, tactics, and institutions can be used to intervene in the structural dynamics identified above and help promote more long-term, sustainable solutions to the obstacles that IP creates for access to medicines.**

We define “human rights” as a set of formal law-based systems and obligations, as well as a group of normative claims about human flourishing and development. Human rights arguments rely on existing legal as well as evolving normative claims and often use institutions, such as the United Nations (UN), to give these claims the force of law. A wide range of sources demarcates the scope of human rights norms and obligations: formal UN treaties and declarations, expert reports, domestic court decisions, regional court decisions, and civil society proclamations are just a few. The documents and institutions that define the human rights system exist at the international, regional, and national levels, and proceedings at one level often influence the other. While our analysis of the human rights system is not exhaustive, it represents a sampling of both national- and international-level action, or a lack thereof.

While focusing on the human right to health, this paper also touches on other health-related rights—for example, the right to life and the right to benefit from scientific progress. Because the cases, UN documents, and international agreements discussed in this paper often examine the right to health in conjunction with these other health-related rights, it sometimes makes sense to look at these rights as a group. Many health-related rights are well entrenched in international law. The Universal Declaration of Human Rights (UDHR) 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.”<sup>1</sup> This right has been defined to include the right to access essential medicines.<sup>2</sup> States have also chosen to protect the right to health in their national laws and constitutions. Over 100 countries have incorporated the right to health into their constitutions, and 160 countries have acceded to the right to health through their international treaty obligations.<sup>3</sup>

**Nevertheless, to date, the access to medicines movement (A2M) has used health-related rights in very limited ways.** The following sections discuss the ways in which the A2M movement has used these rights. Moreover, we analyze the leverage that human rights arguments and institutions might provide to the A2M movement. We first discuss the potential advantages of human rights arguments, and then their potential limitations.

**One advantage is that human rights arguments can be directly enforced in some local courts and sometimes by other bodies (e.g. regional courts).** This category of human rights arguments has the potential to compel implementation of TRIPS flexibilities directly. For example, acceptance of human rights standards could strengthen the legal basis for issuing compulsory licenses, or perhaps even obligate countries to issue such licenses. Arguments about the right to health could be mobilized to encourage courts to grant royalties rather than injunctions in patent cases with health implications. Human rights obligations could thus be used to interpret or affect the implementation of IP-related, national and international legal standards—or even to override and invalidate local IP laws. This strategy is particularly promising if courts are better insulated from the political compromises and pressures facing other branches of government and therefore may be more receptive to legal arguments regarding the health related rights.

**The international human rights system best illustrates the second kind of leverage that human rights might provide: Although this system is designed to be based on dialogue and can only rarely be used to compel immediate legal action, it can help develop and globalize favorable legal norms.** UN documents set a floor with respect to the human rights obligations of states, and UN bodies can develop and articulate the scope of these obligations with some specificity, especially if they obtain input from knowledgeable non-governmental organizations (NGOs). Activists can (and do) work directly within trade and IP institutions, like the World Trade Organization (WTO), to articulate access-friendly norms, but human rights institutions may be more receptive to activist claims regarding health-related rights than the institutions dominated by trade-focused actors. While not all norms articulated in the UN human rights system maybe directly enforceable or effective at the national level, new norms developed in the international human rights system can help educate, as well as reinforce the resolve and authority of local institutions that seek to address IP barriers. For example, they may influence or validate local court decisions. They also may give a mandate, or legal cover, to actors within UN institutions who seek to facilitate local efforts to address IP problems (e.g. the Joint United Nations Programme on HIV/AIDS or the UN Development Programme). In other words, these institutions can contribute to the legitimacy of formal claims countering IP norms.

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<sup>1</sup> Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (Dec. 10, 1948) [hereinafter UDHR].

<sup>2</sup> Comm. on Econ, Soc., & Cultural Rights, CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000) [hereinafter General Comment 14].

<sup>3</sup> HANS V. HOGERZEIL, MELANIE SAMSON, & JAUME VIDAL CASANOVA, RULING FOR ACCESS LEADING COURT CASES IN DEVELOPING COUNTRIES ON ACCESS TO ESSENTIAL MEDICINES AS PART OF THE FULFILLMENT OF THE RIGHT TO HEALTH (2004).

The issue of whether human rights norms can or should have any role in WTO dispute settlement is hotly debated. If strong human rights norms regarding the link between IP and health-related rights were recognized (for example, that a constitutional right to health necessarily requires limits on patentability like those in India's Section 3(d) or that limits on injunctions are a necessary flexibility under international human rights law), these norms could plausibly have some influence on a WTO panel.<sup>4</sup>

**Activists and policy-makers can also use human right arguments in a third, more colloquial manner: A2M activists often make rights claims in an advocacy context that call upon the moral power of human rights.** Formal, existing legal norms do not limit the scope of human rights arguments in this context as they do in front of local courts or the UN, and this can add to their power. For example, activists might demand "patients' rights not patent rights" without saying more. This statement is not a direct legal claim, but rather a human rights argument that some have called (in a non-derogatory fashion) "t-shirt rights," a powerful means of making calls to basic justice through popular action.<sup>5</sup> Such popular, moral rights claims gain power from the more specific norm articulation that goes on in domestic courts or at the UN, but they can also go beyond those arguments, because the precise demands of law do not constrain them. "T-shirt"-type human rights arguments have been important to the A2M movement because it is easier to build an international movement around, for example, the right to life than the right to competition. Civil society movements have the ability to counterbalance the power of governments and pharmaceutical corporations. Nevertheless, popular rights claims that are unmoored from legal claims may not help, and might hinder, activist efforts to gain formal recognition of human rights in front of courts or the UN. Therefore, it is critical to consider how popular rights claims and legal rights claims can provide strategic support for one another, as well as the importance of keeping and make use of a popular dimension in a human rights strategy, as part of a commitment to retaining an activist mooring for efforts to expand A2M.

**A fourth possible advantage of human rights strategies is process-oriented: Employing human rights arguments might allow activists to call attention to key issues, forge new alliances, and engage government officials in new locations.** For example, building norms in international institutions would likely require, and also help to produce, more significant partnerships with other human rights organizations.

Like all strategies, the human rights approach does have potential drawbacks. **First, with regard to using them in litigation contexts, human rights arguments can be simultaneously expansive and vague; courts may decline to accept them out of fear that they are limitless. Excessive use of overly broad "t-shirt" rights may feed this fear. More importantly, despite their supposed independence and impartiality, many courts are intricately linked to the other branches of government and are therefore equally difficult to persuade on these issues.** Furthermore, it will be very hard to use human rights law to prevent nations, such as the United States, that neither protect the right to health within their own constitutions nor recognize the right through their international treaty obligations, from using their trade positions to insist upon heightened IP protections.

**Second, it can be very difficult to get the UN human rights system to delineate the specifics of human rights obligations in new domains, such as health and IP.** This drawback

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<sup>4</sup> See Robert Howse, *The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times*, 3 J. WORLD INTELL. PROP. 493, 504 (2000) (explaining the importance of UN soft law to WTO panel and appellate body decisions).

<sup>5</sup> Alice M. Miller & Carole S. Vance, *Sexuality, Human Rights, and Health*, 7 HEALTH & HUM. RTS. J. 5, 8 (2004).

in turn feeds the courts' fear that human rights may be limitless. The existing international human rights system also does not afford much purchase on corporations and states whose actions impede access to medications in other countries. As Parts III and IV explain, the international human rights system has the most force when regulating the relationship of a state to its people, not a company or state's relationship to another nation's population. Moreover, international negotiations at the UN level are not immune to the power imbalances that we have identified. Due to the presumption against conflicts in international law, it may be very difficult to build arguments that clearly and directly contradict the TRIPS Agreement in the international human rights system. Finally, there are reasonable concerns that work within the UN diverts resources and attention from other activist modalities. Some activists have serious concerns that the whole UN human rights system is under attack and may be retreating from its prior claimed competencies.

**Third, although popular rights claims are powerful forces for uniting civil society and forging new alliances, these broad claims run the risk of getting lost in the sea of other causes for which t-shirts demand action.** Activists must still fight to make people understand why this t-shirt right merits their attention and inspire confidence that change is actually possible on this issue. Moreover, as previously mentioned, the use of t-shirt rights might be in tension with the formalization of human rights, and the formalization of legal rights claims can be an exclusionary and elitist process.

When considering human rights arguments and the use of the human rights system, activists must keep these limitations in mind. Whether a human rights approach can radically change international IP obligations, especially given the potential for conflict with the TRIPS Agreement, must be carefully considered.

### **Human Rights-Based Strategies for the A2M Movement**

This paper aims to evaluate whether human rights law can be used to address the harms patent protection inflicts and serve as a counterweight to prevailing international IP norms. The first strategy this paper examines is the use of human rights arguments in national court cases to oppose heightened IP regimes that erect barriers to access. We assess here whether judicial articulation of health-related rights in the context of IP-related cases will improve access to medication. Our second section looks at whether and how activists might use the UN human rights system to enunciate and enforce specific state obligations with regard to IP law. The paper describes the difficulty of getting UN institutions to recognize such obligations and assesses how much impact UN articulations would have. Our third section analyzes whether activists should use reinterpretations of existing human rights documents to clarify corporate obligations and responsibilities to respect health-related rights. This section also looks at how activists can utilize current UN structures on business and human rights and whether activists can use informal human rights arguments to push for practical accountability strategies. The fourth and final section investigates whether human rights law and, more specifically, the right to health can be used to encourage countries to form alliances that oppose TRIPS-plus free trade agreements (FTAs). This section assesses whether the right to health can serve as a rallying point around which low- and middle-income countries can form alliances.

### **Methodology & Limitations**

The strategies examined in this paper were chosen from a longer list of possible solutions that we composed in February 2013. In order to select the four strategies ultimately analyzed in this paper, we conducted interviews with various members of the A2M community, seeking views from a variety of regions and perspectives. Our selection represents the four strategies that A2M activists and scholars were most interested in learning more about or thought might be the most promising. For example, many activists believed that the court case strategy was promising, while others indicated an interest in learning more about human rights and corporate accountability.

After our selection of four key strategies, we interviewed a broad range of activists and academics to obtain their opinions on the chosen topics. While these interviews informed our research, the normative conclusions in the report are our own. We supplemented our interviews with research among primary and secondary sources, including court decisions, UN documents, FTAs, and academic articles.

Through its analysis of the four selected strategies, this paper examines a broad range of issues and options. Nevertheless, there are many issues and potential solutions that the paper has left out of its analysis. The feasibility of the trans-border application of human rights obligations (for example, using human rights to prevent the U.S. government from imposing trade pressure on developing countries) has not been explored in depth, largely because the experts we consulted felt that such arguments are insufficiently developed or unlikely to have traction. We also do not address in detail the use of regional courts. Although the conclusion of this paper touches on the possibility of using the Inter-American Court of Human Rights to improve access to medications, this idea is not explored at length. In addition, we have not explored the implications of human rights arguments for state obligations to fund pharmaceutical R&D, which we considered beyond our limited mandate. We have not discussed the value of seeking to include references to HR in intellectual property treaties (as the recent Treaty on the Visually Impaired has done). Finally, this paper has not thoroughly explored the impact that human rights arguments have on legislative bills and decision-making. As Part II discusses, it is possible that judicial articulation of the relationship between health-related rights and IP may influence executive and legislative decision-making. This potentiality merits further research and analysis.

Finally, the paper is an attempt to provide resources and information to activists, and our “recommendations” should be seen in this vein — as the conclusions of a research group that has drawn on the expertise of activists, and consulted widely, but that is not made up of access to medicines activists. Of course, activists themselves are in the best position to evaluate the suggestions made here. We have also identified several areas where academics can helpfully contribute. While this paper is not targeted at an academic audience, scholars could play a key role in helping to clarify further and concretize the implications of human rights for IP law. We hope that this paper will also provide background useful in this effort.

## I. Access to Medicines Through Human Rights Law in Domestic Courts

**Key Insights:** In the past few years, domestic courts have displayed a growing willingness to use human rights laws to reinterpret and even strike down IP laws that impede access to medications. Human rights standards could serve as a powerful counter-measure to the political and economic motives that keep harmful IP laws in place. Judicial articulation of the relationship between the right to health and IP law can not only mitigate the detrimental impact of IP law, but also legitimize the broader political actions that prioritize the right to health over IP protection. Although such court cases have not always succeeded, and gains have been incremental thus far, this strategy appears to be gaining momentum. We believe activists should aggressively pursue human rights arguments in IP-related court cases. We consider this to be the most promising of the four approaches we have considered, with the greatest likelihood of providing real results for access in the near future.

### A. Introduction

*In many cases, the discussion is about how much time a person has left to live. Without meaning to dramatize the situation, but still attached to its reality, one could maintain that if private or public resources do not cover the cost of expensive medicines, there is nothing left to discuss. Is this [lack of access] constitutionally tolerable only so that we might improve the judicial protection of patent rights?*<sup>6</sup>

This section examines how courts can and have employed human rights norms to reinterpret and confine IP law to limits consistent with the right to health and related rights. Over the course of the last two decades, some domestic courts have acted as powerful and important protectors of health-related rights. Judicial decisions in some countries have not only mandated that individuals be provided with specific medications,<sup>7</sup> they have also commanded governments to make particular medications available to all citizens.<sup>8</sup> Litigants have typically used human rights arguments in A2M cases to address the ultimate issue: access to particular medications for a single individual, regardless of its IP status. Such cases create concerns about resource allocation, and there is reason to think that individual rights to medicines cannot continue to be protected in the absence of a more structural recognition of the importance of IP law to the affordability and availability of medicines. Recently, however, some courts have begun to articulate a connection between health-related rights and not just medicines as individual treatment, but also *IP law*. These cases show the potential of the strategy addressed in this section.

The opening quotation comes from the briefing for a 2013 Chilean Constitutional Court decision regarding the constitutionality of a bill that would change the Chilean preliminary

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<sup>6</sup> Brief of the Senators before the Tribunal Constitucional [T.C.] [Constitutional Court], 25 enero 2013, Rol de la causa: 2.411-13-CPT, p. 50 (Chile) [Hereinafter Brief of the Senators]. This case was translated by the authors.

<sup>7</sup> See Hans V. Hogerzeil et al., *Is Access to Essential Medicines as Part of the Fulfillment of the Right to Health Enforceable Through the Courts*, 368 LANCET 305 (2006); HOGERZEIL, SAMSON, & VIDAL CASANOVA, *supra* note 3.

<sup>8</sup> See *TAC v. Minister of Health* (South African Constitutional Court 2002).

injunction standard so that pharmaceutical patent owners could obtain injunctions for patents on active ingredients more easily than other patent holders.<sup>9</sup> Although the Chilean court held that this case was not ripe for decision because the bill has not yet been enacted, the brief’s language reveals the strong link between IP and the right to health. Recent court cases and government action have begun to internalize this link and suggest that human rights-based arguments can provide states with a powerful tool to mitigate and combat the harmful effects of IP laws. **Although many of the recent domestic court cases that examine IP laws in light of the right to health are not clear “wins” for the A2M movement, these cases do reveal a growing understanding that protection of the right to health necessarily entails limits on IP protection.**

The remainder of this section addresses three main questions: (1) What is the normative relationship between the right to health and IP?; (2) Can domestic courts be used to articulate this normative relationship?; and (3) Would judicial articulation of these norms improve access to medicines in an efficient, system-wide, and effective manner?

## **B. The Right to Health and IP Protection: The Grammar of a Human Rights Argument**

To determine the proper normative relationship between IP law and the right to health, one must first understand how they relate to one another. In other words, one must determine the appropriate structure or “grammar” of a human rights argument that addresses IP protection in the context of A2M.

Although different national laws and international agreements may define the right to health in slightly distinct ways, the right to health, at its core, protects an individual’s right to access the goods and services he or she needs to enjoy the “highest attainable standard of physical and mental health.”<sup>10</sup> Many nations also protect the right to life, which has been understood to grant individuals the right to access life-saving treatment. Because the full realization of such rights can be impossibly expensive, most nations apply some sort of a limiting principle to these rights. For example, many domestic courts follow the approach outlined by the International Covenant on Economic, Social, and Cultural Rights (ICESCR) and establish an essential minimum core of health rights that are immediately enforceable. Under this approach, non-core elements of the right to health are subject to progressive realization—a concept that takes into account resource constraints.<sup>11</sup> Other nations, such as South Africa, do not protect a minimum core of rights and instead focus on the “reasonableness” of particular measures related to the right to health on a case-by-case basis.<sup>12</sup> Both of these constructions of the right to health set a floor: governments cannot violate a particular core of rights or go below a particular minimum of reasonableness.

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<sup>9</sup> Tribunal Constitucional [T.C.] [Constitutional Court], 25 enero 2013, Rol de la causa: 2.411-13-CPT, p. 50 (Chile) [Hereinafter Chilean Case]. This case was translated by the authors.

<sup>10</sup> International Covenant on Economic, Social, and Cultural Rights, Dec. 16, 1966, art. 15(1)(b)-(c), S. Exec. Doc. D, 95-2, at 13 (1997), 993 U.N.T.S. 3, 5 (entered into force Jan. 3, 1976) [hereinafter ICESCR].

<sup>11</sup> See Alicia Ely Yamin & Oscar Parra-Vera, *How Do Courts Set Health Policy? The Case of the Colombian Constitutional Court*, 6 PLOS MED. 147, 149 (2009); Amy Kapczynski & Jonathan Berger, *The Story of the TAC Case: The Potential and Limits of Socio-Economic Rights Litigation in South Africa*, in HUMAN RIGHTS ADVOCACY STORIES 18-19 (Deena R. Hurwitz & Margaret L. Satterthwaite eds., 2009).

<sup>12</sup> *Id.*

But our understanding of how IP law relates to this floor has not been well described. A human rights argument that affects IP protection must explain whether and how health-related rights require a particular action with respect to IP protection or (in some jurisdictions) require a state to create a reasonable plan to achieve better A2M, including by addressing IP issues. For example, one might argue that health-related rights oblige states to provide their citizens with access to medications. Because patented medications are expensive and developing countries have limited resources, low- and middle-income countries can only realize this obligation if they can obtain drugs more cheaply. Because pharmaceutical companies are unwilling to lower their prices and developed nations are unwilling (and unable) to finance the purchase of patented medications for the developing world, and because price control systems are administratively difficult to enforce and can be undermined by companies that boycott markets in response, developing nations must take out compulsory licenses that take advantage of generic competition, known to be the most reliable means of sustainably reducing the cost of medicines.

As this section will explain, domestic courts have begun to articulate human rights arguments that hint at these obligations. Although no court has held that the right to health, or any health-related right, obliges a state to enact a compulsory license, judicial decisions have stated that certain IP laws violate the right to health when they impede access to generic drugs. **Judicial decisions have thus begun to explain how the resource constraints that IP laws create also produce violations of the right to health.**

Right to health arguments regarding IP law must, however, account for another complexity. IP rights clearly increase the cost of medicines, but IP law could also be understood as protecting the right to health if such laws led to the invention and discovery of new medications. **Effective human rights arguments regarding health-related rights therefore need to address at least two issues, either implicitly or explicitly: First, should states use IP law as opposed to other kinds of levers to lower price and improve availability and accessibility, (e.g. price controls)? Second, do less stringent IP laws better protect health-related rights, given the innovation argument? We believe these questions can be answered affirmatively.**

We have a great deal of documentation regarding the importance of IP flexibilities to A2M, including evidence that action limiting the reach of IP is likely a more sustainable approach than price controls, particularly in resource-poor settings. (Where this is less clear, a country might be held to have an obligation to *either* introduce effective price controls *or* take action on IP.) There is also now a strong consensus—and many important UN documents—which clarify that developing countries can expect little innovation in return for patent protection, but can expect patents to create significant price increases. (Notice, however, that this argument does not address the implications of IP rights for A2M in high-income countries.) **If alternatives to the existing patent system exist that would better serve rights-oriented goals of access *and* innovation—for example, increasing the availability of medicines, and increasing R&D, especially R&D focused on the medical needs of the poor—then human rights plausibly demand that those alternatives be pursued.**<sup>13</sup>

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<sup>13</sup> For a similar point made in is a recent article by the Special Rapporteur on the Right to Food, see Olivier De Schutter, *The Right of Everyone to Enjoy the Benefits of Scientific Progress and the Right to Food: From Conflict to Complementarity*, HUMAN RIGHTS QUARTERLY 33 (2011) 304–350. De Shutter notes, for example, that “there may be a tension between the right to enjoy the benefits of scientific progress and the continued strengthening of IP rights,” and argues that “[i]n order to ensure that scientific progress truly contributes to the advancement of broader aims, such as human development and human rights, the impacts of these



Whether human rights law is used to oppose patent law or as a lens through which patent law can be interpreted, both views insist that IP laws be construed in a way that generates the least harm to health. A human rights law approach to IP demands that such protections ultimately protect health more than they harm it. In countries that cannot expect to obtain substantial innovation in return for IP rights but *can* expect substantial price increases, strong IP rights cannot be justified from a health perspective.

A final issue that A2M activists (and scholars) should consider when setting out the grammar of a human rights argument is whether health-related rights are individual or collective. Should the right to health be enforced on an individual basis, or does it work better as a guarantee at the community level? What kinds of litigation could a group, as opposed to an individual, bring? Would a collective right have greater weight? Might a human rights argument regarding IP law be more persuasive if the health-related rights were held collectively? The differences between individual and collective rights and their relative strengths and weakness should be considered when constructing a human rights argument regarding IP protection.

### C. Human Rights Arguments in the Courts: A Lens and a Counterweight

Discussions with A2M activists and scholars in combination with case law research reveal two ways in which domestic courts can use human rights arguments in IP cases to increase access to medications. First, courts can use human rights law to inform and interpret rules of general applicability that litigants must confront in IP cases, such as the standing doctrine or the standard for a preliminary injunction. Second, courts can use human rights law substantively to overturn IP laws.

The remainder of this section compares and contrasts various court cases from across the globe. Before beginning this analysis, however, its limitations must be noted. These cases were pulled from countries with different legal systems and traditions. Some of the cases come from common law countries, while others come from civil law countries. The civil law legal tradition has its origins in Roman law and subsequently developed in continental Europe and around the world. “Civil law is highly systematized and structured and relies on declarations of broad, general principles, often ignoring the details.”<sup>14</sup> The common law legal tradition evolved in England from the eleventh century onwards. “Its principles appear for the most part in reported judgments, usually of the higher courts, in relation to specific fact situations arising in disputes which courts have adjudicated.”<sup>15</sup> Statutory law supplements jurisprudence in common law countries and the codes of civil law countries.<sup>16</sup> Furthermore, common law tradition is administered through an adversarial system of justice, whereas the civil law system “has historically been coupled with an inquisitorial system of practice.”<sup>17</sup>

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different paths should be carefully measured, and the choices made by states as to which kind of progress to support, assessed on that basis.” *Id.* at 349. He makes arguments very similar to those that have supported calls for an R&D treaty when he says that “[p]rofit-driven research serves the needs of the high-value segments of the markets, while neglecting the real needs of the poorest and most marginalized groups.” *Id.*

<sup>14</sup> William Tetley, *Mixed Jurisdictions: Common Law v. Civil Law (Codified and Uncodified)*, 60 LA. L. REV. 677, 683 (1999-2000).

<sup>15</sup> *Id.* at 684.

<sup>16</sup> *Id.*

<sup>17</sup> Sandra F. Joireman, *Colonization and the Rule of Law: Comparing the Effectiveness of Common Law and Civil Law Countries*, 15 CONST. POL. ECON. 315, 318-19 (2004).



The common and civil law legal traditions “share similar social objectives”: individualism, liberalism and personal rights.<sup>18</sup> Nevertheless, they differ in a few critical ways. First and foremost, in civil law countries, priority “is given to doctrine (including the codifiers’ reports) over jurisprudence, while the opposite is true in the common law.”<sup>19</sup> The distinctive roles of the legislator and judge in each legal system account for this difference: Many civil law countries roughly follow “the Montesquieu theory of separation of powers, whereby the function of the legislator is to legislate, and the function of the courts is to apply the law.”<sup>20</sup> In common law legal systems, on the other hand, the core of the law resides in judicial interpretation and precedent.<sup>21</sup>

Second, while common law systems tend to pay closed attention to the details of fact pattern at hand, civil law countries place greater focus on legal principles.

[The common law judge] analyzes cases presenting similar but not identical facts, extracting from the specific rules, and then, through deduction, determines the often very narrow scope of each rule, and sometimes proposes new rules to cover facts that have not yet presented themselves. The civilist focuses rather on legal principles. He or she traces their history, identifies their function, determines their domain of application, and explains their effects in terms of rights and obligations.<sup>22</sup>

Therefore, common law decisions often have much narrower applications than civil law cases.

Third, the English doctrine of *stare decisis* compels lower courts in common law countries to follow the decisions rendered in higher courts, “hence establishing an order of priority of sources by ‘reason of authority.’”<sup>23</sup> In contrast, the concept of *stare decisis* does not exist in civil law countries. Thus,

[w]hile the civil law principles, frozen into codes and often rigid doctrine, are imposed on courts, most common law rules can be changed from time to time, subject to the doctrine of *stare decisis*. On one hand, the realities of modern life can be addressed in a more timely fashion through the common law . . . . On the other hand, common law judges are sometimes hesitant to change a rule, where the consequences of doing so in relation to the whole of the law are not clear. Less timid to reform, civil law jurisdictions have sometimes hired learned authors to assist in effecting major legal changes.<sup>24</sup>

This difference will be especially important in A2M litigation, where activists will encourage judges to take on new interpretations of law or apply existing standards in more nuanced ways.

Fourth, civil law tends to focus on rights and obligations, whereas “common law is oriented toward the jurisdiction of particular courts to grant the sought-after remedy (‘remedies

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<sup>18</sup> Tetley, *supra* note 14, at 701.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.* at 701-02.

<sup>23</sup> *Id.* at 702.

<sup>24</sup> *Id.* at 705.

precede rights’).”<sup>25</sup> Civil law countries generally do not have “a clearly defined system of remedies, but rel[y] rather on the courts to choose or even create the appropriate remedy. Conversely, the common law does not have a unitary system of rights and obligations.”<sup>26</sup> This distinction may also be critical in A2M cases, where activists seek more novel forms of relief, such as a government order compelling a compulsory license.

Finally, civil law systems are more focused on the supremacy of the state, whereas common law countries tend to focus on the protection of the individual from state intrusion into her affairs. As one scholar commented,

if we are to try and discern a difference in originating conceptions between the two legal traditions, it would be that civil law systems begin with the idea of the state as supreme and the role of individual in obedience to it. English common law, on the other hand, developed to protect the property of individuals and limit the power of the state to expropriate resources. From the time of the Magna Charta in 1215 the common law was supported by the aristocracy as a hedge against encroachment on land and liberty by the state. Civil law, in the French and Roman tradition, on the other hand, developed as an instrument for expanding and administering the empire. It was, in effect, a tool used by the state to regulate its citizens rather than to protect them from the encroachment of the state.<sup>27</sup>

This distinction is relevant to these intellectual property cases as pharmaceutical firms attempt to argue that the state has encroached on its property rights.

The discussion of each of the following cases notes the court and legal system in which it was decided. Although a full analysis of the differences between common and civil law countries and the importance of this distinction for human rights and IP law cases is beyond the scope of this paper, this basic summary of the common and civil law traditions should be kept in mind as one reads through the following decisions.

#### *i. The Lens: How Human Rights Law Can Be Used to Reinterpret IP Protection*

One of the first court decisions to use human rights language expressly to compel a finding in an IP law case was a 2002 patent challenge in front of the Thai Central Intellectual Property and International Trade Court.<sup>28</sup> Thailand has a civil law system, but the contents of its laws were greatly influenced by those of common law countries like Great Britain.<sup>29</sup> In the patent challenge, the plaintiffs used human rights arguments in a very discrete and narrow fashion: to prove that they had the legal standing necessary to bring the case. The defendants contended that because the two HIV-positive patients and the AIDS Access Foundation had no intention of manufacturing the HIV medication at issue and could use other HIV medications to treat the virus, these plaintiffs did not suffer a cognizable injury. Using human rights arguments regarding the right to health and life, the court rejected the defendants’ position:

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<sup>25</sup> *Id.* at 707.

<sup>26</sup> *Id.*

<sup>27</sup> Joireman, *supra* note 17, 317-18 (2004).

<sup>28</sup> See Appendix A for a more detailed description of this case.

<sup>29</sup> Ngamnet Triamanuruck, Sansanee Phongpala, & Sirikanang Chaiyasuta, Overview of Legal Systems in the Asia-Pacific Region: Thailand (Apr. 10, 2004), in *Overview of Legal Systems in the Asia-Pacific* (April 2004), Paper 4, at 4, 1-9, available at [http://scholarship.law.cornell.edu/lps\\_lsapr/4](http://scholarship.law.cornell.edu/lps_lsapr/4).

Medicine is one the fundamental factors necessary for [a] human being, as distinct from other products or other inventions that the consumer may or may not choose for consumption. The treatment of life and [the] health of the human is of [more] importan[ce] than any other property. This was recognized internationally in the 4th Ministerial Meeting of the World Trade Organization at Doha, Qatar . . . . Therefore, the injured parties from the grant of Patent are not limited to the manufacturers or the sellers of [the] medicine protected by the Patent.<sup>30</sup>

Although this argument was only used to grant the plaintiffs standing, the court's powerful articulation of the supremacy of the right to health set an important precedent. The court used human right arguments to inform its interpretation of a legal standard at issue in this patent case and, in doing so, articulated a position firmly in favor of access. The court's reference to the Doha Declaration and TRIPS Agreement to support its position also holds significance: Through this citation, the court asserted the compatibility of its position with international IP right obligations.

The India Board of Patent Appeals mirrored the Thai court's approach in a 2012 decision regarding a post-grant patent opposition.<sup>31</sup> In this case, the defendant again contested the standing of the plaintiff, a non-profit organization "working for the benefit of drug users."<sup>32</sup> The court explained that the non-profit organization was an interested party because the patent opposition would "bring the drug within the reach of the community for whom [the NGO] works, not only because of reduction in cost, but also because of increase in supply." The court further noted that "public interest is a persistent presence in intellectual property law and will not melt into thin air, nor dissolve." In addressing the standing issue, the Indian court, like the Thai court before it, seized the opportunity to articulate the relationship between the public interest and patent law and the implications of this relationship for access. Unlike Thailand, though, India is a common law country. India also has a constitution of "unprecedented magnitude in both scope and length,"<sup>33</sup> including various provisions related to health, which is highly relevant to right to health cases.

The standing doctrine is not the only generally applicable legal standard for which courts have used human rights arguments to inform their decisions. In 2008, the High Court of Delhi found that the public's interest in a particular medication must be taken into account when deciding whether to issue a preliminary injunction.<sup>34</sup> After reviewing international precedents, such as the U.S. Supreme Court's *eBay v. MercExchange*<sup>35</sup> decision, the court concluded that "unlike in cases involving infringement of other products, the Courts have to tread with care [when] pharmaceutical products and more specifically life saving drugs are involved. In such cases, the balancing would have to factor in unknowns such as the likelihood of injury to non-

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<sup>30</sup> The Central Intellectual Property and International Trade Court, Oct. 1, 2002, *Aids Access Foundation, Mrs Wanida C, & Mr Hurn R. v. Bristol-Myers Squibb company and the Department of Intellectual Property*, BC Tor Por 34/2544, RC Tor Por 93/2545 at 7 [Hereinafter Thai Case].

<sup>31</sup> *Sankalp Rehabilitation Trust v. F. Hoffmann-LA Roche AG*, OA/8/2009/PT/CH (2012) (India) [Hereinafter *Sankalp v. Roche*].

<sup>32</sup> *Id.* at para. 4.

<sup>33</sup> BAR COUNCIL OF INDIA, *Brief History of Law in India*, <http://www.barcouncilofindia.org/about/about-the-legal-profession/legal-education-in-the-united-kingdom/> (last visited June 15, 2013).

<sup>34</sup> See Appendix A for more information on this case.

<sup>35</sup> 547 U.S. 388 (2006).

parties and the potentialities of risk of denial of remedies.”<sup>36</sup> The court further explained that, although “India entered into the TRIPS regime, and amended her laws to fulfill her international obligations,”

the Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. Such injuries to third parties are un-[compensable]. Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 [which protects the right to life] so far as those [who] would have or could have access to Erloticip are concerned.<sup>37</sup>

Strategically referencing international precedents that provide “skin deep”<sup>38</sup> support to its position,<sup>39</sup> the Indian court managed to weave respect for the right to health into the preliminary injunction standard. Thus, in this case, human rights law became a lens through which the Indian court interpreted legal standards commonly used in patent cases.

Following India’s example, the South Africa Supreme Court of Appeals examined the preliminary injunction standard in a 2012 infringement suit.<sup>40</sup> Somewhat uniquely, “South Africa is a mixed jurisdiction whose legal system reflects elements of both civil and common law, as well as African tribal customary law.”<sup>41</sup> Under the South African Constitution, “The Constitutional Court, Supreme Court of Appeal and High Courts have the inherent power . . . to develop the common law, taking into account the interests of justice.”<sup>42</sup> In this case, the South African Supreme Court of Appeals held that the “broader public interest, and not only the interests of the litigating parties, must be placed in the scales”<sup>43</sup> and weighed it in the “balance of convenience” test that South African courts use to determine whether a preliminary injunction should be issued.<sup>44</sup>

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<sup>36</sup> F. Hoffmann-LA Roche AG v. Cipla Ltd., I.A 642/2008 IN CS (OS) 89/2008 (2008) (India) [Hereinafter *Roche v. Cipla*].

<sup>37</sup> *Id.* Article 21 of the Indian Constitution state that “No person shall be deprived of his life or personal liberty except according to procedure established by law.” INDIA CONST. art. 21.

<sup>38</sup> Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of Trips Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1637 (2009).

<sup>39</sup> *See id.*

<sup>40</sup> See Appendix A for more information on this case.

<sup>41</sup> Tetley, *supra* note **Error! Bookmark not defined.**, at 692-93 (“In the new Republic of South Africa, where South African legislation and precedents are lacking, Roman-Dutch and English sources are given approximately equal weight, in a kind of pragmatism. There is a considerable respect for both the institutional writers and more recent authors on Roman-Dutch law (a civilian trait), mixed with a view of judicial precedent as of very great importance (a common law characteristic). There is also a recognition of African customary law (‘indigenous law’) which under the present Constitution must be applied where applicable, subject to the Constitution and any relevant legislation.”).

<sup>42</sup> S. AFR. CONST. § 173, 1996.

<sup>43</sup> South Africa Case, *supra* note 8, at 22 para. 46.

<sup>44</sup> In this case, the South African court decided to issue the preliminary injunction. Therefore, some view this case as a “loss.” However, the court ultimately did validate TAC’s argument that the public interest must be weighed as part of the “balance of convenience” test. As two TAC lawyers explained in separate interviews, the facts of the case were very poor: Aventis began to offer a low-cost, “generic” version of the medication at issue right after the case

Joining the case as *amicus curiae*, the Treatment Action Campaign (TAC) argued that the court must construe South Africa's Patent Act "through the prism of the Constitution" to ensure that the act did not derogate the human rights enshrined in the nation's constitution.<sup>45</sup> TAC cautioned that, "[w]hile the purposes served by patent protection are legitimate public purposes, the Patents Act must be interpreted and applied to ensure the public interest in patent protection is in fact served and ensure other rights are not unreasonably limited thereby. In the case of medicines, section 27 is implicated because a medicine may be unavailable or because it may be unaffordable, often as a result of the patent." By arguing that the Patent Act must serve a legitimate public purpose, TAC was able to argue that Constitutional rights must inform the court's interpretation of the Patent Act.

The South African court did not sign onto the full thrust of TAC's argument: it declined to set a general standard whereby courts must read the entire Patent Act through the prism of South Africa's Constitution. Nevertheless, it agreed with TAC's position as it applied to the specifics of the case: The court held "balance of convenience" must account for the public interest. Thus, TAC did succeed in persuading the court to take the public interest into account when interpreting a standard that is frequently at issue in patent cases. TAC perceives the case as a victory, because in all patent cases hereafter, parties can argue against injunctions on public interest grounds, raising arguments about the impact of a patent on access to medicines in the process.

One final case that sheds light on the importance of employing human rights to interpret and cabin intellectual property rights is a 2004 Peruvian decision regarding the right of HIV/AIDS patients to free antiretroviral treatment. In this case, an HIV positive patient brought an *amparo* (a demand for court protection) in order to obtain free antiretroviral treatment. Peru, like most Latin American countries, has a civil law system and allows its citizens to bring *amparo* actions to protect their constitutional rights. The Peruvian Constitutional Court ruled that the right to health, as protected by Article 7 and 9 of the Peruvian Constitution as well as Peruvian law, required the government to provide free antiretroviral treatment to patients with low economic resources. Although this case did not directly deal with IP issues, the court took the opportunity to discuss the effect of the TRIPS Agreement and Doha Declaration on the ability of the Peruvian government to protect the public health of its citizens.<sup>46</sup> As the court explained, "even if the protection of intellectual property is important for the development of new medications, the concern regarding the effect of intellectual property rights on medicines cannot be left to one side. The TRIPS Agreement does not signify an obstruction to the member country to take measures to protect public health and, particularly, the promotion of medication for all." The court then went on to recommend that the state utilize the provisions and measures that allow for the maximum amount of flexibility in its interpretation of the TRIPS Agreement so that the government can achieve its health policy objectives.<sup>47</sup> The court noted that such an

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was initiated. Due to the presence of the low cost, non-infringing generic, the court found that the preliminary injunction did not threaten the public interest. *Id.* at 27.

<sup>45</sup> Brief for the Treatment Action Campaign at 3 para. 6.1, *Cipla Medpro v. Aventis Pharma* 2012 (139/12) (S. Afr.) ("The Patents Act, like any other statute, must be construed consistently with the Constitution. This requires Courts to balance the rights of any patentee with the rights of those who need access to medicines, which are protected in section 27 of the Constitution. The need to balance these rights affects how the Court must interpret and apply the provisions relied upon by the parties.").

<sup>46</sup> Tribunal Constitucional [T.C.] [Constitutional Court], 20 abril 2004, XP. N.º 2945-2003-AA/TC, p. 40 (Peru) [Hereinafter Peruvian Case]. Translated by the authors.

<sup>47</sup> *Id.*

interpretation is clearly inside of the established margins of the Doha Declaration.<sup>48</sup> In this case, involving an individual claiming the right to access medicines who did not himself raise IP issues, the Peruvian Constitutional Court encouraged the Peruvian government to take advantage of its TRIPS flexibilities and to interpret this accord in a way that maximizes human rights protection.

The use of human rights arguments in the Thai, Indian, South African, and Peruvian cases lead to decisions that were in line with public health objectives. However, in at least one case, human rights arguments were used to obtain a decision antithetical to such objectives. In 2001, the Costa Rica Constitutional Court ruled that a plaintiff who suffered from multiple sclerosis was entitled to the brand name drug her doctor prescribed under the right to health.<sup>49</sup> Costa Rica, like Peru, is a civil law country. In this case, the plaintiff challenged the Costa Rican social security system's refusal to reimburse her for branded drugs when suitable generic versions were available. The patient argued that the substitution of the brand name drug for its generic version violated her right to health. Agreeing with the plaintiff, the court held that, "according to constitutional and international obligations of the State in regard to the right to health, when a doctor prescribes a given drug to his patient, it should be this exact drug and not another one that must be delivered by the Social Security scheme."<sup>50</sup> This case provides a very troubling example of how arguments about health rights can lead to irrational conclusions from the perspective of public health and highlights the urgency of bringing accurate understandings of the influence of IP rights (including trademarks, in this case) on health.

**The Thai, Indian, and South African cases are significant because they demonstrate that human rights arguments can be used to inform and interpret patent law in ways that improve A2M without requiring courts to strike down or undermine patent laws more broadly. The Peruvian case supports this norm. However, the Costa Rican case reminds us that these human rights arguments must be carefully articulated in order to prevent pharmaceutical manufacturers from co-opting them for their own purposes.**

## ii. *The Counterweight: How Human Rights Law Can Be Used to Challenge IP Legislation*

Human right arguments can also be used to invalidate detrimental IP laws. Cases that use human rights language substantively to attack patent laws are much more recent. Their success may rest in part on the norm articulation that occurred in the cases where human rights law was only used as a lens.

To our knowledge, the first time litigants used human rights arguments substantively to overturn a harmful IP law was in a 2009 Kenyan case. Kenya primarily has a common law legal system,<sup>51</sup> mixed with elements of Islamic law and customary law.<sup>52</sup> In this case, three HIV-positive patients used the right to health to challenge an "anti-counterfeiting law" that defined the term "counterfeit" so broadly that it made the violation of a patent – and indeed, a patent anywhere in the world – cause for the seizure of generic medicines in Kenya. Agreeing with the

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<sup>48</sup> *Id.*

<sup>49</sup> Tribunal Constitucional [T.C.] [Constitutional Court], 26 Septiembre 2001, Rol de la causa: No. 01-009007-CO, Ms. Vera Salazar Navarro vs. Caja Costarricense de Seguro Social (Costa Rica).

<sup>50</sup> HOGERZEIL, SAMSON, & VIDAL CASANOVA, *supra* note 3, at 28.

<sup>51</sup> Joireman, *supra* note 17, 332.

<sup>52</sup> UNIVERSITY OF OTTAWA, *Common Law Systems and Mixed Systems with a Common Law Tradition*, <http://www.juriglobe.ca/eng/sys-juri/class-poli/common-law.php> (last visited Apr. 15, 2013).

plaintiff's arguments, the Kenyan court agreed that the Anti-Counterfeiting Act must be overturned: "[Any law that] would have the effect of limiting access, . . . would ipso facto threaten the lives and health of the petitioners and others infected with HIV and [AIDS], and would be in violation of their rights under the Constitution."<sup>53</sup>

Cognizant of the preeminence of the constitutional right to health, the Kenyan government argued that the Anti-Counterfeiting Act actually protected that right by preventing harmful, "fake" drugs from reaching the Kenyan population. The court saw through these arguments: "Clearly . . . the tenor and object of the Act is to protect the intellectual property rights of individuals . . . . Had the primary intention been to safeguard consumers from counterfeit medicine, then the Act should have laid greater emphasis on standards and quality."<sup>54</sup> Thus, although the court recognized that the Kenyan government could draft an anti-counterfeiting act that protected the right to health, the court also demanded that any such law prioritize the right to health over intellectual property protection.<sup>55</sup>

Most importantly, the Kenyan court acknowledged that the human rights arguments at play in this case are applicable to all IP cases: "While [] intellectual property rights should be protected, where there is the likelihood, as in this case, that their protection will put in jeopardy fundamental rights such as the right to life [], I take the view that they must give way to the fundamental rights of citizens in the position of the petitioners."<sup>56</sup> It must be acknowledged, however, that the law challenged was unusual and that even the government would not directly defend its terms in court. Nevertheless, this case remains significant because it demonstrates that the right to health can be used to invalidate IP laws when such laws clearly impede access to medications with no corresponding benefits.

The Chilean court mentioned at the outset of this section dismissed a case challenging a pending bill that would create a presumption in favor of pharmaceutical patent holders in cases regarding patented active ingredients.<sup>57</sup> Because the case was not decided, the human rights arguments were not evaluated. The bill in question would create a special exemption for pharmaceutical patent-holders from the general rule on preliminary injunctions in Chile. Under the general or normal rule, Chilean courts only grant preliminary injunctions based on the merits of the case—when the court determines that the party has a "substantial likelihood of success on the merits of the case and faces a substantial threat of *irreparable damage or injury* if the injunction is not granted."<sup>58</sup> The new bill enables civil judges to grant preliminary injunctions in favor of active ingredient patent-holders without looking at the merits of the injunction suit. Although the court declined to decide this case on its merits because it determined that the case was not yet ripe,<sup>59</sup> the briefing of the party opposing the bill is informative. The plaintiffs reasoned that if an individual needs a particular drug to survive, and a law enables a

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<sup>53</sup> Patricia Asero Ochieng, Maurine Atieno, Joseph Munyi, & AIDS Law Project v. Attorney General, (2009) Petition No. 409 (Kenya) at 28-29 para. 52 [Hereinafter Kenya Case].

<sup>54</sup> *Id.* at 43 para. 82.

<sup>55</sup> *Id.*

<sup>56</sup> *Id.* at 46 para. 86.

<sup>57</sup> The Chilean Congress is still in the process of debating this bill. *Chilean Constitutional Court to decide on the constitutionality of the patent linkage bill*, INFOJUSTICE.ORG (Mar. 7, 2013), <http://infojustice.org/archives/28883>. The outcome of the November 2013 elections in Chile will be critical for the viability of this bill. If the left leaning party recaptures the Congress, the bill is unlikely to pass.

<sup>58</sup> *Chilean Constitutional Court to decide on the constitutionality of the patent linkage bill*, INFOJUSTICE.ORG (Mar. 7, 2013), <http://infojustice.org/archives/28883>.

<sup>59</sup> Chilean Case, *supra* note 9. This case was translated by the authors.

pharmaceutical firm to price that drug out of the individual's reach, the law offends the right to health as protected in the Chilean constitution. The plaintiffs did recognize that IP protection can have a beneficial effect on the right to health if it increases the number of innovative medicines available to the country. However, the brief explained that because pharmaceutical patent-holders would not cease to innovate if this bill fails to pass, its harmful effects far outweigh its potential benefits.<sup>60</sup> In response to these arguments, the court first recognized that these arguments were, at their core, an objection to the bill on its merits, and therefore not ripe for decision. However, the court then went on to state that the bill's effect on health is not completely a special feature of the bill itself, but rather a natural consequence of the right to IP that patents entail. The court also noted that this right flows from Chile's obligations as a WTO member and a TRIPS signatory. Thus, the court was skeptical of the right to health arguments, even though it did not rule on them. Chile, like Peru, is a civil law country that allows its citizens to bring *amparo* actions.

About a year and a half before the Chilean decision, an Argentinean court also rejected a heightened IP standard, in part with reference to human rights. In *Novartis v. Monte Verde*, Novartis argued that Argentina must afford the company data exclusivity in order to fulfill its TRIPS obligations. In rejecting that argument, the court stated that "one cannot ignore that developing countries imitate medical products through reverse engineering in order to cover the public health necessities; nor that the right to health – internationally recognized in treaties that carry constitutional weight – is rigorously tied to the right to life, without which the rest of the guarantees of the Constitution lose their purpose."<sup>61</sup> The court also noted that "[t]he reasonability of an impugned legal regime is better understood when one reads it in light of international human rights obligations."<sup>62</sup> Thus, the Argentinian court used human rights obligations to explain why the proposed IP standard was impermissible. (Argentina, like its South American neighbors, has a civil law system.)

Finally, in 2012, the Supreme Administrative Court of Colombia ruled that Abbott must respect Colombian price controls on its HIV medication Kaletra. A civil law country, Colombia allows its citizens to bring complaints before the Colombian Administrative Court. (This court has no direct analog in the United States.) The plaintiffs—NGOs and HIV-positive patients—asked the court to command the Colombian government to issue a compulsory license on the drug. Although the court declined to meet this request, the plaintiffs' arguments did move the court to direct the Colombian government to enforce its price controls. Critically, the Supreme Administrative Court's 2012 decision recognized that the right to health holds implications not only for the government's system of distributing medications, but also for its manner of *acquiring and paying* for medications. The court explained how the right to health necessarily touches on any law that affects the accessibility of medications: "[O]ne must take into account that the right to health has a compensatory character, and for this compensatory character to be effective, the right to health requires that budgetary and procedural aspects be made viable and

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<sup>60</sup> Brief of the Senators, *supra* note 6.

<sup>61</sup> Cámara Federal de Apelaciones [CFed.] [Federal Appeals Court], 1/2/2011, "Novartis Pharma AG c. Monte Verde SA / propiedad industrial e intelectual," Causa No. 5.619/05 (Arg.) (internal citations omitted) [Hereinafter Argentina Case]. This case was translated by the authors.

<sup>62</sup> *Id.* Please note, this sentence is not a perfect translation of the court's language. The court's exact language is: "La razonabilidad del regimen legal impugnado se advierte con más nitidez cuando se lo relaciona con el derecho internacional de los derechos humanos." A more direct translation would read: "The reasonability of an impugned legal regime is advised with more clarity when one connects it with the international right of human rights." However, the translation we provide better captures the essence of the sentence.



balanced.”<sup>63</sup> Based on the right to health and its budgetary implications, the court held that the government must enforce its price controls.

The court did not find, however, that the right to health compelled the issuance of the compulsory license. Recognizing the government’s obligation to protect the private property rights of patent holders, the court explained that the compulsory license system could not be used “until there is internal legislation that adopts clear ways of respecting [the patent holders’] rights.”<sup>64</sup> Although A2M activists have since pointed out that this perspective fundamentally misunderstands the compulsory license system, this holding illustrates the court’s attempt to reconcile property rights with the right to health. By using human rights arguments, the plaintiffs forced the court to take some action to improve access to medications. We believe these human rights arguments may have been important to the court’s final decision.

#### D. The Impact of Court Cases: Concrete Change and Norm Mobilization

Domestic courts can use the right to health to set presumptions against certain types of IP protection or improve the flexibility of legal standards used in IP cases. In other words, courts can use the right to health to set limits on IP protection in their country.

**In addition to their domestic impact, each of these cases sets an international legal precedent that courts in other countries can draw upon.** Although the outcomes of these cases are by no means binding on courts in other nations (and in civil law countries, the outcomes of these cases are generally not even binding on the courts that issue them<sup>65</sup>), they help to articulate and refine a set of legal arguments that other courts may find persuasive. For example, the India decision regarding standing references, the earlier Thai decision on the same issue,<sup>66</sup> and the briefing for the South African case regarding the appropriate standard for a preliminary injunction references the rule the Indian court set forth in *Roche v. Cipla*.<sup>67</sup> When there is little legal precedent for a particular argument, which is certainly true in most cases using human rights arguments to alter IP regimes, the decisions of other courts become especially important.

Like most strategies, however, this one has drawbacks and limitations. First, when going before a court, litigants always face the risk of an adverse decision or a harmful precedent. Just as successful cases can have an international impact, so too can unsuccessful ones. Therefore, it is important that A2M activists choose their cases carefully. Second, these cases are very costly and consume a lot of time and resources. Third, these cases typically only permit incremental gains.<sup>68</sup> **It may be difficult to get courts to accept wide-reaching arguments, particularly where “private rights” are concerned.** For example, although in theory one might argue that the right to health should lead countries to suspend patents on medicines all together (despite TRIPS), that argument will be difficult to make plausible, and even if plausible, difficult to win,

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<sup>63</sup> Tribunal Administrativo de Cundinamarca [Administrative Court of Cundinamarca], Sala, Lab. Febrero 29, 2012, Carlos Enrique Moreno Rubio, Expediente No. 2009-00269-01, (p. 53) (Colom.) [Hereinafter Colombia Case]. This case was translated by the authors.

<sup>64</sup> *Id.* at 55-56.

<sup>65</sup> Siri Gloppen, *Litigating Health Rights: Framing the Analysis*, in LITIGATING HEALTH RIGHTS: CAN COURTS BRING MORE JUSTICE TO HEALTH? 20 (Alicia Ely Yamin & Siri Gloppen eds., 2012).

<sup>66</sup> *Sankalp v. Roche*, *supra* note 31.

<sup>67</sup> Brief for the Treatment Action Campaign at 17 para. 40, *Cipla Medpro v. Aventis Pharma* 2012 (139/12) (S. Afr.).

<sup>68</sup> See Octavio L. Motta Ferraz, *Brazil: Health Inequalities, Rights, and Courts*, in LITIGATING HEALTH RIGHTS: CAN COURTS BRING MORE JUSTICE TO HEALTH? 100 (Alicia Ely Yamin & Siri Gloppen eds., 2012).

because of the conservative nature of courts. Also, directing human rights arguments at courts may mean that A2M groups make less radical arguments than they would make using “t-shirt” rights. Many movements worry that the turn to courts is demobilization or “coopting,” which deserves consideration.

**On the positive side, human rights norms articulated in domestic court cases can have effects on other branches of government.** In our conversations with A2M activists and scholars, many people pointed out that the court cases often spur executive and legislative action. They also noted that executive and legislative branches have begun to speak the language of human rights as a justification for their actions. For example, the Brazilian government employed human right arguments to justify its compulsory license on the HIV medication Efavirenz: In the press release announcing this compulsory license, the Brazilian government invoked the “fundamental human right to health.”<sup>69</sup> Therefore, it is possible that norm articulation at the judicial level trickles down to other branches of government.

**Finally, court cases can plausibly help civil society build movements.** Legal victories can make vernacular, moral arguments more plausible and powerful. Therefore, although the outcomes of court cases may themselves be somewhat incomplete and incremental, they may inspire and support further, more comprehensive action.

## E. Insights & Action Steps

The court cases clearly seem to be a worthwhile strategy for improving access to medications. Before proceeding with cases, though, activists should further discuss and consider what an ideal human rights argument regarding IP protection would look like. Recent litigation on this topic should inform this debate. Furthermore, although this section has declined to analyze case law from high-income countries, decisions from such countries could be useful in constructing human rights arguments. Once the basic grammar of the argument has been laid out, activists should tailor it to specific country contexts. Activists could even develop national litigation action plans.

To ensure the litigation strategy is used effectively, A2M activists facing conservative judiciaries should carefully pick winnable test cases. They should only pursue hard cases after a judicial system or court has demonstrated openness to human rights arguments. **These arguments should be part of a long-term strategy that seeks recognition that the right to health necessitates access to medications, and that where IP laws impede that access more than they enhance it, they must be overturned, bypassed, or reworked.** Although it could be many years before this strategy comes to fruition, very recent court cases suggest that such a strategy is worth pursuing.

To ensure that the A2M movement gets the most mileage out of these cases, access-oriented IP trainings for both judges and lawyers would be useful. Many A2M activists pointed out that judicial unfamiliarity with IP law and its relationship to human rights law presents a substantial impediment to the success of cases.<sup>70</sup> Successful court cases provide an important opportunity for education and awareness-raising. In the future, access-oriented organizations and

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<sup>69</sup> Press Release, Ministro de Estado da Saúde, Declara de interesse público os direitos de patente sobre o Efavirenz, para fins de concessão de licença compulsória para uso público não comercial (Apr. 25, 2007).

<sup>70</sup> Interview with A2M Academic; Interview with A2M Activist; Interview with A2M Activist; Interview with A2M Activist.

institutions may also wish to support training sessions for both judges and lawyers that would educate them about IP and human rights and the connections between the two.

Another potential tool for awareness-raising and education would be a database of human rights related IP cases. There are many cases across the globe that deal with the relationship between IP and health-related human rights. A database consolidating these cases would be a valuable resource. The Global Health and Human Right Law Database at the O’Neill Institute for National and Global Health Law of Georgetown University is one such database.<sup>71</sup> Although this database is not IP-specific, it has begun to catalog a wide range of judgments, international and regional legal instruments, and national constitutions involving health and human rights.

<b>Key Action Steps</b>	
<b><i>Short Term</i></b>	<ul style="list-style-type: none"> <li>• Activists should identify IP cases they can join as parties or amicus curiae. A2M activists should encourage human rights activists to join these cases to broaden the base of intervention in these settings;</li> <li>• Activists and academics should develop a conceptual mapping that clearly articulates the relationship between IP and human rights in the context of access to medicines. Activists should also develop litigation strategies, which should be tailored to specific country contexts;</li> <li>• Activists should use the outcomes of favorable domestic court cases to educate governmental actors, including legislators, administrators, judges, and civil society about the relationship between IP and the right to health;</li> <li>• Activists should promote the training of judges and other government officials about IP law, human rights, and the relationship between the two;</li> <li>• Activists should create a database that contains important case law, international and regional instruments, and national laws pertaining to the link between IP and health-related human rights.</li> </ul>
<b><i>Long Term</i></b>	<ul style="list-style-type: none"> <li>• Activists should consider international forums where IP law cases that implicate the right to health could be brought. For example, activists should consider bringing a case in front of the Inter-American Commission on Human Rights;</li> <li>• Through incremental steps, activists should encourage courts to articulate a norm wherein all IP laws that affect the right to health can only be upheld if they improve access to medications more than they harm it.</li> </ul>

<sup>71</sup> *Global Health and Human Rights Law Database*, O’NEILL INSTITUTE FOR NATIONAL AND GLOBAL HEALTH LAW, <http://www.law.georgetown.edu/oneillinstitute/global-health-law/who-health-and-human-rights-database.cfm> (last visited June 10, 2013).

## II. Access to Medicines Through the UN Human Rights System

**Key Insights:** A number of international human rights treaties contain rights that bear on access to medicines, and there are a variety of UN mechanisms that activists could use to help hold states accountable. In this section, we include considerations of the right to health and other health-related rights. Human rights bodies have stated that the right to health includes access to medicines, recognized the impact of TRIPS on access and called upon states to utilize its flexibilities, and recommended that states avoid TRIPS-plus provisions in FTAs. There is potential for further work in the UN human rights system to enunciate more specific obligations and stimulate more focused reviews of state practices. Stronger norms and more trenchant public assessments are possible based on human rights arguments, but processes for achieving results are challenging. Pursuing a system-wide strategy that incorporates all of the political and expert bodies would require tremendous resources with uncertain rewards. We recommend that A2M activists assess and pursue selected mechanisms that are likely to be the most feasible and productive, especially as applied to specific strategic moments and country contexts.

### A. Previous Developments in the UN Human Rights System

The vast majority of the world's countries have recognized a right to health under international human rights law. All members of the UN recognize a right to health through the UDHR, whose obligations they pledge to uphold, although it is not in itself a binding treaty.<sup>72</sup> The ICESCR, however, makes that right binding on parties, and it applies to 160 countries, with the exceptions—notable for our particular concerns—of the United States and South Africa. Article 12 of that treaty recognizes a right to the “highest attainable standard of physical and mental health,” although states may “achiev[e] progressively the full realization of the rights.” Health-related rights are also recognized in other UN treaties,<sup>73</sup> so activists need not focus exclusively on states parties to ICESCR. They may consider strategies to support building norms around these rights, such as the right to life and bodily integrity, in any of the relevant treaty bodies.<sup>74</sup>

**General Comment 14 of the Committee on Economic, Social, and Cultural Rights (CESCR) is an expert interpretation of the right to health. It states that providing access to essential drugs, as defined by the WHO Action Programme on Essential Drugs, is a “core obligation” of states under the ICESCR.** This means that resource constraints do not justify non-compliance with this obligation. The general comment does not indicate clearly whether full realization of the right to health includes access to additional medicines, subject to progressive realization as states' resources permit. In the two places where the general comment refers to core obligations or minimum standards, it cites the WHO essential medicines list, but in its general discussion of the “right to health facilities, goods and services,” it refers to “essential drugs” without referencing the WHO list.<sup>75</sup> **The Human Rights Council, which is composed of**

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<sup>72</sup> For details on the UDHR and other UN documents relevant to A2M, please see Appendix B.

<sup>73</sup> The Covenant on the Rights of the Child (CRC), the Convention on the Elimination of Discrimination Against Women (CEDAW), the Convention on the Rights of Persons with Disabilities (CRPD), and the International Covenant on Civil and Political Rights (ICCPR).

<sup>74</sup> A treaty body is an expert committee tasked with monitoring states' compliance with a particular treaty.

<sup>75</sup> General Comment 14, *supra* note 2, at 4, 7, 16.

**UN member countries and adopts resolutions by vote, has recently confirmed that the right to health includes access to medicines generally, not just medicines on the WHO list.**<sup>76</sup>

A number of UN rights-oriented actors have recognized the tension between A2M and IP. They sometimes express this as a conflict between A2M and existing IP laws and other times as a conflict within human rights, since ICESCR Article 15 recognizes a right to benefit from scientific progress but also recognizes creators' rights. In 2001, the High Commissioner for Human Rights recommended that states implement TRIPS in ways that respect the balance between creators' rights and the public interest reflected in Article 15, which includes use of flexibilities. In 2005, the CESCR issued General Comment 17 on authors' rights, which cautions that creators' rights do not necessarily coincide with national or international IP laws. **The Human Rights Council has called upon states to pursue policies to promote access and noted states' right to use TRIPS flexibilities.** At the same time, however, it has recognized that IP protection is important for developing new medicines.

Those human rights bodies that have attempted to resolve the tension between strong IP protections and the right to health have done so in favor of the right to health. The treaty bodies and the special rapporteur on the right to health<sup>77</sup> have made a range of recommendations. Between 2004 and 2009, the now-defunct NGO 3D submitted shadow reports on a variety of countries that were up for review, urging the CESCR, the Committee on the Rights of the Child (CRC), and Human Rights Committee (HRC) to recommend that developing countries use TRIPS flexibilities and that all countries conduct impact assessments concerning the effect of potential FTAs on the right to health. The treaty bodies frequently did recommend impact assessments, even cautioning Switzerland about the impact of trade rules on the right to health in its partner countries. We are not aware of any studies evaluating the influence of these observations, and we recommend that A2M activists investigate them as they assess the usefulness of work in the UN. In addition, A2M activists should note that 3D's success was a result of coordinated advocacy at the national and international levels involving human rights, child rights, and development advocates.

**While the treaty bodies have referred to “concerns” and “recommendations,” the special rapporteur on the right to health has made stronger statements about what states “should” do. Specifically, developing countries should use TRIPS flexibilities and not sign TRIPS-plus FTAs.** Developed countries should not pressure developing countries to enter TRIPS-plus FTAs. The special rapporteur has also visited a few countries each year and made recommendations—for instance, that Vietnam should not accept TRIPS-plus provisions in the Trans-Pacific Partnership Agreement.

Importantly, some recent UN documents have gone a bit further. For example, **the special rapporteur in the field of cultural rights has suggested that it may be necessary to delink research and development costs from product prices in order to fulfill the right to benefit from scientific progress in the ICESCR.** This is of some significance and suggests that there are linkages between human rights standards and recent efforts to create a global system that promotes R&D in better alignment with global health needs. **In addition, in the same report, the special rapporteur on cultural rights noted that, while “in accordance with intellectual property treaties, States must establish ‘minimum standards of protection,’ . . .**

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<sup>76</sup> Human Rights Council, Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/23/L.10/Rev.1 (June 11, 2013).

<sup>77</sup> The Special Rapporteur is an expert whose mandate to investigate the right to health comes from the Human Rights Council, but he expresses his views in an independent capacity.

surpassing these may not always be compatible with human rights standards.”<sup>78</sup> This is a recognition, similar to those made in certain of the domestic court cases discussed in Part I, that health-related rights may not simply *recommend* the use of TRIPS flexibilities, but may *require* it. *Appendix B* provides summaries and references for these documents, as well as other key UN documents.<sup>79</sup> Although these documents are “success stories,” further research is needed to understand what made them possible and how much impact they have actually had at the national level changing policy.

There are a number of weaknesses in the current set of human rights standards vis-a-vis A2M. While states undertake to guarantee the right to health and other health-related rights as part of their treaty obligations, the specific obligations necessary to fulfill these rights in light of A2M and IP are not well-developed. Even where precise norms are suggested (e.g. no TRIPS-plus), they are typically phrased as recommendations or at best as “should” rather than “must.” The treaty bodies have recommended impact assessments of trade rules, but they have not specified what sort of impact should lead a state not to agree to the rules. Finally, the strongest statements come from the special rapporteurs, whose reports are useful for advocacy, but these statements have arguably less authority than do general comments and responses to specific communications that are put forth by human rights treaty bodies.

To evaluate whether it is feasible to make further progress on A2M in the UN human rights system, we must address the following: (1) whether it is possible, conceptually and politically, to make strong human rights arguments for specific norms on IP and A2M; (2) whether it is feasible to use UN human rights mechanisms to establish these norms and hold states accountable for them; and (3) whether statements by UN human rights bodies will have enough impact on states’ behavior to make the whole strategy worth activists’ time and resources.

## B. Targeting Stronger and More Specific Human Rights Norms for IP and A2M

While it is possible to make the argument that some TRIPS provisions themselves are inconsistent with the right to health, we do not elaborate on such arguments here. International law and international institutions are loathe to recognize direct conflicts between international treaties, perhaps especially where, as is true here, there is no direct relationship or hierarchy between the legal institutions that house the various treaties. And of course, there are challenges to getting innovative or more radical arguments accepted by the human rights bodies, especially the political (governmental) ones.

However, it is possible to use human rights institutions to argue that states can, and indeed must, implement laws domestically that protect A2M, making use of the fact that TRIPS commitments require substantial interpretation. **In our view, the goals in engaging UN institutions should be to argue that states must make changes to patent law that will improve access and that are arguably (or possibly) consistent with TRIPS, and to argue that states must also refrain from preventing other states from making such changes.** The process of working toward this goal may also put pressure on states, which could be helpful to A2M activists as part of a larger process of influencing norms.

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<sup>78</sup> Human Rights Council, Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed, The right to enjoy the benefits of scientific progress and its applications, A/HRC/20/26 (May 14 2012), para 59.

<sup>79</sup> In addition, the website for the Special Rapporteur on the right to health collects many of the relevant documents at: <http://www.ohchr.org/EN/Issues/Health/Pages/OverviewMandate.aspx>.

**One major task for A2M activists is to develop specific target norms and human rights arguments to support them. Provisionally, we suggest three lines of argument for putting obligations on states with regard to their patent law within the UN human rights system.** First, access to (essential) medicines is a core obligation under the right to health.<sup>80</sup> States must guarantee the availability, accessibility, acceptability, and quality of such medicines.<sup>81</sup> The specific relationship of IP protections to each prong of this right should be clearly articulated. For example, high IP protections interfere with accessibility, since people are not able to afford medicines. They also interfere with availability, since generic suppliers may be necessary to produce medicines in sufficient quantity, particularly in emergencies. The extent of this interference with A2M in developing countries is much greater than the marginal additional incentive for the development of new medicines yielded by high IP protections in developing countries. Since retrogressive measures violate the right to health,<sup>82</sup> increasing IP protections—for example by signing onto FTAs that impose higher IP protections—plausibly violate that right.

Second, General Comment 14, read in the light of the most recent Human Rights Council resolution, suggests that A2M generally (not limited to those on the WHO essential drugs list) is necessary to achieve the full realization of the right to health. Since high IP protections make access to medicines impossible for many people, progressive realization of the right to health requires at least some steps with regard to IP law. (Such arguments need to address the problems with alternative measures to reduce price, such as price controls—see above, Part I.B). Third, progressive realization requires that states move as expeditiously as possible toward the full realization of rights.<sup>83</sup> Therefore, if a particular change to IP law will increase access and is possible, it is an obligation. **Furthermore, while the obligation of progressive realization is subject to resource constraints, the use of IP flexibilities is a way for states to free up resources for health. Thus, it should not be subject to the same limits regarding progressive implementation as initiatives that are net drains on resources.** For example, issuing compulsory licenses can radically reduce the cost of medicines and requires minimal technical expertise and administrative capacity. According to this theory, a country violates the right to health if it refuses to issue compulsory licenses when a license would significantly increase access.

Although these arguments take as starting points the principles enunciated in general comments, to reach formal legal acceptance they must be developed in light of IP and A2M facts and then incorporated by human rights bodies. There are political challenges to this process, particularly where the UN's political bodies are involved, and there are also doctrinal challenges (for example, the confusion regarding whether the right to access medicines applies to *all* medicines or only essential medicines, as described above). When developing specific norms around IP and human rights, activists may also face counter-arguments not yet discussed. For example, if it is argued that an FTA will increase a country's resources and thus contribute to realization of rights overall, might signing it be consistent with human rights obligations from the perspective of a treaty body that addresses all socioeconomic rights? What other rights obligations are also affected—positively or negatively—by the FTA? Can arguments about progressive realization like the ones made above succeed in the human rights system? Our

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<sup>80</sup> General Comment 14, *supra* note 2.

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*



interviews suggested no clear answer to these questions. **It will thus be important for A2M activists considering work in the UN to investigate more thoroughly how human rights bodies have understood the right to health, the application of rights concepts to particular means to achieve such rights, and the current scope and applicability of key principles like the concept of progressive realization.**

To develop obligations of states not to interfere with other states' ability to make changes to patent law, one might argue as follows. States must "respect" the enjoyment of the right to health in other countries and ensure that it is given "due attention" in international agreements.<sup>84</sup> Therefore, they may not pressure countries to adopt IP protections that interfere with realizing the right. The strength of this argument depends on human rights bodies' willingness to recognize trans-border human rights obligations. The CESCR, among other treaty bodies, has begun developing this approach: Its concluding observations to Switzerland suggest some willingness, but they specifically recommend that Switzerland not interfere with other states' obligations, rather than detailing the scope of Switzerland's own obligations. The existing language of "respect" and "due attention" also seems too weak to permit a straightforward inference that states must weigh other states' interests in public health above their own economic interests. Trans-border obligations in general are a new frontier,<sup>85</sup> and any strategy that relies on their further development faces substantial difficulties.

**In sum, these arguments for specific obligations with regard to IP law have some existing support and can likely be articulated further in ways that are reasonably founded on existing human rights law, especially through application to A2M factual settings.** Developing a research base of the specific environments in which IP issues clash with health rights and applying principles and arguments to the facts to develop new norms is a classic mode of human rights standards development. However, because the norms discussed here also would be extremely progressive, getting them officially recognized within the UN would require substantial, supportive NGO work and receptive human rights bodies. (It is perhaps worth noting here that while we focus on formal UN human rights bodies, very important elaborative work can also happen with UN secretariats and agencies, and independent expert commissions can also play an important role.)

In certain contexts, framing access to medicines in terms of other health-related rights might offer certain additional opportunities.<sup>86</sup> For example, the right to be free from torture and ill-treatment could help to address the difficulties with state obligations and progressive realization that arise with regard to the right to health. The special rapporteur on torture has argued that the following violate the right to be free from torture and ill-treatment: failure to provide pain medications that are on the WHO essential medicines list, denying opiate substitution treatment to drug users, or denying antiretroviral drugs to HIV-positive drug users on the assumption that they will not adhere to treatment.<sup>87</sup> Furthermore, lack of resources does not justify torture or ill-treatment. Therefore, one could argue that countries must address IP barriers where necessary to provide medicines, the denial of which constitutes torture. An argument founded on torture could, in addition, reach countries, such as the United States, that

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<sup>84</sup> *Id.*

<sup>85</sup> UNIVERSAL HUMAN RIGHTS & EXTRATERRITORIAL OBLIGATIONS (Mark Gibney & Sigrun Skogly eds., 2009).

<sup>86</sup> For a helpful collection of some of these rights, those most directly related to health, see <http://www.ohchr.org/EN/Issues/Health/Pages/InternationalStandards.aspx>.

<sup>87</sup> Special Rapporteur on Torture, *Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment*, U.N. Doc. A/HRC/22/53 (Feb. 1, 2013) (by Juan E. Mendez).



have ratified the Convention against Torture but not the ICESCR. It could also tap into the powerful moral discourse against torture. However, the right to be free from torture may be difficult to generalize outside of very specific contexts. To address A2M outside these particular contexts, one would need to push for an expansion of the definition of torture, or else use the right to health as described in this section.

### C. Available Mechanisms in the UN Human Rights System

Discussions with A2M activists and others involved in human rights work at the UN suggested to us seven possible mechanisms A2M activists should consider: a Human Rights Council resolution, a treaty body general comment(s), expert guidelines, expert consultations, shadow reporting, participation in a Universal Periodic Review (UPR), and treaty body complaints. The first four would develop general norms. The last three could both develop norms and apply them to particular states. We summarize how NGOs can use each mechanism and whether each would be feasible for A2M activists.

#### i. *Mechanisms for Developing Human Rights Norms*

**Human Rights Council resolutions** are authoritative and high profile: The council is the inheritor of the UN Charter's opening, if troubled, commitment to human rights. (Its predecessor body, the Commission on Human Rights, was created by the Charter in 1946.) The council retains its salience because of the prominence of the institution and its consensus-driven resolutions. However, it is made up of governmental representatives and so is a political, rather than independent expert, body. This geopolitical grounding, along with the council's preference for consensus, often makes specific or innovative language difficult to achieve. When major developments of law are recognized here, they tend to have been supported by large coalitions of NGOs, who can lobby governments and commit resources to a process that may take years. Brazil has sponsored council resolutions on A2M in the past, and specific support from countries in the future would be important to work at the council. However, even developing countries that promote A2M concerns might be reluctant to push a resolution that suggested that they were required to use certain TRIPS flexibilities, and developed countries will likely continue to oppose any progressive work on IP. Developed countries will likely reject any obligations not to pressure developing countries for higher IP protections. Even so, advocating for such positions around council meetings might help develop the arguments and build networks of NGOs that can help them be recognized in other forums.

A2M activists might aim for a **general comment** from the CESCR addressing IP and access to medicines, either as a stand-alone comment or included in a broader comment. A general comment may foster increased accountability, but it requires a foundation of information and practices gleaned by the committee from state reports, which could include information on national court cases, and individual complaints (see below for more on complaints). This record does not exist yet, so a general comment could only be a long-term goal. NGOs pushing for a comment, which is a several-year process, need strong initial support from at least 1-2 committee members and some UN agencies. Many committee members are open to innovative rights ideas and willing to address unpopular issues if there is a strong argument for violation of a right. However, the CESCR's willingness to address IP and A2M might depend on whether current committee membership included an expert on the right to health. Additionally, the CESCR might

be hesitant at this point, because there were some negative reactions to its treatment of IP in General Comment 17. Moreover, some treaty committees have tended recently to leave detailed elaborations and contentious topics to the special rapporteurs. When there is a sufficient normative record at the national level, it might be worth re-considering a new general comment, depending on the expertise of the CESCR at that time and A2M activists' ability to partner with powerful allied NGOs. Moreover, treaty bodies and independent experts can "share" the development of a conceptual framework; so depending on initiatives among the rapporteurs (see below), the CESCR or another treaty body could be approached (the CRC and the newly created Committee on the Rights of Persons with Disabilities, or CRPD, may be promising venues.)

**Expert guidelines** can be a source of norms to be cited by civil society groups, treaty negotiators, or participants in human rights mechanisms, especially if a UN agency promulgates them. Guidelines can be useful within UN agencies as well. To generate expert guidelines, an agency or agencies can work with like-minded governments to host a meeting, whose agenda and participants the hosting agency and collaborating states determine. Some A2M activists think expert guidelines in rights and A2M are unnecessary because norms already exist, while others argue that progress in holding states accountable will require more specific and stronger norms about how human rights obligations constrain IP law, such as those discussed in Section B. If A2M activists develop consensus on the usefulness of expert guidelines, strategic alliances with "insider" human rights NGOs could be helpful. Fundraising with governments, the political impacts of leaving out important actors, and the fact that a UN agency likely could not promulgate guidelines on IP without involving the WTO would constrain the kinds of possible guidelines. The Global Commission on HIV & the Law in 2012 essentially suggested such a process to generate guidelines through a roundtable of relevant actors.<sup>88</sup> Because this process is a collaboration of nations and UN institutions, it is unlikely to produce a document that is radical or instantly influential, but it might be a valuable way to begin to explore challenges and articulate more concrete norms for IP and A2M.

Moreover, with the support of the Office of the High Commissioner on Human Rights (OHCHR), bodies such as the Human Rights Council, treaty bodies, and special rapporteurs can convene and participate in **expert consultations** for discussion of particular topics among UN representatives, academics, government representatives, and NGOs. Through a resolution (A/HRC/20/L.18), the Human Rights Council has called for an expert consultation on the right to benefit from science for October 2013. These consultations are basically informational, but final documents can provide the core for arguments for new standards. A2M activists should participate as much as possible to generate ideas and awareness.

## ii. *Mechanisms for Applying Human Rights Norms to Particular States*

Activists could continue 3D's work on creating **shadow reports**—NGO reports that parallel a state party report to a treaty body on steps taken in fulfillment of obligations—to any relevant treaty committee, aiming for concluding observations that are specific, hortatory, and reviewable.<sup>89</sup> For example, instead of recommending generally that a state conduct an impact

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<sup>88</sup> *Risks, Rights and Health*, GLOBAL COMMISSION ON HIV AND THE LAW (2012), <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>.

<sup>89</sup> For information on shadow reporting, see *Making the Mountain Move: An Activist's Guide to How International Human Rights Mechanisms Can Work for You*, INTERNATIONAL GAY & LESBIAN HUMAN RIGHTS COMMISSION, <http://www.iglhrc.org/sites/default/files/186-1.pdf> (last visited June 9, 2013); and *Simple Guide to the UN Treaty*

assessment, a committee could say: “*The Committee is concerned that agreeing to an FTA with X provision will violate your treaty obligations because of its impact on the right to health, specifically because of its intended result in tightening the access to X drugs, resulting in a denial of affordable medicines to treat Y disease for Z populations. In order to assess this potential impact, Z country should carry out an impact assessment of the FTA in an open and transparent manner engaging with all stakeholders.*” However, committees other than the CESCR tend not to have broad health mandates and will be primarily concerned with the health of specific groups (minorities, persons under the age of 18 with disabilities, rural women). They will likely consider it outside their mandates to develop new standards for health and IP broadly. The CRPD might be particularly open to new ideas, since it has a mandate to monitor a new treaty with many terms and obligations that have not yet been elaborated. Key constituents of this treaty body include groups seeking expanded access to medicines for care and treatment, as well as materials and resources (such as books in Braille), for individuals with physical, developmental, and intellectual disabilities, including sight and hearing impairment.

In general, committees are often willing to be critical and consider novel analysis leading to more specific and stronger observations. However, their formal practice aims for constructive dialogue, preferring to recommend measures for compliance rather than accuse countries of violations. Committees more seriously consider reports from NGOs that they know, so A2M activists would need to work with NGOs experienced in this work (e.g. Center for Reproductive Rights for shadow reporting to the CESCR). Of course, such NGOs have their own priorities. It seems worth pushing the limits of shadow reporting, if the A2M community can form the NGO partnerships necessary. It would be important to focus on sympathetic experts on the committees, identify strategic times, and target willing countries so the work would have maximum impact. Simultaneously, the treaty bodies’ independence and innovative thinking have at times recently generated a fierce critique among states, both developed and developing, who are threatening to curtail their powers through a “reform” process.

The **UPR** is a new process that requires each country in the UN to report to the Human Rights Council every four years on its compliance with the UDHR and any treaties to which it is a party.<sup>90</sup> NGOs can submit reports, lobby states to ask specific questions, and attend the council’s relevant sessions. The UPR is more visible than country reviews in treaty bodies, both to other states and to NGOs, and it is a more efficient use of states’ resources just to submit one human rights report, so some advocates feel the UPR may become increasingly important as states put most of their effort into it and not into the treaty bodies. (This is coupled with recent attacks on treaty bodies.) Many NGOs are excited about the UPR, as it allows space to legitimize previously marginalized issues in the right geopolitical moment, but it is not an ideal venue for changing norms in whole or for dealing with specific contestations of an issue like access to medicines. Participation also requires a big Geneva-based coalition, which does not exist for health activists. A recent submission by a small coalition of A2M NGOs illustrates this problem: The submission urged a review of how U.S. trade policy affects access to medicines, but the

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*Bodies*, INTERNATIONAL SERVICE FOR HUMAN RIGHTS (2010), <http://www.ishr.ch/guides-to-the-un-system/simple-guide-to-treaty-bodies>. For a discussion of 3D’s work, see Davinia Ovet, *Making Trade Policies More Accountable and Human Rights-Consistent: A NGO Perspective of Using Human Rights Instruments in the Case of Access to Medicines*, in ECONOMIC GLOBALISATION AND HUMAN RIGHTS 170 (Wolfgang Benedek, Koen De Feyter, & Fabrizio Marrella, eds., 2007).

<sup>90</sup> For information on the UPR process, see Human Rights Project, *A Practical Guide to the United Nations’ Universal Periodic Review (UPR)*, URBAN JUSTICE CENTER (2010), <http://www.hrpujc.org/documents/UPRtoolkit.pdf>.

OHCHR chose not to include the information in the UPR report, perhaps in part because the submission lacked an “inside ally” in Geneva.<sup>91</sup> UPR work, like much of the work described here, requires substantial investment of resources and commitment to a multi-year plan. The cost-to-benefit ratio seems less favorable than in other domains, though it may be worth consideration if it does grow in importance.

Using a treaty-based petition method, called an “individual complaint” or “communication,” offers another avenue for both norm development and pressuring individual states. An affected individual or group can bring a **complaint** against a state that has ratified or opted into one of the complaint mechanisms of the UN’s treaty system. For the right to health or other health-related rights, the Optional Protocol to the ICESCR or a complaint to another treaty body might be considered. Petitioners can use complaints publically to generate criticism of a state, and a complaint’s arguments or the actual decision of the treaty body (its “views”) on a complaint may influence other proceedings at the UN or domestic court cases. In the IP context, it might be worth having people bring a complaint against their own state, but trans-border obligations are so new that having petitioners in one state bring a complaint against another state for interfering with access to medications would be an uphill battle. There are an enormous number of complaints in the UN system, and most are rejected on admissibility grounds, so A2M activists would need support from a prominent NGO working with the CESC. They would also need to keep their eyes open for an appropriate case—one where IP protections are interfering with A2M and could be remedied without clearly violating trade agreements, and where the case has exhausted domestic remedies. With good briefing and appropriate support, the CESC might decide such a case favorably, based on its record of general comments and concluding observations.

The individual complaint strategy, however, needs more exploration. Right now, only ten states are subject to the individual complaint mechanism of the ICESCR, and we did not develop any detailed ideas about what specific kind of case might be brought through such a complaint. Moreover, complainants must first exhaust domestic remedies,<sup>92</sup> and the CESC cannot enforce its decision on a complaint.

### iii. *Pursuing the Most Feasible Options*

**In sum, expert consultations, expert guidelines, and shadow reporting appear to be the most feasible options for working in the UN system at this point.** A complaint might be useful if A2M groups can identify and bring an appropriate case. A general comment might be possible later, after other activities in the UN human rights system, as well as national and regional jurisprudence and legislation, have built up norms. A Human Rights Council resolution with significantly more developed content than we have seen to date seems less realistic than other options, but working on it might have networking benefits regardless of the outcome. Regardless of strategy, to do any work in the UN human rights system, A2M activists will need to (1) specify what concrete norms they are trying to establish; (2) bring other human rights NGOs on board; and (3) commit to a multi-year effort.

**Besides the challenge of developing normative arguments that will be acceptable to human rights bodies and the structural challenges in using the various mechanisms, A2M**

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<sup>91</sup> For the submission, see <http://www.wcl.american.edu/pijip/go/blog-post/groups-call-for-human-rights-review-of-u-s-medicine-policy>.

<sup>92</sup> For information on individual complaints, see *Simple Guide to the UN Treaty Bodies*, *supra* note 89.

**activists' ability to make progress in the UN will also be limited by human rights NGOs' willingness to participate.** We are not aware of any NGOs doing concentrated work on A2M in the UN human rights system. There are health groups that work in the UN, but they are very focused on issues like HIV/AIDS, maternal mortality, or mental health. It could be hard to convince these groups to devote some of their limited resources to another group's cause. To encourage participation by major human rights groups, A2M activists might try to find ways to frame the IP issue so that these groups can incorporate it into issues they are already pursuing, such as women's rights or the rights of people with disabilities.

#### *iv. Putting an Issue on the International Agenda: A Case Study on Violence Against Women*

The experience of activists working on violence against women illustrates a campaign's progress toward putting a new issue on the international human rights agenda. It thus suggests practical considerations for the A2M movement in devising a long-term strategy.

The movement to combat violence against women as a human rights issue had its roots in women's groups, many in Latin America and Asia and others in North America and Western Europe, that were concerned about political torture, war-time sexual slavery, rape, and domestic violence.<sup>93</sup> An international women's rights movement developed out of a series of conferences that women's groups organized, sometimes alongside official UN meetings, starting in Mexico City in 1975 and Brussels in 1976. These were important forums for women to overcome their ideological differences and raise awareness.<sup>94</sup> By constructing the category of "violence against women," activists could unite women from north and south working on a variety of disparate issues in a common campaign.<sup>95</sup>

The issue of violence against women gained legitimacy with states and in the UN through a combination of "t-shirt" rights actions and the participation of academic experts presenting evidence on its causes and consequences, such as at the UN expert group meeting on Violence in the Family in 1986; world events highlighting the problem, such as the shooting of 14 female students at the University of Montreal; and pressure on globally respected NGOs such as Amnesty International and Human Rights Watch to do more work on women's rights.<sup>96</sup> Leading up to the UN World Conference on Human Rights in Vienna in 1993, a U.S.-based NGO called the Center for Women's Global Leadership, working in tandem with the newly forming regional networks on women's rights, led a global campaign to overcome the division in the UN between women's rights and human rights. Advocates published articles in mainstream human rights journals on violence against women in particular.<sup>97</sup> The international network on women's rights, which brought many women to the Vienna conference, and the support of particular states, especially Canada, the Netherlands, and the U.S., were key to the success of the conference in redefining women's rights as human rights.<sup>98</sup> The Vienna Conference called for a

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<sup>93</sup> MARGARET E. KECK & KATHRYN SIKKINK, *ACTIVISTS BEYOND BORDERS: ADVOCACY NETWORKS IN INTERNATIONAL POLITICS* 174-76 (1998).

<sup>94</sup> Jutta Joachim, *Comparing the Influence of NGOs in Transnational Institutions: the UN, the EU and the Case of Gender Violence*, Paper Prepared for the 43<sup>rd</sup> Annual Convention of the International Studies Association (March 24-27, 2002), <http://isanet.ccit.arizona.edu/noarchive/joachim.html>.

<sup>95</sup> KECK & SIKKINK, *supra* note 93, at 171-72, 197.

<sup>96</sup> Jutta Joachim, *supra* note 94.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*; KECK & SIKKINK, *supra* note 94, at 187.



special rapporteur and a declaration on violence against women, a UN General Assembly resolution adopting the declaration, and a UN Commission on Human Rights resolution adopting the rapporteur, all of which happened in the next two years.<sup>99</sup> Over the next decade, resolutions calling on the UN human rights system to “mainstream” gender analysis were passed; trainings of UN experts, national policymakers and others were sponsored as part of protecting women against violence; and new norms, such as the state’s “due diligence” obligation to protect woman from violence, whether or not the state was the actor initially responsible for the violence, were adopted throughout the human rights treaty system.

Notwithstanding this success in getting the UN to acknowledge the issue, several scholars have pointed to ways in which this triumph was incomplete. Human rights ideas must be translated into local terms in order to be effective, and “the idea that everyday violence against women is a human rights violation” has not “moved readily from transnational to local settings.”<sup>100</sup> Concrete changes on violence take a long time and are tied to other human rights issues that may not have full state support, such as women’s economic equality. Furthermore, although framing women’s rights in terms of violence, especially sexual violence, helped to muster support, it has left broader women’s justice issues neglected.<sup>101</sup> Indeed, the original NGO call had been for a rapporteur on *discrimination against women*, but the more limited, body-focused violence proved more successful in recruiting state support.

**This example suggests that putting a new issue on the UN agenda is a long-term process that can take 15 years or more and involves significant work to build up activist networks.** Moreover, victories may be tempered by compromises and alliances that are necessary to achieve success. Local activist groups provide an important foundation, and framing the issue for transnational relevance is key to building international networks. Both commitment by certain organizations to spearhead a campaign and participation by mainstream human rights NGOs are also important. Academics can help by developing the theoretical arguments necessary to incorporate the new issue in the human rights system. Once a campaign is successful in putting the new issue on the UN agenda and pushing for its incorporation in UN statements, only local follow-up can ensure that the idea will have practical impact.

#### D. Would UN Human Rights Statements Actually Impact A2M?

The third key question in Part II is whether any of these activities in the UN human rights system could positively influence states’ behavior and, thereby, actually increase access to medicines. All of the mechanisms discussed above produce “soft law,” which is “not legally binding because states have not formally agreed to be bound by the provisions . . . Nevertheless, [it] can have considerable political and legal weight.”<sup>102</sup> Soft law documents often draw on the norms in binding instruments. As a general matter, soft law may have an impact in a variety of ways. It can acquire unforeseen authority and even become customary law; influence the drafting of hard law; raise awareness; provide technical guidance; or serve as a reference in national and international jurisprudence or other international instruments. Soft law has the most impact when

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<sup>99</sup> SALLY ENGLE MERRY, HUMAN RIGHTS AND GENDER VIOLENCE: TRANSLATING INTERNATIONAL LAW INTO LOCAL JUSTICE 12 (2006).

<sup>100</sup> *Id.* at 1-2, 136-37.

<sup>101</sup> Alice M. Miller, *Sexuality, Violence against Women, and Human Rights: Women Make Demands and Ladies Get Protection*, 7 HEALTH & HUM. RTS. 16, 19 (2004).

<sup>102</sup> *Human Rights Standards: Learning from Experience*, INTERNATIONAL COUNCIL ON HUMAN RIGHTS POLICY 11 (2006), [http://www.ichrp.org/files/reports/31/120b\\_report\\_en.pdf](http://www.ichrp.org/files/reports/31/120b_report_en.pdf).

NGOs publicize it to influence public opinion and embarrass or pressure a government. Because of this real impact, states increasingly want to control the development of soft law. Most drafters take government views into account, because texts need government support to have impact.

We interviewed over a dozen activists about what impact they thought any UN statement could have on access to medicines. Almost everyone was at least somewhat skeptical that UN statements would have a significant impact. A few interviewees saw no possibility of any impact. Most expressed reserved optimism, often identifying specific ways UN documents might make a difference. They suggested that UN statements could be useful for bringing the issue into international discussion, especially if NGOs work with media and mobilize public opinion; advocates might use them to pressure the government; or the statements might play a role in national jurisprudence or debate over legislation. Several cautioned that in order to have an impact, UN statements must come at strategic moments, name particular countries, and target countries where governments are potentially open to such intervention. Domestic courts have used UN statements to interpret treaty obligations,<sup>103</sup> but there is disagreement about how much influence such statements in general are likely to have. **There is no consensus about the viability of a UN strategy for increasing A2M, but there is consensus that the extent of practical impact depends on governments' willingness to implement recommendations and follow-up activities by local activists. Moreover, governmental willingness itself is a creation of competing forces.**

The WTO is another place that UN statements on human rights and IP might have impact. Dispute settlement jurists in the Appellate Body have demonstrated some willingness to use soft law to interpret trade rules, so it is plausible that they would look at human rights documents in interpreting TRIPS.<sup>104</sup> In the *Shrimp/Turtle* case, the Appellate Body found that evolving concepts should be interpreted in light of the “contemporary concerns of the community of nations,” and it looked at nonbinding declarations on natural resources to understand the term “exhaustible natural resources” in the GATT.<sup>105</sup> Similarly, the WTO could construe TRIPS flexibilities broadly by using human rights statements to interpret TRIPS. Note that WTO dispute resolution would be relevant only if UN statements encouraged states to take steps that pushed the flexibilities permitted in TRIPS, states did so, and other states challenged them as violating TRIPS.

Finally, while the UN statements discussed above are all soft law, their usefulness is not identical. However, not everyone agrees about which mechanisms are most useful. A general comment is potentially more useful than shadow reporting or a petition under the individual complaint mechanism in the sense that it expresses an authoritative interpretation of treaty obligations that should influence all country reviews and individual complaints. Such a comment also provides a generally applicable reference for national legislation and jurisprudence. However, shadow reports generating good concluding comments or a strong decision on an individual complaint can have more influence on the particular country at issue than a generic statement would. Moreover, groundbreaking decisions on petitions in the treaty bodies have morphed into statements of general interpretation of the treaty over time, through repeated invocation by the treaty body and NGOs. Expert guidelines are less authoritative than statements

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<sup>103</sup> See Part I.

<sup>104</sup> Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 77-79 (2004).

<sup>105</sup> WTO Appellate Body Report on United States-Import Prohibition of Certain Shrimp and Shrimp Products, WTO Doc. WT/DS58/AB/R (Oct. 8, 1998).

by the human rights bodies, and their impact depends upon who issues them (ideally a UN agency) and whether all stakeholders were included in the process. Expert consultations do not produce soft law at all, but rather gather information and opinions and propose new norms.

### E. Insights & Action Steps

**We conclude that even though a Human Rights Council resolution or general comment might have the greatest salience or impact, there are other mechanisms that are more feasible at this point.** Expert consultations, expert guidelines, and shadow reporting (with the aim of supportive concluding comments) appear to be the most worthwhile options because of their greater feasibility. To maximize their impact, these mechanisms must be utilized in connection with action on the local level. **We recommend that A2M activists assess and pursue selected human rights mechanisms that are likely to be the most feasible and productive, especially as applied in specific, strategic moments and country contexts. This may be particularly valuable to help support and disseminate successes at the national level.**

Key Action Steps	
<i>Short Term</i>	<ul style="list-style-type: none"> <li>• To assess the usefulness of work in the UN, activists and academics should research what impact existing UN statements on A2M have had on states' behavior (e.g. Switzerland's actions since receiving the concluding observations from the CESCR in 2010);</li> <li>• To assess the strength of human rights arguments about IP and A2M, activists and academics should research human rights bodies' understanding of progressive realization;</li> <li>• Activists should develop consensus within the A2M community on target norms for IP and A2M at the UN;</li> <li>• Activists should participate in expert consultations, such as the October 2013 meeting on the right to science;</li> <li>• Investigate whether it is possible to build a coalition of NGOs to push A2M issues at the UN.</li> </ul>
<i>Long Term</i>	<ul style="list-style-type: none"> <li>• Activists should participate in the development of expert guidelines with a UN agency;</li> <li>• Activists should submit shadow reports when there is a country up for review that faces decisions about IP policy, such as in FTA negotiations, and where there is government willingness or civil society activism that can use the concluding comments/recommendations productively. Include positive national court decisions in shadow reports to drive the record on evolving norms.</li> </ul>



### III. Access to Medicines Through Corporate Accountability

**Key Insights:** Pharmaceutical corporations have traditionally rejected the notion that they have *obligations* under the right to health, in part because the international human rights system, focused on states as central players, has not historically considered corporate actors to be directly governed by human rights law. Recent developments, including the emergence of the UN Working Group on Business & Human Rights, may give A2M activists new tools for campaigns against companies. In addition, informal arguments and human rights language continue to be essential for bringing pharmaceutical corporations to the table and for promoting practical solutions for greater accountability.

#### A. Corporate Social Responsibility and the Right to Health

Pharmaceutical corporations' decisions regarding patents, licenses, pricing, and lobbying are at the root of the conflict between IP and A2M. Despite normative shifts that have accepted corporate social responsibility (CSR) as good business practice (see *Appendix C*), **there remains little clarity with regard to which corporate activities are legally mandated and which are socially desirable practices.** This is a critical problem for the A2M movement, as it represents an area where both the content of the right to health and the understanding of who bears responsibility for ensuring the rights are evolving. While the state duty to protect against third-party abuse is grounded in international human rights law, states are “not held responsible for corporate-related human rights abuse per se.”<sup>106</sup> And because corporations are not sovereign entities and are incapable of ratifying human rights treaties, the corporate responsibility to respect human rights is of unclear status under international law.

Many argue that the human rights system, as it currently stands, is not effective at holding corporations accountable, and that other arguments may prove more persuasive. While it is necessary to consider alternative arguments, there may be space for human rights language to play a role. This section explores whether and how activists might harness existing, but underutilized, human rights frameworks as a tool in the greater push for corporate accountability.

#### B. Evolving Human Rights Norms Regarding Corporate Accountability

Over the last decade, there have been significant attempts to develop legal norms that articulate the human rights obligations of corporate actors. In 2003, the UN Sub-Commission on the Promotion and Protection of Human Rights drafted the *Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regards to Human Rights* (the Norms), which “would have imposed on companies, within their ‘spheres of influence the same human rights duties [for selected rights] that states have accepted for themselves under treaties they have ratified.”<sup>107</sup> The Norms triggered an immediate divide: Many human rights NGOs were supportive because the Norms proposed putting binding obligations on companies directly under international law, while business networks were opposed to the document’s “non-

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<sup>106</sup> Rep. of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corps. and Other Bus. Enter., U.N. Doc. A/HRC/11/13 (Apr. 22, 2009), available at <http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.13.pdf>.

<sup>107</sup> JOHN RUGGIE, JUST BUSINESS: MULTINATIONAL CORPORATIONS AND HUMAN RIGHTS at xvii (2013).

voluntary” language.<sup>108</sup> Due to lack of government support from within the Commission (now Human Rights Council), the Norms were never endorsed. The task of clarifying the intersection of human rights and business practices was turned over to John Ruggie.

In 2011, six years after the Human Rights Council created John Ruggie’s mandate, the *UN Guiding Principles on Business and Human Rights* (Ruggie Framework) was developed and unanimously endorsed by the council. The Ruggie Framework was influenced by Ruggie’s “rejection of certain key features of the Norms”<sup>109</sup> or as Ruggie called it, “normicide.” He concluded that the Norms were a “distraction from rather than a basis for moving [his] mandate forward” and thus sought to dissociate his framework from them almost entirely. **Alongside the Ruggie Framework, the Human Rights Council created a Working Group on Business & Human Rights (WG), which set out to promote the dissemination and implementation of the Framework.**<sup>110</sup>

**The Ruggie Framework rests on the three pillars of “respect, protect, and remedy”:** 1) States have a *duty* to protect against human rights abuses by third parties, including business enterprises, 2) corporations have an independent responsibility to respect human rights and to avoid infringing on the rights of others, and 3) victims of human rights abuses must have access to remedy, through both judicial and non-judicial processes. To many human rights and A2M advocates, the Ruggie Framework was a disappointing culmination of a decades-long struggle to define and enforce corporate accountability. Compared to the Norms, the framework, fell “short of establishing an effective accountability mechanism by which to regulate the behavior of pharmaceutical companies.”<sup>111</sup> Nonetheless, the Ruggie Framework is the current normative structure, and it applies to all human rights (unlike the Norms, which selected key rights) and therefore can be developed for health and health-related rights.

**SUMMARY OF RELEVANT UN HUMAN RIGHTS/CORPORATE DOCUMENTS FOR A2M**

*UN Guiding Principles on Business and Human Rights (Ruggie Framework) – “Respect, Protect, Remedy”*

- Submitted by John Ruggie in 2011
- 1) State duty to protect, 2) Corporate responsibility to respect, and 3) Need for effective remedy;
- Unanimously endorsed by the Human Rights Council in 2011;
- Working Group established in 2011 – continues to promote effective implementation of the Framework.

*Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines (Hunt’s Guidelines)*

- Submitted by Paul Hunt in 2008;
- A2M is a shared responsibility between public and private actors, with specific obligations on patent-holders, intended to provide practical and specific guidance to pharmaceutical companies;
- Never endorsed by the Human Rights Council.

*Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regards to Human Rights (the Norms)*

- Submitted by sub-committee of experts in 2003;
- Outlined mandatory obligations imposed upon corporations by international law;
- Declared to have “no legal standing” and were abandoned.

<sup>108</sup> *Id.* at 53.

<sup>109</sup> David Bilchitz, The Ruggie Framework: An Adequate Rubric for Corporate Human Rights Obligations? (Apr. 24, 2009) (unpublished manuscript), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1394367](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1394367).

<sup>110</sup> UN WORKING GROUP ON HUMAN RIGHTS, <http://www.business-humanrights.org/UNWorkingGroupPortal/AboutWorkingGroup> (last visited Apr. 23, 2013).

<sup>111</sup> Anand Grover et al., *Pharmaceutical Companies and Global Lack of Access to Medicines: Strengthening Accountability Under the Right to Health*, 40 J. L. & MED. ETHICS 234 (2012).

Ruggie’s mandate overlapped with that of Paul Hunt (special rapporteur on the right to health, 2002-2008), who sought to establish normative clarity for the application of human rights and CSR to pharmaceutical corporations and life-saving medicines. His *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines* (Hunt’s Guidelines) set out to demonstrate that not only did pharmaceutical companies share states’ responsibilities for increasing access to medicines, but as patent-holders, they also had additional human rights *obligations*. Hunt’s Guidelines were criticized for conflating the obligations of states with the obligations of corporations and for its silo-focus on the pharmaceutical sector.<sup>112</sup> Unlike the Ruggie Framework, Hunt’s Guidelines failed to gain traction in the Human Rights Council and were not adopted. **Consequently, there is no formal UN-sanctioned document or comment that explains what an application of the Ruggie Framework to pharmaceutical corporations would look like or how it could work to increase access to medicines.**

### C. Application of the Ruggie Framework to Hunt’s Guidelines

Even though the Ruggie Framework is incomplete, it is still a consequential document. Without it, there would be no formally endorsed document at the UN on the intersection of human rights and business practices. Even those we spoke to who questioned its effectiveness still considered it “an important piece of the puzzle.”

Members of the A2M community agree that a major barrier to enforcing corporate accountability is the lack of clarity generally and, more particularly, the lack of specific obligations of states, versus those of corporations. One academic in the A2M movement, Suerie Moon, writes that “many of the Hunt Guidelines for pharmaceutical companies clearly fall under the Ruggie principle of ‘respect’, but some...ascribe to private actors the obligations that...would better be ascribed to states.”<sup>113</sup> Moon argues for the use of a “two-tier” framework, in which “the company’s responsibility to respect is fundamental, whereas other activities may be socially-desirable and important for fulfilling the right to health, but are secondary.”<sup>114</sup> These secondary activities may fall under the state’s obligation to protect.<sup>115</sup> Moon considered Hunt’s Guidelines in light of the Ruggie principle and argues that some of Hunt’s recommended actions are clearly required by Ruggie’s framework: “Among these were the first four guidelines that recommend that companies ‘should adopt a human rights policy statement,’ ‘integrate human rights... into the strategies, policies, programmes, projects and activities of the company,’ ‘should always comply with the national law of the State where it operates, as well as any relevant legislation of the State where it is domiciled,’ and ‘should refrain from any conduct that will or may encourage a State to act in a way that is inconsistent with its obligations arising from national and international human rights law,’ including the right to health.”<sup>116</sup>

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<sup>112</sup> John S. Gardner and James P. Kelly III, Corporate Social Responsibility or UN Corporate Governance?: Reflections on the United Nations Draft Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, Panel Discussion Before The Federalist Society (Dec. 11, 2007), available at [http://www.fed-soc.org/publications/pubID.466/pub\\_detail.asp](http://www.fed-soc.org/publications/pubID.466/pub_detail.asp) (last visited Apr. 23, 2013).

<sup>113</sup> Suerie Moon, *Respecting the Right to Access to Medicines: Implications of the UN Guiding Principles on Business and Human Rights for the Pharmaceutical Industry, Health and Human Rights*, Vol. 15 (2013), at p 41. Available at <http://www.hhrjournal.org/>.

<sup>114</sup> *Id.* at 35.

<sup>115</sup> See Appendix C for more information.

<sup>116</sup> *Id.* at 38.

Ruggie’s approach also provides clear support for transparency and information disclosure and suggests that companies must respect the use of TRIPS flexibilities in order to “do no harm.”<sup>117</sup> Moon also argues, however, that the Ruggie framework does not provide significant support for obligations to refrain from seeking trivial patents, to invest in research for neglected diseases, or to issue voluntary licenses in low- and middle-income countries. She points out that imposing such obligations on companies might be both ineffectual and let states off the hook for what are fundamentally state-based obligations (for example, to ensure affordability and availability of medicines).<sup>118</sup>

As Moon’s article suggests, there are likely significant limits to the Ruggie approach because it emphasizes values like transparency and negative obligations not to interfere (to “respect” rights) over substantive obligations to promote or protect rights. The precise obligations that might be developed under the Ruggie Framework require further exploration. In addition, activists must consider closely the strategic value of the kinds of norms that might be developed with reference to the new WG and the possibility that such norms would be ineffectual, limited, and/or might work against concepts of state responsibility.

**If activists wish to develop concepts of corporate liability, they could push for comment or clarification within the WG.** For example, the WG has previously undertaken missions to the United States to look at implementations of the Ruggie Framework: In April 2013, the International Corporate Accountability Roundtable (ICAR) convened civil society stakeholders to present to the WG on their perspectives of U.S. implementation of the Ruggie Framework.<sup>119</sup> Further, the WG makes annual reports to the Human Rights Council and the General Assembly, and it receives submissions from civil society. To our knowledge, the WG has not taken up IP or pharmaceutical issues in any of its work. In December 2012, the WG held its first annual United Nations Forum on Business and Human Rights. However, according to a summary of discussions, no pharmaceutical corporations were present and no A2M issues addressed.<sup>120</sup> **But as the WG develops its work plan, there may be openings for A2M activists to push for greater pharmaceutical responsibility through the Ruggie Framework.**

#### D. Human Rights Arguments and Practical Solutions

In addition to claims that the Ruggie Framework is weak, many A2M activists and academics remain reluctant to engage the WG process, deeming it unlikely to be the best use of resources and likely to lead to very marginal outcomes. Notably, however, human rights norms for pharmaceutical companies might be developed without formally invoking the Ruggie Framework. One such strategy would use human rights in their “t-shirt,” or campaigning, sense to push for corporate accountability mechanisms for pharmaceutical companies.

**Corporate ombudsperson positions** might help in increasing due diligence for human rights protection, although some activists fear that such persons would be easily captured by corporate interests. This may be why, when Paul Hunt originally proposed the creation of an

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<sup>117</sup> *Id.*

<sup>118</sup> *Id.* at 40.

<sup>119</sup> *Civil Society Consultation for US Country Visit of UN Working Group on Business and Human Rights*, INT’L CORP. ACCOUNTABILITY ROUNDTABLE, <http://accountabilityroundtable.org/analysis/civil-society-consultation-for-us-country-visit-of-un-working-group-on-business-and-human-rights> (last visited Apr. 23, 2013).

<sup>120</sup> U.N. Human Rights Council, *Summary of discussions of the Forum on Business and Human Rights, prepared by the Chairperson, John Ruggie*, U.N. Doc. A/HRC/FBHR/2012/4 (Dec. 4 and 5, 2013), available at [http://www.ohchr.org/Documents/Issues/Business/ForumSession1/A\\_HRC\\_FBHR\\_2012\\_4\\_en.pdf](http://www.ohchr.org/Documents/Issues/Business/ForumSession1/A_HRC_FBHR_2012_4_en.pdf).

ombudsperson in his 2008 report on his visit to GlaxoSmithKline, he specifically noted that it should be an “independent” and “external” mechanism.<sup>121</sup> For example, an ombudsperson might be developed within the WG group, to help specifically monitor general pharmaceutical activity on corporate accountability and A2M issues. There is some relevant precedent: The International Finance Corporation has instruments to review investments that go awry, while the UN Sanctions Committee on Al-Qaeda recently instated an ombudsperson to assess delisting requests. Informal human rights-based arguments were useful in pushing for the position on the sanctions committee, as outside groups voiced concerns over the lack of transparency.

**A2M activists could also push for greater utilization of the Access to Medicines Index** as a reporting mechanism to encourage corporate accountability. The index was developed in 2008 by the Access to Medicine Foundation, a Netherlands-based NGO, and shows which companies do the most to improve A2M and how.

### E. Insights & Action Steps

If activists see possibilities in the area of corporate accountability, they could use the WG process to create clarity on the application of the Ruggie Framework to the pharmaceutical industry, and thus contribute to an understanding of state-versus-corporate obligations. Activists might also use informal human rights arguments to promote pharmaceutical grievance accountability mechanisms such as ombudspersons, or develop reporting tools to help activists monitor corporation’s compliance with their human rights obligations.

However, none of these strategies will truly be effective unless pharmaceutical corporations agree to accept obligations placed on them by formal documents or bow to pressure exerted on them by other human rights arguments. As such, human rights language should be utilized not just in the WG, but also across UN and non-UN mechanisms, such as shadow reporting and national court cases, to help develop norms on pharmaceutical companies’ social responsibility. Furthermore, while this paper outlines areas where activist pressure may help to make human rights claims on corporations, we must be cognizant that current human rights systems may not provide the structures necessary to exert corporate change.

**We recommend further discussion among activists of the benefits and limits of formal human rights work on corporate liability, and that “informal” human rights language be invoked in campaigning to help concretize norms on pharmaceutical companies’ moral and legal obligations.**

Key Action Steps	
<i>Short Term</i>	<ul style="list-style-type: none"> <li>• Activists could engage the WG on Business &amp; Human Rights by attending their meetings (such as the Forum on Business and Human Rights) and submitting reports to promote A2M issues and push for greater pharmaceutical corporate accountability;</li> <li>• Activists and academics could work to clarify the obligations of</li> </ul>

<sup>121</sup> U.N. Human Rights Council, *Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights, including the Right to Development*, U.N. Doc. A/HRC/11/12/Add.2 (May 5, 2009), available at [http://www.who.int/medicines/areas/human\\_rights/A\\_HRC\\_11\\_12\\_Add\\_2.pdf](http://www.who.int/medicines/areas/human_rights/A_HRC_11_12_Add_2.pdf).

	<p>corporations using the WG;</p> <ul style="list-style-type: none"> <li>• Activists could use informal human rights arguments to pressure corporations to adopt codes of conduct/“good business practices” such as corporate accountability reporting tools, including indices or external ombudsperson positions. Activists should be involved in the development of accountability tools (such as the ATM Index).</li> </ul>
<i>Long Term</i>	<ul style="list-style-type: none"> <li>• Activists could utilize human rights language across court cases to push for normative interpretation of pharmaceutical corporations’ “social responsibility.”</li> </ul>



## IV. Access to Medicines Through Multilateral Alliances

**Key Insights:** Activists already utilize human rights arguments to oppose TRIPS-plus provisions in FTAs. Human rights arguments could be additionally employed at all levels by activists to help generate political will and foster solidarity for the formation of multilateral alliances. Heightened negotiating power resulting from multilateral alliances might provide developing countries with the opportunity and strength to oppose TRIPS-plus FTA provisions and stem the proliferation of IP norms that threaten access to medicines.

### A. Background on FTAs and A2M

This section examines how human rights arguments might be utilized to protect health-related rights in the context of FTAs. Activists have already begun to utilize human rights arguments at the national level in the context of bilateral and multilateral trade negotiations. The most visible efforts to date have focused on opposing existing FTA proposals. This strategy has met with some success. For example, although other factors were involved, the rejection of the U.S.-Thailand FTA was due in part to protesters and united NGO opposition whose principles drew from the right to health.<sup>122</sup>

Human rights arguments might be more extensively utilized to not only oppose existing proposals, but also frame the initial terms of the deliberations and shape resulting treaties. To achieve pro-access outcomes, this paper suggests that multilateral alliances between developing countries might provide additional leverage to counter the demands and established pro-IP norms of developed countries. (In the context of this paper, we use the term “multilateral alliances” to refer merely to alliances between more than one country – not to refer to work in the context of international organizations such as the UN.) Such multilateral alliances come in a variety of possible forms. In assessing their value, we address several key questions: (1) What form should alliances take?; (2) What impact could multilateral alliances in FTAs have on A2M?; (3) How could the right to health be utilized to develop this strategy, and what role does the right to health play in framing this strategy?

### B. The Nature of a Possible Alliance

Multilateral governmental alliances could take a variety of informal and more formal structures. Informal agreements are the most likely form of alliance. For instance, informal agreements between nations that they will not sign onto any TRIP-plus provisions in bilateral or multilateral FTAs would require less political maneuvering compared to a formal alliance, yet could have impact on FTA negotiations. Semi-formal alliances, such as a group of nations allying together in the context of a larger proposed FTA, could also prove beneficial. While more formal agreements could have more significant impacts, the political challenges of orchestrating such arrangements are prohibitive.

Multilateral alliances could also incorporate a variety of state actors. While arrangements between national leaders or FTA negotiation delegations are clearly desirable, activists should be cognizant of and pursue opportunities to ally other state actors. For example, the health ministers

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<sup>122</sup> Beatrice Lindstrom, *Scaling Back TRIPS-Plus: An Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific*, 42 INT’L L & POL. 917 (2010).

of ten South American countries issued a joint declaration in 2006 committing to take an active role in any FTA negotiations to prevent TRIPS-plus provisions.<sup>123</sup> While such alliances may have less direct impact, they are likely more politically feasible and can serve a crucial signaling function.

All alliances, informal or formal and between leaders or ministers, will require political will. Generating and fostering commitment to preventing TRIPS-plus provisions will therefore be the biggest challenge activists will face regarding this strategy. Thus, it should be noted that multilateral governmental-alliance efforts require coordinated work by NGOs and other advocacy organizations. This will depend not only upon cooperation within larger organizations that have offices in countries across the world, but between and with national-level organizations and grassroots movements.

### C. The Possible Impact of Multilateral Alliances

Developed nations, but the U.S. in particular, have recently pursued a strategy of targeted bilateral FTA negotiations with nations in key trade regions. This strategy is designed in part to enable the U.S. to negotiate IP requirements beyond those of TRIPS. To counterbalance the economic weight of countries such as the U.S., developing countries could band together in informal or formal alliances to increase their negotiating power. For example, in 2012, €31.7 billion of goods were traded between the European Union (EU) and Thailand. In contrast, the Association of Southeast Asian Nations (ASEAN) represents the EU's "third largest trading power outside Europe with annual bilateral trade...of €13 billion."<sup>124</sup> Significantly, multilateral alliances also provide windows of opportunity for increasingly powerful BRICS (Brazil, Russia, India, China, and South Africa) countries to lend support to less powerful nations.<sup>125</sup> Moreover, multilateral agreements provide openings for more developed countries to lend support to protections for lower- or middle-income countries. For example, during the last round of Trans-Pacific Partnership negotiations, New Zealand was surprisingly vocal with regard to the impact of IP provisions on A2M.

**By increasing developing countries' negotiating power, a multilateral alliance might be able to counter pressure for pro-IP provisions in a particular FTA and build pressure for provisions explicitly protecting the right to health. This process could help to redefine norms for future FTA negotiations.** A successful alliance, even an informal one, could have a broader impact by redefining norms and serving as a template for future FTA negotiations with other developing countries.

### D. The Practical and Normative Role of the Right to Health

There are five major ways that activists could utilize the right to health within the context of multilateral alliances. **First, one of the main challenges of developing multilateral alliances, particularly those that aim to counter pressure from powerful developed**

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<sup>123</sup> Martin Khor, *South American Ministers vow to avoid TRIPS-plus measures*, THIRD WORLD NETWORK, <http://www.twinside.org.sg/title2/twninfo414.htm> (last visited Apr. 23, 2013).

<sup>124</sup> *EU and Thailand launch negotiations for Free Trade Agreement*, EUROPEAN COMM'N, (Mar. 6, 2013), <http://trade.ec.europa.eu/doclib/press/index.cfm?id=875>. (last visited Apr. 23, 2013).

<sup>125</sup> See Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J. OF L. & MED. 345 (2008).



**countries, is to mobilize the political will necessary to forge alliances and oppose TRIPS-plus provisions. Human rights arguments can be employed by activists on a national basis to target all political levels.** The blueprint for this initial strategy has already been developed by NGOs that foster grassroots IP and FTA movements and oppositions, lobby governmental officials, and petition trade representatives. For example, the Third World Network (TWN) is currently employing human rights and health impacts arguments to develop popular opposition to Malaysia signing onto the Trans-Pacific Partnership.<sup>126</sup> The proposed change is that the language of human rights would now be employed more directly to generate not only national-level opposition to TRIPS-plus provisions, but also support for multilateral alliances to oppose TRIPS-plus provisions. This would work synergistically in conjunction with other strategies, such as a national court case strategy for the utilization of compulsory licenses. It is important to note, though, that some activists reported to us that developing countries tend to be reluctant to invoke human rights arguments in FTA negotiations because human rights standards—for example, in the domain of labor rights—might work against their perceived national interests or serve as disguises for protectionism.

**Second, where viable, the right to health could be utilized to generate new or reframe existing formal multilateral trade alliances that collectively negotiate multilateral FTAs that protect TRIPS flexibilities.** This formal alliance strategy would involve commitments from heads of state and cooperative work by alliance representatives. For example, the EU has recently proposed the creation of an EU-ASEAN Pharmaceutical Consultative Working Group.<sup>127</sup> In such cases, activists could also focus on utilizing human rights arguments to build solidarity on A2M issues between the designated representatives within formal alliances.

**Third, the right to health could play a role not only in generating multilateral alliances and opposing TRIPS-plus provisions, but also in framing the content and norms of FTAs to ensure access to medicines is protected.** If alliances grow out of a commitment to the right to health, then activists could mobilize to advocate for more than the current opposition of TRIPS-plus provisions. This could include shifting the starting point of any FTA discussion to one wherein TRIPS flexibilities are non-negotiable (or there is some type of ceiling on IP protection) or explicit recognition of the right to use compulsory licenses. Activists should look for opportunities to draw from existing UN reports or court cases in this area.

## **E. Insights & Action Steps**

**We recommend that activists continue to invoke human rights as a political tool to encourage south-south alliances, particularly informal ones, and to help generate leverage against regressive FTAs.** If concerted references to human rights are made, and arguments about the specific relationship between HR and particular IP provisions in question in FTAs are developed, this would also strengthen such arguments made in other forums. This approach could be particularly useful for NGOs that already have regional and multinational networks. Politically, some have suggested that a successful alliance is most likely in the Latin American or Caribbean context. However, activists should be open to other opportunities. For example, activists in ASEAN countries could push for the renewal of EU-ASEAN trade negotiations that

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<sup>126</sup> FTA MALAYSIA, <http://www.ftamalaysia.org/index.php> (last visited Apr. 23, 2013).

<sup>127</sup> Leo Kasim and Bandar Seri Begawan, *ASEAN to address pharmaceutical industry*, THE BRUNEI TIMES (Apr. 15, 2013), available at <http://www.bt.com.bn/business-national/2013/04/15/asean-address-pharmaceutical-industry>.

are founded upon human rights principles.<sup>128</sup> At this stage, however, informal alliances are likely the most feasible targets for activists to pursue.

<b>Key Action Steps</b>	
<b><i>Short Term</i></b>	<ul style="list-style-type: none"> <li>• Activists might identify countries where right to health arguments can be utilized to not only mobilize citizen opposition to TRIPS-plus provisions, but also to support the formation of A2M-protecting multilateral alliances;</li> <li>• Activists might lobby politicians, trade negotiators, international body representatives, and ministers regarding their human rights obligations to oppose TRIPS-plus provisions and form multilateral alliances.</li> </ul>
<b><i>Long Term</i></b>	<ul style="list-style-type: none"> <li>• Activists might utilize human rights as a political tool to encourage informal alliances of countries committed to protecting the right to health;</li> <li>• Where possible, existing or newly formed formal alliances of nations could utilize their heightened power to negotiate FTAs that protect TRIPS flexibilities and uphold the right to health;</li> <li>• Activists could seek to generate alternative IP and FTA norms and language recognizing health-related rights, for inclusion in FTAs.</li> </ul>

<sup>128</sup> *Overview of FTA and Other Trade Negotiations*, EUROPEAN COMM'N (Apr. 9, 2013), available at [http://trade.ec.europa.eu/doclib/docs/2006/december/tradoc\\_118238.pdf](http://trade.ec.europa.eu/doclib/docs/2006/december/tradoc_118238.pdf).

## Conclusion

<b>Key Action Steps</b>	
<b><i>Strategy I: Court Cases</i></b>	<ul style="list-style-type: none"> <li>• Activists should identify court cases in which they can intervene, as well as laws or standards they can challenge. Activists should also identify courts that may be receptive to human rights arguments;</li> <li>• Activists and academics should develop a litigation strategy that delineates how protection of the right to health necessitates reduced IP protection;</li> <li>• Activists should train judges and lawyers on the link between IP law and the right to health;</li> <li>• Activists should push other branches of government to use judicially articulated norms regarding the right to health to justify their own policy choices.</li> </ul>
<b><i>Strategy II: UN Human Rights System</i></b>	<ul style="list-style-type: none"> <li>• Activists can use the UN to exchange and export good national standards and practices, although the impact depends on states' openness and activists' use of UN statements for advocacy;</li> <li>• The major barriers are: (1) A2M activists and academics have not fully articulated the relationship between human rights standards and IP law; (2) Good national standards are insufficiently developed to provide a foundation; and (3) A2M is not a priority for human rights NGOs;</li> <li>• Activists should develop target norms and selectively participate in relevant expert consultations to express their views, as resources permit;</li> <li>• If activists want to pursue expert guidelines and shadow reporting, they should investigate whether they can generate the necessary support from human rights NGOs.</li> </ul>
<b><i>Strategy III: Corporate Responsibility</i></b>	<ul style="list-style-type: none"> <li>• Activists should consider engaging the WG on Business &amp; Human Rights to clarify the obligations of corporations under the Ruggie Framework and push for increased conversation around A2M issues;</li> <li>• Activists should continue to use human rights language in corporate campaigns, and endeavor to develop more concrete norms.</li> </ul>
<b><i>Strategy III: Multilateral Alliances</i></b>	<ul style="list-style-type: none"> <li>• Activists could seek to build informal and formal multilateral alliances among a variety of state actors to ensure unified opposition to FTA provisions that violate the right to health;</li> <li>• Activists could utilize the right to health to build multilateral alliances committed not only to oppose TRIPS-plus provisions, but also to generate pro-A2M provisions and norms.</li> </ul>

This paper has surveyed four distinct strategies for increasing access to medicines through the use of human rights law: using human rights arguments in domestic court cases, working in the UN human rights system, increasing corporate responsibility, and building multilateral opposition to TRIPS-plus FTAs. The table above sets out key conclusions and actions steps. While bringing human rights arguments into court cases dealing with access to medicines has already proven to be a useful strategy, the other three strategies would be more experimental. All four strategies require careful targeting of circumstances that will maximize feasibility and impact.

**Future advocacy campaigns should take into account the ways in which the distinct strategies surveyed in this paper relate, support, and borrow from one another.** Almost any work within the UN human rights system would produce statements or reports that could bear on domestic court cases. Domestic courts could use UN soft law, such as a favorable general comment or expert report, to bolster their human rights conclusions and reach access-improving decisions. Conversely, the norm articulation in which these courts engage is useful to activists interested in establishing similar norms within the UN. UN-produced soft law is also useful in the negotiation of multilateral alliances and could serve as a rallying tool to create such networks. The norm articulation that occurs in domestic court cases can also serve this role. The human rights-based reasoning of domestic court cases could inspire and motivate the legislative and executive branches of low- and middle-income countries to re-think their IP policies and form alliances around the right to health that are needed to enforce access-oriented policies in the face of pressures from the developed world. Finally, UN soft law, access-improving court decisions, and growing multilateral alliances around the right to health bring attention to the topic and place pressure on pharmaceutical firms. Although human rights language may not directly increase corporate responsibility, the outcomes human rights arguments help produce, both at a national and international level, may help bring firms to the negotiating table in the interest of protecting their own reputations. **In sum, these strategies should not be viewed in isolation: each strategy draws strength from and bolsters the others.**

As an illustration of the linkages among human rights institutions and strategies, consider a hypothetical advocacy campaign built around the Colombia Kaletra case.<sup>129</sup> In addition to using human rights arguments in the case itself, prior to the case, activists could have pushed for expert guidelines on when countries have to issue compulsory licenses in the interest of public health. If such a framework had existed, it might have influenced the court to require a compulsory license. Since the court did not do this, activists might consider several options for following up. They could issue a shadow report for Colombia's next treaty body reviews, recommending that the bodies express concern about the health impact of the failure to issue a compulsory license. Within six months of the court's decision, the plaintiffs could have petitioned the Inter-American Commission to review the case in either its adjudicative function or its investigative and reporting function. Both options merit further research.<sup>130</sup> Positive results from the inter-American system could contribute to establishing norms in the UN or domestic courts, especially in Latin America, where the Inter-American Court's decisions are legally

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<sup>129</sup> See *supra* Part I.

<sup>130</sup> In the adjudicative mode, the Commission and Court's complicated jurisprudence dealing with economic, social, and cultural rights would require particular attention to evaluate the admissibility and potential results of a case under the right to health. It would also be important to consider the fact that the adjudicative mode only permits consideration of individualized harms, while the investigative mode permits consideration of generalized harms that affect broad sectors of society, which might be more appropriate to IP issues.

binding and even the commission's investigations have had real impact on national human rights practices. Finally, to preserve Colombia's ability to issue compulsory licenses in the future, a multilateral alliance committed to the right to health might be able to help Colombia resist FTAs that restrict compulsory licensing. Thus, different human rights-based strategies can not only bolster one another by their successes, but also compensate for each other's failures.

We conclude that human rights-based strategies are not a panacea for dealing with A2M problems, but they can make a true difference if A2M activists apply each of the strategies analyzed in this paper in a targeted way and build advocacy campaigns that take advantage of the potential linkages among strategies. Such advocacy will require coordination among A2M activists and efforts to build coalitions with human rights groups.

## Appendix A: Domestic Court Cases

*These cases are listed in chronological order. All translation work was performed by the authors.*

1. **Chile Case, Chile, Tribunal Constitucional [T.C.] [Constitutional Court], March 22, 2013, Rol de la causa: 2.411-13-CPT.** (This case was translated by the authors. This case and accompanying filings are available at <http://www.tribunalconstitucional.cl/wp/expedientes?rol=2411>.)

<b>Topic</b>	<b>The validity of a proposed preliminary injunction law</b>
<i>Summary of Case</i>	On March 5, 2013, the Chilean Constitutional Court reviewed the constitutionality of the patent linkage bill that is currently being debated in the Chilean Congress. A group of senators brought the opposition to this bill. This bill enables pharmaceutical patent holders to obtain a preliminary injunction on active ingredient patent without a merit-based examination. This law would create a special exemption for pharmaceutical patent holders from the general rule on preliminary injunctions in Chile. Under the general or normal rule, Chilean courts only grant preliminary injunctions based on the merits of the case—when the court determines that the party has a “substantial likelihood of success on the merits of the case and faces a substantial threat of <i>irreparable damage or injury</i> if the injunction is not granted.” <sup>131</sup> The new bill enables civil judges to grant preliminary injunctions in favor of active ingredient patent-holders without looking at the merits of the injunction suit. Instead, the judge is permitted to grant the preliminary injunction if the patent-holder can produce sufficient evidence that the patent was filed. Crucially, pharmaceutical patent-holders are the only type of patent-holders eligible for these non-merit based preliminary injunctions.
<i>General Issue &amp; Decision</i>	Is this patent linkage bill constitutional? The constitutionality of the bill is not yet ripe for decision on the merits.
<i>Relevant Human Rights Issues &amp; Decision</i>	The group of senators that brought this opposition argued that the patent argued that the bill was unconstitutional, in part, because it violated the right to health, as protected by Article 19 of the Chilean Constitution. The court ultimately stated that these right to health arguments were merit-based and therefore not ripe for decision because the bill has not yet passed into law.
<i>Relevant Language</i>	<p><b>Language of the Court:</b></p> <p>In response to the right to health arguments, the court first recognized that these arguments were, at their core, an objection to the bill on its merits and therefore not ripe for decision because the bill has not yet passed.</p> <p>The court then went on to state that the bill’s effect on health is not a special</p>

<sup>131</sup> Chilean Constitutional Court to decide on the constitutionality of the patent linkage bill, Infojustice.org (Mar. 7, 2013), <http://infojustice.org/archives/28883>.

	<p>feature of the bill itself, but rather a natural consequence of the right to intellectual property that patents entail. The court also noted that this right flows from Chile’s obligations as a WTO member and a TRIPS signatory. Thus, the court was skeptical of the right to health arguments, even though it did not rule on them.</p> <p><b>Brief of the Plaintiffs:</b></p> <p>“This bill] would be an unjustifiable limit, unreasonable, disproportionate and constitutionally intolerable to access to health and to the right to enjoy goods necessary to obtain the highest standards of health, as pharmaceutical medications are.”</p> <p>“If we do not approve [the preliminary injunction law], will medical innovators in Chile cease to exist? Absolutely not. Once more is it worth pointing that the group that will benefit from this law are not small and medium sized business but rather huge multinational pharmaceutical corporations.”</p>
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**2. Sankalp Rehabilitation Trust v. F. Hoffmann-LA Roche AG, India, Intellectual Property Appellate Board, Nov. 2, 2012.**

<b>Topic</b>	<b>Standing in patent oppositions</b>
<i>Summary of Case</i>	A generic drug manufacturer and a non-profit organization “working for the benefit of drug users” filed two post-grant patent oppositions on a Hepatitis-C medication. After the Indian Patent Opposition Board rejected both of these oppositions, the non-profit organization appealed. The non-profit organization claimed that the invention was obvious in light of the prior art.
<i>General Issues &amp; Decision</i>	<ol style="list-style-type: none"> <li>1. Did the non-profit organization demonstrate the requisite standing? The non-profit organization has standing to bring the patent opposition.</li> <li>2. Was the invention obvious in light of the prior art? The court held that the invention was obvious and, therefore, the patent was invalid.</li> </ol>
<i>Relevant Human Rights Issues &amp; Decision</i>	<ol style="list-style-type: none"> <li>1. Was the non-profit organization an interested organization due sufficient to demonstrate the requisite standing? The non-profit organization has standing to bring the patent opposition because it works for and represents the interests of the community of HCV and HIV sufferers in Thailand.</li> </ol>
<i>Relevant Language</i>	“The continuance of an unworthy patent on the Register is not only against the interest of other persons carrying on the same business but also against the public interest. For the protection of valid patents, we have no doubt to prevent the busybodies and unnecessary interferences. But, it is as much against the public interest to allow unworthy patents to be on the Register, as it is to prevent third parties having no interest from attacking a deserving patent. While liberally construing the words ‘person interested’, we could balance the cause of justice by

	<p>awarding exemplary costs against an opponent who really has no interest in the grant of patent. The interest should not be a fanciful interest. We must take a common sense approach to construe the interest that the opponent has in opposing the grant of a patent. In the present case, the appellant claims that it is a society which works for the community of HCV and HIV sufferers. This is not challenged. The invention is admittedly for the use in the case of hepatitis-C. The continuance or removal of the patent will definitely affect the interest of the community for whom the appellant claims to work. The appellant has challenged the patent on several grounds, if the challenge succeeds, the monopoly will be broken. This is something that the appellant is interested in, since it will bring the drug within the reach of the community for whom it works, not only because of reduction in cost, but also because of increase in supply. When the Act includes” a person doing research” in the definition of person interested, an interest which is an academic one and not necessarily commercial, and when the Act only uses the word “includes” which is a word which is not restrictive, we may correctly apply the Ajay Industrial case and the Thailand Court case. If the law intended that there should be a presumption of validity, it will state it explicitly. We cannot read it in, that would amount to “legislating.” Further public interest is a persistent presence in intellectual property law and will not melt into thin air, nor dissolve. We therefore hold that the appellant who works for a community which needs the medicine is definitely a ‘person interested’ The locus standi objection is rejected.”</p>
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2. ***Asociación Red Colombiana de Personas Conviviendo y Viviendo con el VIH y el SIDA, REOLVIH, y Otros v. Ministerio de Salud y Protección Social, Colombia, Tribunal Administrativo de Cundinamarca [Administrative Court of Cundinamarca], Appeal from the sentence of the lower court, Feb. 29, 2012.*** (This case was translated by the author. For more information on this case, please contact Peter Mayburduk at Public Citizen.)

<b>Topic</b>	<b>Compulsory licensing and price controls</b>
<i>Summary of Case</i>	The plaintiffs, NGOs, and HIV-positive patients asked the Colombian Administrative Court to command the Colombian government to issue a compulsory license on Abbott’s HIV drug Kaletra.
<i>Issues</i>	Must Colombia issue a compulsory license on Kaletra?
<i>Decision</i>	Although the court declined to force the Colombian government to issue a compulsory license, court ruled that the government must enforce its price controls on Kaletra. The court also ruled that if Abbott failed to respect Colombia’s price controls, the government must commence parallel importation of the drug.
<i>Relevant Language</i>	“[T]he fact that the savings in the price of this type of product is not directly represented in the economy of the patients that need the medications and that they obtain through [the Colombian Social Security System], but rather in the balance of the other needs of the system . . . does not mean that these savings loose importance . . . [T]his savings does not translate into a benefit for individuals in



	<p>particular, but rather for the healthcare system as a whole.</p> <p>Furthermore, it should be remembered that the social security system constitutes an essential and obligatory public service, that conforms [the rights] established by Article 48 and 49 of the Political Constitution, [which establish that the social security system] should be provided and guaranteed by the state in all of its stages under conditions of efficiency, universality, and solidarity.</p> <p>Additionally, the right to health has been elevated as a fundamental condition given its connection with the right to life, which is inviolable from all point[s] of view.</p> <p>The State must safeguard these rights so that people can obtain the services they are owed, the protection and recovery of health, in dignified and efficacious conditions.”</p>
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**3. *Cipla Medpro (PTY) Ltd. v. Aventis Pharma SA, South Africa, The Supreme Court of Appeal of South Africa, July 26, 2012.***

<b>Topic</b>	<b>Preliminary injunctions in patent oppositions</b>
<i>Summary of Case</i>	The pharmaceutical corporation Aventis sued Indian generic drug manufacturer Cipla for infringing the former’s patent on its cancer drug Taxotere. Aventis sought a preliminary injunction that would restrain Cipla from manufacturing, offering for sale, selling, and exporting the cancer drug. “Upon proof of a well grounded apprehension of irreparable harm,” South African courts will issue a preliminary injunction to a patent holder if his prospects of success in the action and the “balance of convenience if an interdict were to be granted” weigh in his favor. Shortly after Aventis initiated this suit, it began to offer a low-cost, “generic” version of the patented medication at issue. The Treatment Access Campaign (TAC) joined this case as <i>amicus curiae</i> .
<i>Issues</i>	Should the court grant Aventis a preliminary injunction?
<i>Decision</i>	<p>Yes. Because Aventis offers a low cost, “generic” version of its patented medication, Taxotere, the grant of a preliminary injunction would not endanger public interest. “[T]he only implication for health care of granting an [injunction] is that patients who receive private health care, and who are not able to recover the cost of treatment from a private medical fund, will be obliged to pay 10% more for treatment than they might have done had Cipla’s product remained on the market. Neither Cipla nor the TAC has identified any other prejudice that might be suffered by the public.”</p> <p>However, courts must take the public interest into account as part of the balance of convenience test when deciding whether to grant a preliminary injunction.</p>
<i>Relevant</i>	<p><b>TAC’s Briefing:</b></p> <p>“12. Because section 45(1) of the Patents Act creates exclusive rights, which are</p>

<p><i>Language</i></p>	<p>exceptional, it must be justified.<sup>11</sup> The exclusive rights are very powerful indeed, entitling the holder to an extended monopoly. The statutory monopoly that is granted to a patentee has been held by this Court to be a “means of encouraging inventors to put their inventions into practice because by this means they obtain the financial rewards their inventive gifts warrant”.<sup>12</sup> However, the Court also noted that “an essential quid pro quo of the theory” is that the “benefit to the public ... is served.”<sup>13</sup> The broad purpose of the patent system has also been described extra-curially by Cameron J, writing with Berger, as being intended to “pursue innovation and subsequent commercialization” in the public interest.<sup>14</sup> Indeed, the authors describe a patent as a ‘liberty-infringing privilege’.</p> <p>13. While the purposes served by patent protection are legitimate public purposes, the Patents Act must be interpreted and applied to ensure the public interest in patent protection is in fact served and ensuring other rights are not unreasonably limited thereby. In the case of medicines, section 27 is implicated because a medicine may be unavailable or because it may be unaffordable, often as a result of the patent.</p> <p>14. Various provisions of the Patents Act are designed to ensure that the rights of patent holders are not exercised unreasonably to preclude access to knowledge and products. While mindful that this Court cannot prejudge the constitutional validity of its provisions, at a general level, mechanisms to dispute the validity of a patent are crucial to protecting rights such as section 27 rights.</p> <p>15. The respondents’ defen[s]e of lack of clarity<sup>15</sup> protects not only patentees and competitors but the public generally. The test is whether a patent is reasonably certain. Arguably the test ought to be stricter under the Constitution, but crucially, when applying the test courts must be astute to ensure that the public purposes of the section are advanced. Commercially of course, potential competitors need to know the limits of the field that is closed to them. The public purposes might be viewed as two-fold. First, part of the quid pro quo represented by the patent is that knowledge about innovation is placed in the public realm so as to advance further innovation and to enable the invention to be worked by competitors in due course. So the patentee must meet its part of the bargain. Secondly, the lodgment of ambiguous claims can confuse competitors and deter the bringing of products to market and thus compromise access. It can also encourage overzealous attempts at their enforcement, which can also limit access especially when interim relief is sought and granted.”</p> <p><b>The Decision:</b></p> <p>“[44] The TAC founded its objections upon s 27(1) of the Constitution, which guarantees to everyone the right to have access to health care services, which, it has been said, includes a right to have access to affordable medicines. In its heads of argument the TAC submitted that the Patents Act must be construed ‘through the prism of the Constitution’ and in a way that appropriately balances the rights of a patentee against the constitutional rights of others, and that it ‘must be interpreted and applied to ensure the public interest in patent protection is in fact</p>
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	<p>served and ensuring other rights are not unreasonably limited thereby’.</p> <p>[45] What we are to make of viewing the legislation through the prism of the Constitution was not developed by the TAC. Section 39(2) indeed calls upon a court to ‘promote the spirit, purport and objects of the Bill of Rights’ when interpreting legislation, as pointed out by the TAC, but that does not open the door to changing the clear meaning of a statute. If the clear meaning conflicts with the Bill of Rights then the remedy is to strike it down, but there has been no challenge to the constitutional validity of any of the provisions of the Act that are now material. There is also no suggestion that the meaning of those provisions is not clear. The disputes centre instead on the application of those provisions to the facts of this case. On the assumption that the patent is not revocable for want of an inventive step I cannot see how s 39(2) or the prism of the Constitution comes into play so as to deny Aventis its right to enforce its patent.</p> <p>[46] The TAC is on stronger ground when it advances factors to be taken account of when weighing the balance of convenience. In that respect it submitted that the broader public interest, and not only the interests of the litigating parties, must be placed in the scales when weighing where the balance of convenience lies. Apart from decisions to that effect in this country, 33 we were referred to cases in other jurisdictions, particularly the United States, where injunctions against infringement have been refused on that ground.”</p>
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4. *Novartis Pharma AG v. Monte Verde SA, Argentina, Cámara Federal de Apelaciones [Federal Jan. 2, 2011, Causa No. 5.619/05.* (This case was translated by the author.)

<i>Topic</i>	<b>Data exclusivity laws</b>
<i>Summary of Case</i>	Novartis sued Monteverde, an Argentinean generic manufacturer over the latter’s use of clinical trial data Novartis had produced. Novartis produced this data in order to gain regulatory approval for its drug, Gleevec, in the United States and Europe. Novartis argued that Argentina must afford the company an exclusive right to the data in order fulfill its TRIPS obligations.
<i>Issues</i>	Must Argentina afford Novartis exclusive rights in its data in order to comply with its TRIPS obligations?
<i>Decision</i>	Argentina’s current IP laws are TRIPS compliant. Argentina does not need to provide Novartis with exclusive rights in its data to fulfill its TRIPS obligations.
<i>Relevant Language</i>	“Public access to medicines constitutes an aspect of the right to health that the State should regulate, making sure to avoid conflicts or dualisms with the intellectual property rights that the TRIPS agreement protects. Strictly imposing the demand that every company conduct their own tests on active ingredients and then seek authorization for them would negate this obligation. The lack of medications that this [data exclusivity] obligation would cause is a serious obstacle to the right [to health], above all else, in countries that have adopted policies of

[using] generics in the health environments.”
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**5. Patricia Asero Ochieng, Maurine Atieno, Joseph Munyi, & AIDS Law Project v. Attorney General, Kenya, High Court of Kenya, 2009, Petition No. 409.**

<b>Topic</b>	<b>The validity of an anti-counterfeiting law</b>
<i>Summary of Case</i>	The plaintiffs, three HIV-positive patients, challenged an anti-counterfeiting law that would have likely prohibited the sale of generics. UN Special Rapporteur for Health Anand Grover also joined this case as an Interested Party. The plaintiffs and the special rapporteur relied on the human right to equality, life, and health, as articulated in both the Kenyan Constitution as well as various international human rights treaties, to argue that the Anti-Counterfeit Act was unconstitutional and contrary to Kenya’s international treaty obligations.
<i>Issues</i>	Does the Kenyan Anti-Counterfeiting Act violate the Kenyan Constitution and Kenya’s international obligations?
<i>Decision</i>	Kenya’s Anti-Counterfeiting Act is unconstitutional and incompatible with Kenya’s international obligations.
<i>Relevant Language</i>	<p>“52. [Any law that] would have the effect of limiting access, . . . would ipso facto threaten the lives and health of the petitioners and others infected with HIV and [AIDS], and would be in violation of their rights under the Constitution. The state’s obligation with regard to the right to health [] encompasses not only the positive duty to ensure that its citizens have access to health care services and medication but must also encompass the negative duty not to do anything that would in any way affect access to such health care services and essential medicines. Any legislation that would render the cost of essential drugs unaffordable to citizens would thus be in violation of the state’s obligations under the Constitution.</p> <p>53. I take this view because, from the pleadings and submissions before me, while the petitioners, Interested Party and the Amicus on one hand and the respondents on the other have taken diametrically opposed positions on this petition, they are in agreement that the petitioners have certain rights which are guaranteed under the Constitution and by international law. The petitioners, as citizens of Kenya, have the right to life guaranteed under Article 26(1); they have the right to human dignity provided for under Article 28; they also have the right to the highest attainable standard of health guaranteed under Article 43(1) of the Constitution.</p> <p>54. I have also not heard the respondents to dispute the right of children such as the 2nd petitioner’s son to the highest attainable standard of health provided for under Article 53(1)c) or to deny that the best interests of the child should be the primary consideration in all matters involving children.</p> <p>55. The rights which the petitioners see as likely to be violated by the</p>

implementation of the Act are guaranteed under the Constitution of Kenya and under international law. The parties have referred the court to various decisions in which the High Court has applied international law and urged the court to be guided by those decisions. However, Article 2 of the Constitution now makes it clear that all international treaties to which Kenya is a party are now part of the laws of Kenya. I am therefore bound by the Constitution to have regard to these treaties.

56. In my view, the right to health, life and human dignity are inextricably bound. There can be no argument that without health, the right to life is in jeopardy, and where one has an illness that is as debilitating as HIV/AIDS is now generally recogni[z]ed as being, one's inherent dignity as a human being with the sense of self worth and ability to take care of oneself is compromised. What may not be agreed upon by the parties is the meaning and implication of the right to health, and the nature and implication of the positive obligation that recognition of this right in the Constitution and international treaties places on the state."

"83. The Anti-Counterfeit Act has, in my view, priority[z]ed enforcement of intellectual property rights in dealing with the problem of counterfeit medicine. It has not taken an approach focused on quality and standards which would achieve what the respondents have submitted is the purpose behind the Act: the protection of the petitioners in particular and the general public from substandard medicine. Protection of consumers may have been a collateral issue in the minds of the drafters of the Act. This is why for instance, the rights of consumers of generic medicine are alluded to in the proviso to Section 2 of the Act.

84. However, the right to life, dignity and health of people like the petitioners who are infected with the HIV virus cannot be secured by a vague proviso in a situation where those charged with the responsibility of enforcement of the law may not have a clear understanding of the difference between generic and counterfeit medicine. The primary concern of the respondent should be the interests of the petitioners and others infected with HIV/AIDS to whom it owes the duty to ensure access to appropriate health care and essential medicines. It would be in violation of the state's obligations to the petitioners with respect to their right to life and health to have included in legislation ambiguous provisions subject to the interpretation of intellectual property holders and customs officials when such provisions relate to access to medicines essential for the petitioners' survival. There can be no room for ambiguity where the right to health and life of the petitioners and the many other Kenyans who are affected by HIV/AIDS are at stake.

85. Further, contrary to the respondents' counsel's assertion, the Anti-Counterfeit Act, being later in time, would prevail over the Industrial Property Act in the event of a conflict, and the proviso to Section 2 may not be of much help to the petitioners. Should the Act be implemented as it is, the danger that it poses to the right of the petitioners to access essential medicine which they require on a daily basis in order to sustain life is far greater and more critical than the protection of the intellectual property rights that the Act seeks to protect. The right to life, dignity and health of the petitioners must take precedence over the intellectual

	<p>property rights of patent holders.</p> <p>86. While such intellectual property rights should be protected, where there is the likelihood, as in this case, that their protection will put in jeopardy fundamental rights such as the right to life of others, I take the view that they must give way to the fundamental rights of citizens in the position of the petitioners.”</p>
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**6. F. Hoffmann-LA Roche AG v. Cipla Ltd., India, High Court of Delhi, Mar. 19, 2008.**

<b>Topic</b>	<b>Preliminary injunctions in patent oppositions</b>
<i>Summary of Case</i>	The pharmaceutical corporation Roche Hoffman sued Indian generic drug manufacturer Cipla for infringing the former’s patent on its cancer drug Erlotinib. Roche sought a preliminary injunction that would restrain Cipla from manufacturing, offering for sale, selling, and exporting the cancer drug.
<i>Issues</i>	Should the court grant Roche a preliminary injunction?
<i>Decision</i>	No. “[T]his Court is of the opinion that as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life saving drug, the balance has to be tilted in favour of the latter.”
<i>Relevant Language</i>	<p>“If the defendant is restrained from manufacturing and marketing their anti-cancer drug in the market it would cause great prejudice to public health and public interest and create a grave public health crisis with disastrous consequences. In such cases, where the balance of convenience is heavily tilted towards the defendant an injunction ought not to be granted due to the overwhelming interest of society.”</p> <p>“Undoubtedly, India entered into the TRIPS regime, and amended her laws to fulfill her international obligations, yet the court has to proceed and apply the laws of this country, which oblige it to weigh all relevant factors. In this background the Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if [an] injunction were granted. Such injuries to third parties are un-[compensable]. Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 [which protect the right to life and personal liberty] so far as those would have or could have access to Erloticip are concerned. It is precisely this consideration that was emphasized as a relevant and significant factor in American Cyanamid and Roussel Uclaf. Even the United States Supreme Court was not unmindful of such considerations when recently it disavowed the liberal practice, of granting injunctions, and underlining the necessity of weighing</p>

	<p>relevant factors, including public interest, in eBay (Supra). In another decision, Cordis Corporation v. Boston Scientific Corporation 2004 US App. LEXIS 11557, the US Court of Appeals for Federal Circuit affirmed the refusal to enjoin the defendant, in a patent infringement action where the product was a drug-eluting stent. The court held that such injunction would inhibit a broad choice of availability of such stents. The court compared the public interest in protection of the patentee’s right with the broader public interest in availability of the product, and held: ‘While crediting the validity of this point, this court also acknowledges that it cannot control in every case, without obliterating the public interest component of the preliminary injunction inquiry. Thus, for good reason, the courts have refused to permanently enjoin activities that would injure the public health.’ (Emphasis supplied)”</p>
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7. *Azanca Alhelí Meza García v. Ministry of Health, Peru, Tribunal Constitutional [T.C.] [Constitutional Court], April 20, 2004.* (Translated by the author).

<i>Topic</i>	<b>Standing in patent oppositions</b>
<i>Summary of Case</i>	An HIV-positive patient of low economic resources request access to free antiretroviral treatment from the state through an <i>amparo</i> action—a protective order from the court.
<i>General Issue &amp; Decision</i>	Was the plaintiff entitled to free antiretroviral treatment provided through the state? Yes, the plaintiff was entitled to treatment under the Constitution and laws of Peru.
<i>Relevant Human Rights Issues &amp; IP Issues</i>	Even though it was not asked to do so, the Court discussed the TRIPS agreement and the Doha Declaration and the effect of those agreements on the State’s ability to set its own public health policies.
<i>Relevant Language</i>	<p><b>“About the legal aspects related to the TRIPS agreement and public health in developing countries”</b></p> <p>40. “Even though this theme is not directly derived from the petition at issue in the complaint, this Tribunal considers it to be advisable to pronounce some aspects related to the rights of intellectual property recognized in international agreements; like the exceptions that are established and recognized formally in diverse international documents in the setting of the WTO, of which Peru has been a member since 1995.”</p> <p>“In effect, when they inform some difficulty in the fulfillment of the national objectives related to public health, with the following affectation of the right itself and the life of the citizens – specifically in the cases related to sickness like HIV/AIDS, tuberculosis, malaria, and other epidemics, they have established, through the DOHA declaration of Nov. 14, 2001 on the TRIPS Agreement and Public Health, that even if the protection of intellectual property is important for the development of new medications, the concern regarding the effect of intellectual property rights on</p>

	<p>medicines cannot be left to one side. The agreement about the protection of intellectual property does not signify an obstruction to the member country to take measures to protect public health and, particularly, the promotion of medication for all.”</p> <p>41. “In this sense, given the difficulties involved in the provision of essential medicines for the treatment of sicknesses like HIV/AIDS, it is recommendable that the State of Peru, through its policy on health concerning the prevention and protection against AIDS, and as a subject of rights and obligations as a member of the WTO, utilize the maximum of provisions and measures that allow for a flexible interpretation of the agreement on the protection of intellectual property that are clearly inside of the established margins of the DOHA agreement, which permits the accomplishment of their objectives in health policy.”</p> <p>42. “It is important to remember, then, that in the frame of the Doha Declaration, that they agree that the member countries that are less advanced – as is our country – are not obligated, with respect to pharmaceutical products, to implement or apply Sections 5 or 7 (referring to the topic of patents) of Part II of the Agreement on Trade-related aspects of Intellectual Property Rights, nor to respect the rights forecasted in these sections until Jan. 1, 2016, without prejudice in new extensions.”</p>
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**8. *AIDS Access Foundation, Mrs. Wanida C, & Mr. Hurn R. v. Bristol-Myers Squibb & the Department of Intellectual Property, Thailand, The Central Intellectual Property and International Trade Court, Oct. 1, 2002.***

<i>Topic</i>	<b>Standing in patent oppositions</b>
<i>Summary of Case</i>	Two HIV-positive patients and the Thai AIDS Access Foundation challenged a Bristol-Myer Squibb patent on a “better formula for oral use of Dydeoxy Purine Nucleocide,” better known as “DDI.” Although Bristol-Myer Squibb’s original patent application only claimed a fixed dosage of the medication at issue, this fixed dosage language was later deleted so that the patent covered all dosage formulations. The plaintiffs argued that the Thai Department of Intellectual Property conspired with the defendant to delete the fixed dosage language and that such an action amounted an “illegal amendment to the Inventive Patent in material sense.”
<i>General Issue &amp; Decision</i>	<p>1. Did the plaintiffs demonstrate the requisite standing? The plaintiffs have standing to bring the patent opposition.</p> <p>2. Was the patent invalid? The court reinstated the fixed dosage language.</p>
<i>Relevant Human Rights Issues &amp; Decision</i>	Was the non-profit organization an interested party sufficient to demonstrate the requisite standing? [Yes.]



<i>Relevant Language</i>	<p>“Since the medicine is one of the fundamental factors necessary for human being, as distinct from other products or other invention[s] that the consumers may or may not choose for consumption. The treatment of life and health of the human is of the most important than any other property. This was recognized internationally...[at Doha]...in which it was confirmed of the importance of the Treaty on the Rights on Intellectual Property (TRIPS) in relation to public health. It was insisted that the TRIPS be interpreted and implemented so as to promote the rights of the members to protect the countries’ public health, especially, the promotion and support of the access to medicine of the people as a whole. Therefore, the injured parties from the grant of Patent are not limited to the manufacturers or the sellers of medicine protected by the Patent. The patients or those in need of the medicine are also interested parties to the grant of the Patent. Even though the Plaintiffs No. 2 and No. 3 have never had [a] legal relationship with the Defendant, and are not the manufacturer of [a] medicine not are they [a] business competitor of the Defendant, they are patients of a disease that requires treatment from the medicine protected by the Defendant’s Patent. The Plaintiffs No. 2 and No. 3 are therefore the direct interested parties.”</p>
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## Appendix B: Relevant International Human Rights Documents

### 1. Declarations

<b><i>Title</i></b>	<b>Universal Declaration of Human Rights (UDHR)</b>
<i>Relevant Language</i>	Article 25(1) states that “[e]veryone has a right to a standard of living adequate for the health and well-being of himself and of his family, including . . . medical care.” This is a non-binding declaration by all members of the United Nations, rather than a binding treaty. Available at: <a href="http://daccess-dds-ny.un.org/doc/RESOLUTION/GEN/NR0/043/88/IMG/NR004388.pdf">http://daccess-dds-ny.un.org/doc/RESOLUTION/GEN/NR0/043/88/IMG/NR004388.pdf</a>

### 2. Treaties

<b><i>Title</i></b>	<b>International Covenant on Economic, Social, and Cultural Rights (ICESCR)</b>
<i>Summary</i>	Recognizes the right to the “highest attainable standard of physical and mental health” (Article 12) and the right “to enjoy the benefits of scientific progress” (Article 15), but it also recognizes creators’ rights (Article 15). This is a binding treaty to which most countries are parties, including most developing countries and all European countries, but not the United States and South Africa. However, the force of the treaty is weakened by the allowance for progressive realization of rights (Article 2) and the lack of sanctions for violation. Available at: <a href="http://www.ohchr.org/Documents/ProfessionalInterest/cescr.pdf">http://www.ohchr.org/Documents/ProfessionalInterest/cescr.pdf</a>
<b><i>Title</i></b>	<b>Convention on the Rights of the Child (CRC)</b>
<i>Summary</i>	Recognizes the child’s right to the highest attainable standard of health (Article 24) but permits progressive realization of that right. Almost every UN member state is a party to the treaty, but the United States is not. Available at: <a href="http://www.ohchr.org/Documents/ProfessionalInterest/crc.pdf">http://www.ohchr.org/Documents/ProfessionalInterest/crc.pdf</a>
<b><i>Title</i></b>	<b>Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)</b>
<i>Summary</i>	Article 12, declares that “States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.” Almost all UN member states have ratified, except the United States. Available at: <a href="http://www.ohchr.org/Documents/ProfessionalInterest/cedaw.pdf">http://www.ohchr.org/Documents/ProfessionalInterest/cedaw.pdf</a>
<b><i>Title</i></b>	<b>Convention on the Rights of Persons with Disabilities (CRPD)</b>
<i>Summary</i>	Recognizes “the right to the highest attainable standard of health without discrimination on the basis of disability” (Article 25). Available at:

	<a href="http://www.un.org/disabilities/documents/convention/convoptprot-e.pdf">http://www.un.org/disabilities/documents/convention/convoptprot-e.pdf</a>
<b>Title</b>	<b>International Covenant on Civil and Political Rights (ICCPR)</b>
<b>Summary</b>	Recognizes an individual's "inherent right to life" in Article 6. The majority of states, including the United States, are parties. Available at: <a href="http://www.ohchr.org/Documents/ProfessionalInterest/ccpr.pdf">http://www.ohchr.org/Documents/ProfessionalInterest/ccpr.pdf</a>

### 3. General Comments by Treaty Bodies

<b>Title</b>	<b>CESCR General Comment 14 on the right to health (2000)</b>
<b>Summary</b>	The provision of essential medicines is a core obligation under the right to health. States parties to the ICESCR must "adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization," and any retrogressive measures violate the right. States must also "respect the enjoyment of the right to health in other countries." Available at: <a href="http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G00/439/34/PDF/G0043934.pdf">http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G00/439/34/PDF/G0043934.pdf</a>
<b>Title</b>	<b>CESCR General Comment 17 on author's rights (2005)</b>
<b>Summary</b>	States that the right to protection of creations is a human right that derives from the inherent dignity of all persons. However, an author's right to benefit from his work does not necessarily coincide with national or international agreements as to intellectual property rights, which primarily protect business interests. Available at: <a href="http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G06/400/60/PDF/G0640060.pdf">http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G06/400/60/PDF/G0640060.pdf</a>
<b>Title</b>	<b>CRC General Comment 3 on HIV/AIDS (2003)</b>
<b>Summary</b>	Holds that states must ensure that "children have sustained and equal access to comprehensive treatment." Available at: <a href="http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G03/408/16/PDF/G0340816.pdf">http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G03/408/16/PDF/G0340816.pdf</a>
<b>Title</b>	<b>HRC General Comment 6 on the right to life (1982)</b>
<b>Summary</b>	Interprets that right to mean that states parties to the ICCPR should take "all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics." Available at: <a href="http://www.unhchr.ch/tbs/doc.nsf/%28Symbol%29/84ab9690ccd81fc7c12563ed0046fae3">http://www.unhchr.ch/tbs/doc.nsf/%28Symbol%29/84ab9690ccd81fc7c12563ed0046fae3</a>

### 4. Human Rights Council Resolutions (formerly the Human Rights Commission)

<b><i>Title</i></b>	<b>E/CN.4/RES/2001/33 (Access to medication in the context of pandemics such as HIV/AIDS, 2001)</b>
<b><i>Summary</i></b>	Recognizes access to essential medicines as a fundamental component of the right to health and calls upon states to pursue policies to promote the availability and accessibility of pharmaceuticals for all, as well as to take account of the right health in their actions as members of international organizations. Available at: <a href="http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2001-33.doc">http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2001-33.doc</a>
<b><i>Title</i></b>	<b>E/CN.4/RES/2002/31 (The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, 2002)</b>
<b><i>Summary</i></b>	Created the mandate for a special rapporteur on the right to health. Available at: <a href="http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2002-31.doc">http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2002-31.doc</a>
<b><i>Title</i></b>	<b>E/CN.4/RES/2002/32 (Access to medication in the context of pandemics such as HIV/AIDS, 2002)</b>
<b><i>Summary</i></b>	Similar to the 2001 resolution of the same name but also notes the importance of the Doha Declaration. Available at: <a href="http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2002-32.doc">http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2002-32.doc</a>
<b><i>Title</i></b>	<b>E/CN.4/RES/2005/23 (Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria, 2005)</b>
<b><i>Summary</i></b>	“Calls upon States to conduct an impact assessment of the effects of international trade agreements” on the right to health. Available at: <a href="http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2005-23.doc">http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2005-23.doc</a>
<b><i>Title</i></b>	<b>A/HRC/RES/12/24 (Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, 2009)</b>
<b><i>Summary</i></b>	Recognizes access to essential medicines as a fundamental component of the right to health and states’ right to use TRIPS flexibilities but also recognizes that IP protection is important for development of new medicines. It invites an expert consultation on human rights considerations related to access to medicines. Available at: <a href="http://daccess-ods.un.org/access.nsf/Get?Open&amp;DS=A/HRC/RES/12/24&amp;Lang=E">http://daccess-ods.un.org/access.nsf/Get?Open&amp;DS=A/HRC/RES/12/24&amp;Lang=E</a>
<b><i>Title</i></b>	<b>A/HRC/RES/12/27 (The protection of human rights in the context of HIV and AIDS, 2009)</b>
<b><i>Summary</i></b>	Reaffirms that TRIPS should be interpreted to promote production of generic HIV/AIDS drugs. Available at: <a href="http://www2.ohchr.org/english/issues/hiv/docs/A-HRC-RES-12-27.pdf">http://www2.ohchr.org/english/issues/hiv/docs/A-HRC-RES-12-27.pdf</a>

<i>Title</i>	<b>A/HRC/RES/17/14 (The right of everyone to the enjoyment of the highest attainable standard of physical and mental health in the context of development and access to medicines, 2011)</b>
<i>Summary</i>	Contains similar content to the 2009 resolution 12/24 and then invites the special rapporteur to prepare a report on “existing challenges with regard to access to medicines.” Available at: <a href="http://daccess-dds-ny.un.org/doc/RESOLUTION/GEN/G11/148/54/PDF/G1114854.pdf">http://daccess-dds-ny.un.org/doc/RESOLUTION/GEN/G11/148/54/PDF/G1114854.pdf</a>
<i>Title</i>	<b>A/HRC/20/L.18 (Promotion of the enjoyment of the cultural rights of everyone and respect for cultural diversity, 2012)</b>
<i>Summary</i>	Calls for the OHCHR to convene a meeting on the right to scientific progress. Available at: <a href="http://daccess-ods.un.org/access.nsf/Get?Open&amp;DS=A/HRC/20/L.18&amp;Lang=E">http://daccess-ods.un.org/access.nsf/Get?Open&amp;DS=A/HRC/20/L.18&amp;Lang=E</a>
<i>Title</i>	<b>A/HRC/23/L.10/Rev.1 (Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, 2013)</b>
<i>Summary</i>	Indicates that the right to health includes access to non-essential medicines and urges states to take various measures to improve access to medicines. Available at: <a href="http://ap.ohchr.org/documents/E/HRC/d_res_dec/A_HRC_23_L10_Rev1.doc">http://ap.ohchr.org/documents/E/HRC/d_res_dec/A_HRC_23_L10_Rev1.doc</a>

## 5. Special Rapporteur on the Right to Health

The special rapporteur has a mandate from the Human Rights Council to investigate the right to health but expresses his expert views in an independent capacity.

<i>Title</i>	<b>A/HRC/11/12 (Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, 2009)</b>
<i>Summary</i>	Recommends that in order to protect the right to health, developing countries should use TRIPS flexibilities to prevent IP law from being a barrier to access to medicines. However, it recognizes that FTAs and other pressure from developed countries make that difficult. Available at: <a href="http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf">http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf</a>
<i>Title</i>	<b>A/HRC/17/43 (Expert consultation on access to medicines as a fundamental component of the right to health, 2011)</b>
<i>Summary</i>	Summarizes the results of a 2010 expert consultation where various individuals identified the problems they see with A2M and IP law. The final recommendations are similar to those in the 2009 report. Available at: <a href="http://daccess-dds-ny.un.org/doc/RESOLUTION/GEN/G11/148/54/PDF/G1114854.pdf">http://daccess-dds-</a>

	<a href="http://ny.un.org/doc/UNDOC/GEN/G11/118/42/PDF/G1111842.pdf">ny.un.org/doc/UNDOC/GEN/G11/118/42/PDF/G1111842.pdf</a>
<b>Title</b>	<b>A/HRC/17/25/Add.2 (on the special rapporteur's 2010 mission to Guatemala, 2011)</b>
<b>Summary</b>	Recommends that Guatemala eliminate regulatory barriers that discriminate against purchasing of generic drugs make use of available TRIPS flexibilities and avoid signing FTAs with additional TRIPS-plus provisions. Available at: <a href="http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/118/28/PDF/G1111828.pdf">http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/118/28/PDF/G1111828.pdf</a>
<b>Title</b>	<b>A/HRC/20/15/Add.2 (on the special rapporteur's 2011 mission to Vietnam, 2012)</b>
<b>Summary</b>	Recommends that Vietnam not accept TRIPS-plus measures in the Trans-Pacific Partnership Agreement. Available at: <a href="http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-15-Add2_en.pdf">http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-15-Add2_en.pdf</a>

## 6. Other Special Rapporteurs

These special rapporteurs have mandates from the Human Rights Council but express their expert views in an independent capacity.

<b>Title</b>	<b>A/HRC/20/26 (Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed, 2012)</b>
<b>Summary</b>	Indicates that the right to science implies access by everyone without discrimination to the benefits of science and recommends delinking drug prices from R&D costs. Available at: <a href="http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-26_en.pdf">http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-26_en.pdf</a>
<b>Title</b>	<b>A/HRC/22/53 (Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Mendez, 2013)</b>
<b>Summary</b>	Argues that in some contexts denial of access to medicines constitutes torture or ill-treatment. Available at: <a href="http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf">http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf</a>

## 7. Other Expert Statements

These are expert opinions by UN affiliates that do not bind states but may guide UN human rights bodies or other international and national policymakers

<i>Title</i>	<b>E/CN.4/Sub.2/2001/13 (Report of the High Commissioner on the impact of TRIPS on human rights, 2001)</b>
<i>Summary</i>	Notes that whether TRIPS is consistent with human rights depends largely on how it is implemented. States should implement it so as to respect the balance between creators' rights and the public interest that is reflected in ICESCR Article 15. That includes use of flexibilities in the interest of public health. Available at: <a href="http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G01/143/45/PDF/G0114345.pdf">http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G01/143/45/PDF/G0114345.pdf</a>
<i>Title</i>	<b>HIV/AIDS and Human Rights: International Guidelines (OHCHR/UNAIDS, revised 2003)</b>
<i>Summary</i>	Recommends in Guideline 6 that states “enact legislation . . . to ensure widespread availability of . . . safe and effective medication at an affordable price.” States should ensure that bilateral and international agreements do not impede access to medicines. There are additional specific recommendations related to technology transfer, nondiscrimination, and other topics. Available at: <a href="https://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub02/jc905-guideline6_en.pdf">https://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub02/jc905-guideline6_en.pdf</a>
<i>Title</i>	<b>UNDP Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement (2010)</b>
<i>Summary</i>	Designed as a resource for governments and an advocacy tool for civil society. It recommends that countries implement TRIPS flexibilities and resist pressures to agree to TRIPS-plus obligations. It explains the various flexibilities. Available at: <a href="http://www.undp.org/content/undp/en/home/librarypage/poverty-reduction/good-practice-guide-improving-access-to-treatment-by-utilizing-public-health-flexibilities-in-the-wto-trips-agreement.html">http://www.undp.org/content/undp/en/home/librarypage/poverty-reduction/good-practice-guide-improving-access-to-treatment-by-utilizing-public-health-flexibilities-in-the-wto-trips-agreement.html</a>
<i>Title</i>	<b>UNDP Global Commission on HIV &amp; the Law (2012)</b>
<i>Summary</i>	Proposes that “[t]he UN Secretary-General must convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products. Such a regime should be consistent with internal human rights law and public health requirements, while safeguarding the justifiable rights of inventors.” It also recommends developed countries stop pressure for high IP protections and actually suspend TRIPS, but in the meantime, developing countries should use flexibilities. Available at: <a href="http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&amp;Health-EN.pdf">http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&amp;Health-EN.pdf</a>

## 8. Treaty Bodies' Country Reviews



The treaty bodies (expert committees) issue concluding observations after their periodic reviews of states' compliance with treaty obligations, often including recommendations from NGOs' shadow reports.

<b><i>Title</i></b>	<b>E/C.12/1/Add. 100 (CESCR concluding observations on Ecuador, 2004)</b>
<b><i>Summary</i></b>	CESCR recommended that Ecuador conduct an impact assessment concerning the effect of trade rules on the right to health and take its treaty obligations into account in negotiating trade agreements. Available at: <a href="http://www.unhchr.ch/tbs/doc.nsf/%28Symbol%29/E.C.12.1.Add.100.En">http://www.unhchr.ch/tbs/doc.nsf/%28Symbol%29/E.C.12.1.Add.100.En</a>
<b><i>Title</i></b>	<b>E/C.12/CHE/CO/2-3 (CESCR concluding observations on Switzerland, 2010)</b>
<b><i>Summary</i></b>	CESCR recommended that Switzerland do an impact assessment of trade agreements' effect on access to medicines in its partner countries. Available at: <a href="http://www2.ohchr.org/english/bodies/cescr/docs/co/E.C.12.CHE.CO.2-3.doc">http://www2.ohchr.org/english/bodies/cescr/docs/co/E.C.12.CHE.CO.2-3.doc</a>
<b><i>Others</i></b>	<b>CRC has made a variety of similar comments recommending impact assessments of trade agreements</b>
<b><i>Titles</i></b>	<b>Botswana</b> in 2004 (CRC/C/15/Add.242) <b>El Salvador</b> in 2004 (CRC/C/15/Add.232) <b>Ecuador</b> in 2005 (CRC/C/15/Add.262) <b>Nicaragua</b> in 2005 (CRC/C/15/Add.265) <b>Philippines</b> in 2005 (CRC/C/15/Add.259) <b>Thailand</b> in 2006 (CRC/C/THA/CO/2) <b>Peru</b> in 2006 (CRC/C/PER/CO/3) Available at: <a href="http://www2.ohchr.org/english/bodies/crc/sessions.htm">http://www2.ohchr.org/english/bodies/crc/sessions.htm</a>

## Appendix C: Clarification on Corporate Accountability

### Corporate Social Responsibility: Classical Perspectives

Efforts to increase corporate social responsibility (CSR) have arisen from a multitude of theories: For some, CSR is a “strategic tool to achieve economic objectives and, ultimately, wealth creation” (Garriga & Mele, 2004). For others, it is a way to improve the competitive advantage of a firm, as “context-focused philanthropy can offer companies a new set of competitive tools that well justifies the investment of resources” (Porter & Kramer, 2002). CSR can arise from social demands, as academics often argue that because “business depends on society for its existence, continuity and growth...Social demands are generally considered to be the way in which society interacts with business and gives it a certain legitimacy and prestige” (Garriga & Mele, 2004). And of course, CSR arises from perceived ethical obligations: Many uphold that the relationship between business and society is embedded with ethical values, leading to a “vision of CSR from an ethical perspective and as a consequence, firms ought to accept social responsibilities as an ethical obligation above any other consideration” (Garriga & Mele, 2004). However, the overarching trend is that CSR has been voluntary. Only recently has this self-governance begun to cave to pressure from external social and market forces, including both legal and social accountability. As such, the use of human rights law and language in conversations surrounding CSR is still relatively new. In 2000, the UN launched the Global Compact, which asks “companies to embrace, support and enact, within their sphere of influence, a set of core values in the areas of human rights, labour standards, the environment and anti-corruption.”<sup>132</sup>

<sup>132</sup> <http://www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/index.html>