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9-1-2011

# The Rights-Based Approach to Intellectual Property and Access to Medicine: Parameters and Pitfalls

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## Recommended Citation

Narula, Smita, "The Rights-Based Approach to Intellectual Property and Access to Medicine: Parameters and Pitfalls" (2011). *New York University Public Law and Legal Theory Working Papers*. Paper 299.  
[http://lsr.nellco.org/nyu\\_plltwp/299](http://lsr.nellco.org/nyu_plltwp/299)

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**THE RIGHTS-BASED APPROACH TO INTELLECTUAL PROPERTY  
AND ACCESS TO MEDICINE: PARAMETERS AND PITFALLS\***

Smita Narula\*\*

Access to essential medicines is a fundamental component of the human right to adequate health. In the face of global pandemics, rising drug costs continue to attract a great deal of attention and have opened up a space for the broader conversation around the interaction of states' human rights obligations with their international financial commitments, particularly in the realm of trade and intellectual property.

The relationship between human rights and intellectual property is a troubled one and is epitomized by the contentious issue of access to patented medicines.<sup>1</sup> Patent protection can interfere with access to medicine in two key ways: by granting monopolies in pharmaceutical production, raising the cost of medicines to often unaffordable prices; and by providing a profit mechanism that incentivizes research of diseases primarily affecting countries with lucrative markets over diseases prevalent in developing countries.<sup>2</sup> The result is a “global drug gap” wherein novel drugs are often inaccessible to most of the world's population.<sup>3</sup>

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\* This Paper will appear as part of a collection to be published as: *BALANCING WEALTH AND HEALTH: GLOBAL ADMINISTRATIVE LAW AND THE BATTLE OVER INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN LATIN AMERICA* (Rochelle Dreyfuss and César Rodríguez Garavito, eds.).

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<sup>1</sup> LAURENCE R. HELFER AND GRAEME W. AUSTIN, *HUMAN RIGHTS AND INTELLECTUAL PROPERTY MAPPING THE GLOBAL INTERFACE* (New York: Cambridge University Press, 2011), at 90.

<sup>2</sup> *Id.* at 140. The authors add that a number of other obstacles, such as poverty and limited government funding of health care, also interfere with access to medicine in developing countries. *Id.* at 142.

<sup>3</sup> *Id.* at 140.

Helfer and Austin suggest that the human right to health offers a valuable framework for addressing this gap by: “refram[ing] existing legal discourses that privilege legal rules protecting intellectual property over those protecting individual rights and social values”; “provid[ing] a mechanism to hold governments accountable for providing at least minimal levels of health care”; and “emphasiz[ing] the need to restructure incentives for medical research and innovation toward the treatment of neglected diseases and the health needs of the world’s poor.”<sup>4</sup>

This Paper provides an overview of the rights-based approach to access to medicines, and focuses on the work of international human rights bodies, mechanisms, and procedures on the question of balancing intellectual property and human rights. A plethora of human rights committees, actors and institutions have developed out of the canon of human rights law to monitor the implementation of various treaties and to breathe normative content into various rights, including the right to health.

Part I of this Paper outlines both the broad and specific parameters of the rights-based approach to intellectual property and access to medicine, while Part II addresses the impediments and obstacles to implementing such an approach in practice. These obstacles arise in connection to key inter-related deficits in international human rights law around the issues of legitimacy, accountability, and domestic capacity.

The Paper concludes that the full and equitable realization of the right to adequate health depends greatly on the capacity and political inclination of domestic actors to enforce international norms. Conclusions regarding the extent to which human rights primacy can be realized in the realm of access to medicines are therefore highly country and context-specific.

## **I. THE RIGHTS-BASED APPROACH TO INTELLECTUAL PROPERTY AND ACCESS TO MEDICINE**

The human right to health, protected under various international, regional and domestic constitutional instruments, has served as the starting point for the human rights community’s

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<sup>4</sup> *Id.* at 144.

interactions with access to medicine and the intellectual property regime. A number of human rights institutions and actors have played a critical role in the development of these norms.<sup>5</sup> These include treaty bodies such as the Committee on Economic, Social and Cultural Rights;<sup>6</sup> inter-governmental bodies such as the U.N. Human Rights Council (formerly the Commission on Human Rights);<sup>7</sup> and special procedures and individual office holders such as the U.N. High Commissioner for Human Rights,<sup>8</sup> and the U.N. Special Rapporteurs on the rights to health and food.<sup>9</sup>

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<sup>5</sup> For a comprehensive compilation of relevant texts from international actors see HELFER AND AUSTIN, *supra* note 1, at 53- 56.

<sup>6</sup> See, e.g., Committee on Economic, Social & Cultural Rights, *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He Is the Author*, art. 15(1)(c), U.N. Doc. E/C.12/GC/17 (Jan. 12, 2006) [hereinafter General Comment No. 17] (asserting that States parties must “ensure that intellectual property regimes contribute, in a practical and substantive way, to the full realization of all the Covenant rights”); ECOSOC, Committee on Economic, Social & Cultural Rights, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, U.N. Doc. E/C12/2001/15 (Dec. 14, 2001) [hereinafter CESCR 2001] (“national and international intellectual property regimes must be consistent with” economic, social and cultural rights obligations). See also Committee on the Rights of the Child, *General Comment No. 3: HIV/AIDS and the Rights of the Child*, ¶28, U.N. Doc. CRC/GC/2003/3 (Mar. 17, 2003) (“The obligations of States parties under the Convention extend to ensuring that children have sustained and equal access to comprehensive treatment and care, including necessary HIV-related drugs”).

<sup>7</sup> See, e.g., Commission on Human Rights, Res. 2001/33, U.N. Doc. E/CN.4/RES/2001/33 (Apr. 23, 2001) [hereinafter Commission on Human Rights 2001] (states must “adopt legislation or other measures, in accordance with applicable international law” to “safeguard access” to such medications “from any limitations by third parties”); Commission on Human Rights, *Access to Medication in the Context of Pandemics such as HIV/AIDS*, U.N. Doc. E/CN.4/RES/2002/32 (Apr. 22, 2002) [hereinafter Commission on Human Rights 2002]; Human Rights Council, *Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, Res. 12/24, U.N. Doc. A/HRC/RES/12/24 (Oct. 2, 2009).

<sup>8</sup> See, e.g., Commission on Human Rights, *Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, U.N. Doc. E/CN.4/Sub.2/2001/13 (June 27, 2001) [hereinafter Report of the High Commissioner 2001] (analyzing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and criticizing TRIPS implementation from a human rights perspective).

<sup>9</sup> See, e.g., U.N. Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest*

Regional and domestic actors are also increasingly involved in the development and implementation of human rights norms as they relate to the issue of access to medicine. At the regional level, these include the Inter-American Commission on Human Rights<sup>10</sup> and the African Commission on Human and Peoples' Rights.<sup>11</sup> Domestically, a number of courts have played a critical role in translating these norms into tangible rights and benefits.<sup>12</sup>

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*attainable standard of physical and mental health*, 61<sup>st</sup> Sess., UN Doc. A/61/338 (2006) [hereinafter Special Rapporteur on the Right to Health 2006]; U.N. Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*, UN Doc. A/63/263 (Aug. 11, 2008) (prepared by Paul Hunt) [hereinafter Special Rapporteur on the Right to Health 2008] (addressing the human rights obligations of pharmaceutical companies); U.N. Special Rapporteur on the Right to Food, Report to U.N. General Assembly, U.N. Doc. A/64/170 (July 23, 2009) (prepared by Olivier De Schutter) (addressing the interaction between human rights and intellectual property); U.N. Special Rapporteur of the Commission on Human Rights on the Right to Food, *Report to Commission on Human Rights*, U.N. Doc. E/CN.4/2004/10, ¶ 39 (Feb. 9, 2004) (prepared by Jean Ziegler) (addressing the interaction between human rights and intellectual property).

<sup>10</sup> See, e.g., *Jorge Odir Miranda Cortez et al v. El Salvador*, Case 12.249, Report No. 29/01, OEA/Ser.L/V/II.111 Doc. 20 rev. at 284 (2000) (a claim by HIV-infected individuals that the El Salvador government had violated, *inter alia*, the rights to life and health by failing to provide antiretroviral drugs; the Inter-American Commission issued a precautionary measures order and declared the complaint admissible, but the case ended in a friendly settlement after the El Salvadorian Supreme Court ordered that drugs be provided in a similar case).

<sup>11</sup> See, e.g., African Commission on Human and Peoples' Rights, *Resolution on Access to Health and needed Medicines in Africa*, ACHPR/Res.141 (XXXVIII)08 (November 24, 2008) (urging states to “guarantee the full scope of access to needed medicines” and calling on states to fulfill their duties by promoting, protecting, and fulfilling access to medicines).

<sup>12</sup> See, e.g., *South Africa - Minister of Health v Treatment Action Campaign (TAC)*, 5 SA 721 (CC 2002) (holding that the South African government's restrictions on the distribution of anti-retroviral drugs to pregnant women amounts to a violation of the constitutional right to health); *López, Glenda y otros v. Instituto Venezolano de los Seguros Sociales (IVSS) s/ acción de amparo*. Expediente 00-1343. Sentencia N° 487; *Cruz del Valle Bermúdez y otros vs. MSAS s/amparo*, Expediente N° 15.789, Sentencia N° 196 (Venezuelan Constitutional Court 1999) (ordering the Venezuelan government to provide anti-retrovirals on a regular and reliable basis to a group of individuals living with with HIV/AIDS); *Viceconte, Mariela v. Estado Nacional (Ministerio de Salud y Ministerio de Economía de la Nación) s/ Acción de Amparo*, Causa no. 31.777/96 (Argentinian Federal Administrative Court of Appeals 1998) (finding

This section summarizes some of the most salient points of the human rights approach as it has emerged over the past decade, and outlines domestic and international responsibilities for both states and third parties.

### **A. The Right to Health and Access to Medicines under International Human Rights Law**

#### **1. Right to Health and Access to Medicines: The Framework**

The right to health is primarily codified under Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which asserts that states must recognize “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>13</sup> The right to health includes “underlying determinants of health, such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education

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a violation of the right to health under Art. 12 of the ICESCR and ordering the Argentinian government to produce and distribute a vaccine).

<sup>13</sup> International Covenant on Economic, Social, and Cultural Rights, art. 12, Dec. 16, 1966, 993 U.N.T.S. 3 [hereinafter ICESCR], *available at* <http://www2.ohchr.org/english/law/pdf/cescr.pdf>. The right to health is also contained in other international as well as regional instruments. *See, e.g.*, Convention on the Elimination of All Forms of Discrimination against Women [CEDAW], art. 12, Dec. 18, 1979, 1249 U.N.T.S. 13, *available at* <http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm>; Convention on the Rights of the Child [CRC], art. 24(2)(b), Nov. 20, 1989, 1577 U.N.T.S. 3, *available at* <http://www2.ohchr.org/english/law/pdf/crc.pdf>; African [Banjul] Charter on Human and Peoples' Rights, art. 16, June 27, 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58, *available at* <http://www1.umn.edu/humanrts/instree/z1afchar.htm>; American Declaration of the Rights and Duties of Man, art. 11, EA/Ser.L.V/II.82 doc. 6 rev.1 (1948), *available at* <http://www1.umn.edu/humanrts/oasinstr/zoas2dec.htm>; and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, “Protocol of San Salvador,” art. 10, Nov. 14, 1988, O.A.S.T.S. No. 69, 28 I.L.M. 156 (1989), *available at* <http://www.oas.org/juridico/english/treaties/a-52.html>; European Social Charter, art. 11, Oct. 18, 1961, 529 U.N.T.S. 89 *available at* <http://conventions.coe.int/Treaty/en/Treaties/Html/035.htm>.

and information.”<sup>14</sup> Additionally, it requires the availability and accessibility of “[f]unctioning public health and health-care facilities, goods and services, as well as programmes.”<sup>15</sup> Access to essential medicine is conceptualized as a sub-component of the broader right to adequate health.<sup>16</sup>

The rights-based framework for access to medicines rests on four pillars: availability; accessibility; cultural acceptability; and quality.<sup>17</sup> Specifically, states must ensure *availability* of medicines. This could include, for example, making use of compulsory license flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to ensure sufficient quantities of medicines within their countries, and supporting research and development of drugs to address diseases that place a particular burden on developing countries.<sup>18</sup>

On the issue of *accessibility* of medicines, states must ensure access in geographic, physical and economic terms and without discrimination. Geographic or physical accessibility means that health services must be physically accessible to all individuals in all parts of the country, while economic accessibility concerns the issue of affordability of medicines, which in turn has

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<sup>14</sup> ECOSOC, Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 14: The right to the highest attainable standard of health* (Art. 12), ¶ 4, U.N. Doc. E/C.12/2000/4 (August 11, 2000), available at <http://www.unhcr.org/refworld/pdfid/4538838d0.pdf> [hereinafter “General Comment No. 14”].

<sup>15</sup> *Id.* ¶ 12(a).

<sup>16</sup> See, e.g., U.N. Special Rapporteur on the Right of Everyone to the Highest Attainable Standard of Physical and Mental Health, *Addendum: Mission to the World Trade Organization*, ¶ 18, U.N. Doc. E/CM.4/2004/49/Add.1 (Mar. 1, 2004) (prepared by Paul Hunt) (asserting that the right to health encompasses “access to essential medicines”).

<sup>17</sup> General Comment No. 14, *supra* note 14, ¶ 12; Special Rapporteur on the Right to Health 2006, *supra* note 9, ¶¶ 47-51; African Commission on Human and Peoples’ Rights, *Resolution on Access to Health and needed Medicines in Africa*, ACHPR/Res.141 (XXXIII)08 (November 24, 2008).

<sup>18</sup> Special Rapporteur on the Right to Health 2006, *supra* note 9, ¶ 47 (stating that countries “might have to make use of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities by passing and using compulsory licence legislation, thereby ensuring that medicines reach their jurisdictions in adequate quantities”).

implications for how medicines are priced.<sup>19</sup> States must also ensure accessibility of information on the basis of which individuals can, *inter alia*, make informed decisions about the medicines that they are taking.<sup>20</sup> The World Health Organization has also highlighted that essential medicines must be available in appropriate dosage forms, which may for example require adaptation to local limitations in refrigeration or distribution.<sup>21</sup> Calls for both availability and accessibility have been especially pronounced in the face of various global pandemics such as HIV/AIDS, malaria, and tuberculosis.<sup>22</sup>

*Cultural acceptability*, the third pillar of the access to medicine framework, calls on states to: support the proper use of traditional medicines and the integration of those medicines into national programs; and ensure compliance with medical ethics so that clinical trials are carried out with informed consent.<sup>23</sup> Finally, states must ensure that medicines are of good *quality*.<sup>24</sup>

## 2. Right to Health and Access to Medicines: The Duty-Bearers

### a. States

States are the primary duty-bearers under international human rights law and must *respect, protect, and fulfill* rights<sup>25</sup> in

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<sup>19</sup> General Comment No. 14, *supra* note 14, ¶ 12(b); Special Rapporteur on the Right to Health 2006, *supra* note 9, ¶ 49.

<sup>20</sup> General Comment No. 14, *supra* note 14, ¶ 12(b); Special Rapporteur on the Right to Health 2006, *supra* note 9, ¶ 49.

<sup>21</sup> World Health Organization, ‘Essential Medicines Lists’, *available at* [http://www.who.int/medicines/services/essmedicines\\_def/en/index.html](http://www.who.int/medicines/services/essmedicines_def/en/index.html).

<sup>22</sup> *See, e.g.*, Commission on Human Rights 2002, *supra* note 7 (calling upon states to promote: “availability... of pharmaceuticals... to treat pandemics such as HIV/AIDS; “accessibility to all without discrimination, including the most vulnerable sectors of the population”; and “assurance that pharmaceuticals... are scientifically and medically appropriate and of good quality).

<sup>23</sup> General Comment No. 14, *supra* note 14, ¶ 12(c); Special Rapporteur on the Right to Health 2006, *supra* note 9, ¶ 50.

<sup>24</sup> General Comment No. 14, *supra* note 14, ¶ 12(d); Special Rapporteur on the Right to Health 2006, *supra* note 9, ¶ 51.

<sup>25</sup> *See* Office of the High Commissioner for Human Rights, International Human Rights Law, <http://www.ohchr.org/EN/ProfessionalInterest/Pages/InternationalLaw.aspx> (last visited Jul. 27, 2011).

line with the guidance outlined above. The duty to respect is essentially a duty of non-interference with existing access to rights.<sup>26</sup> Under the duty to protect, states must exercise *due diligence* to ensure that non-state actors—such as corporations—are not interfering with individual rights.<sup>27</sup> This includes a duty to investigate all instances in which a private individual or corporation may be interfering with human rights,<sup>28</sup> and to take steps to remedy violations that have taken place.<sup>29</sup> As noted above, this may also include regulating the price, availability, and accessibility of medicine. The duty to fulfill includes the duty to *facilitate* and in some cases *provide* human rights.<sup>30</sup> Inherent in these obligations is the duty to provide an effective remedy when human rights violations have taken place.<sup>31</sup>

While the ICESCR allows for “progressive realization” of the rights contained therein,<sup>32</sup> States parties have an immediate obligation to: ensure non-discrimination in the provision of economic, social and cultural rights; and take immediate steps

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

<sup>27</sup> See, e.g., *General Comment No. 14*, *supra* note 14, ¶ 33 (“The obligation to *protect* requires States to take measures that prevent third parties from interfering with article 12 guarantees.”). See also I/A Court H.R., *Vélásquez Rodríguez v. Honduras*, Judgment of July 29 1989, Series C, No. 4, ¶¶ 172, 176, available at [http://www1.umn.edu/humanrts/iachr/b\\_11\\_12d.htm](http://www1.umn.edu/humanrts/iachr/b_11_12d.htm).

<sup>28</sup> See, e.g., *Vélásquez Rodríguez*, *supra* note 27, ¶ 176 (“The State is obligated to investigate every situation involving a violation of the rights protected by the Convention.”).

<sup>29</sup> *Id.* ¶ 172.

<sup>30</sup> See, e.g., *General Comment No. 14*, *supra* note 14, ¶ 13 (“The obligation to *fulfil (facilitate)* requires States *inter alia* to take positive measures that enable and assist individuals and communities to enjoy the right to health. States parties are also obliged to *fulfil (provide)* a specific right contained in the Covenant when individuals or a group are unable, for reasons beyond their control, to realize that right themselves by the means at their disposal.”).

<sup>31</sup> International Covenant on Civil and Political Rights, art. 2(3), Dec. 16, 1966, 999 U.N.T.S. 171 [hereinafter ICCPR], available at <http://www2.ohchr.org/english/law/pdf/ccpr.pdf>.

<sup>32</sup> ICESCR, *supra* note 13, art. 2(1). For an interpretation of the legal obligations of Article 2(1), see generally ECOSOC, Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 3: The nature of States parties obligations (Art. 2, ¶ 1 of the Covenant)*, U.N. Doc. E/1991/23 (Dec. 14, 1990), available at [http://www.unhcr.ch/tbs/doc.nsf/\(Symbol\)/94bdbaf59b43a424c12563ed0052b664?Opendocument](http://www.unhcr.ch/tbs/doc.nsf/(Symbol)/94bdbaf59b43a424c12563ed0052b664?Opendocument) [hereinafter *General Comment No. 3*].

toward the realization of these rights.<sup>33</sup> Economic, social and cultural rights also include a “minimum core” of attendant obligations that states must realize as soon as possible.<sup>34</sup> Additionally, states may not engage in conduct that causes this realization of human rights to regress.<sup>35</sup>

The principle of non-discrimination is a central tenet of international human rights law. States must ensure both non-discrimination and substantive equality in the enjoyment of human rights.<sup>36</sup> Vulnerable groups, in particular, must not be left out of the purview of rights protections and states may need to take special measures to ensure their substantive equality.<sup>37</sup> Specific covenants protect those members of the population that might suffer from discrimination, and commentary on the right to health emphasizes the obligation to provide health services to socially disadvantaged groups.<sup>38</sup> A rights-based approach additionally emphasizes principles of participation, inclusion, and

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<sup>33</sup> *Id.* ¶¶ 1-2; ECOSOC, Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 20: Non-discrimination in economic, social and cultural rights (art. 2, ¶ 2, of the International Covenant on Economic, Social and Cultural Rights)*, ¶ 7, U.N. Doc. E/C.12/GC/20 (July 2, 2009), available at <http://www2.ohchr.org/english/bodies/cescr/docs/E.C.12.GC.20.doc> [hereinafter General Comment No. 20]; ICESCR, *supra* note 13, at art. 2(2); Comm. on the Elimination of Racial Discrimination, *General Recommendation No. 14: Definition of discrimination (Art., par. 1)*, ¶ 2, U.N. Doc A/48/18 (Mar. 22, 1993), available at <http://www.unhcr.ch/tbs/doc.nsf/%28Symbol%29/d7bd5d2bf71258aac12563ee004b639e?OpenDocument>; Human Rights Comm., *General Comment No. 18: Non-Discrimination*, ¶ 7, U.N. Doc. HRI/GEN/1/Rev.1 (Nov. 10, 1989), available at <http://www.unhcr.org/refworld/docid/453883fa8.html>.

<sup>34</sup> *General Comment No. 3*, *supra* note 32, ¶ 10. For an interpretation of the core obligations of the right to health, see General Comment No. 14, *supra* note 14, ¶ 43-45.

<sup>35</sup> See *General Comment No. 3*, *supra* note 32, ¶ 9 (“any deliberately retrogressive measures in that regard [in contrast to progressive realization] would require the most careful consideration and would need to be fully justified by reference to the totality of the rights provided for in the Covenant and in the context of the full use of the maximum available resources.”).

<sup>36</sup> General Comment No. 14, *supra* note 14, ¶ 12(b); General Comment No. 20, *supra* note 33, ¶ 8.

<sup>37</sup> General Comment No. 20, *supra* note 33, ¶ 27; Special Rapporteur on the Right to Health 2006, *supra* note 9, ¶ 52, 54; General Comment No. 14, *supra* note 14, ¶ 35.

<sup>38</sup> General Comment No. 14, *supra* note 14, ¶¶ 12, 19.

accountability.<sup>39</sup> Finally, international human rights law recognizes that no one state can act alone to fulfill the rights at stake. Under the obligation of “international cooperation” states must cooperate in ensuring the fulfillment of economic and social rights globally.<sup>40</sup>

The principles outlined above are aimed primarily at states but increasingly human rights bodies are also addressing the responsibilities of multi-state actors such as intergovernmental organizations, and non-state actors such as corporations. These actors, who were on the sidelines of the conversation as recently as a decade ago, are now very much at its center.

### *b. International Organizations*

Human rights bodies have called upon both states and international organizations, such as the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), to take account of states’ human rights obligations when negotiating, signing and implementing international agreements. States are urged to integrate human rights policies into domestic legislation that implements international obligations,<sup>41</sup> as well as to

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<sup>39</sup> See The Human Rights Based Approach to Development Cooperation: Towards a Common Understanding Among the UN Agencies (May 2003), available at [http://www.crin.org/docs/resources/publications/hrbap/HR\\_common\\_understanding.doc](http://www.crin.org/docs/resources/publications/hrbap/HR_common_understanding.doc).

<sup>40</sup> ICESCR, *supra* note 13, art. 2(1) (“Each State Party to the present Covenant undertakes to take steps, individually *and through international assistance and co-operation*, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant...”); U.N. Charter art. 1 (purpose of the United Nations is achieving international cooperation to solve economic, social, cultural and humanitarian problems and promoting human rights for all without distinction).

<sup>41</sup> See, e.g., ECOSOC, Sub-Commission on the Promotion & Protection Of Human Rights, *Intellectual Property Rights and Human Rights*, Res. 2000/7, U.N. Doc. E/CN.4/Sub.2/RES/2000/7 (Aug. 17 2000) [hereinafter Sub-Commission 2000] (urging members to implement the minimum standards of the TRIPS Agreement bearing in mind both their human rights obligations as well as the flexibility inherent in the TRIPS Agreement, and recognizing that “human rights are the first responsibility of Governments”); Commission on Human Rights, *Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria*, Resn 2004/26 (April 16, 2004) ¶ 10(b)

take into account their obligations when negotiating and signing new international agreements.<sup>42</sup> States do not leave their human rights obligations at the door when entering into international agreements such as TRIPS. Foreign states must also respect the ability of other states to implement their human rights obligations. In other words, powerful states must refrain from exerting their influence in a manner that undermines the ability of weaker states to fulfill their economic, social and cultural rights obligations.<sup>43</sup> Finally, states have a duty to facilitate, wherever possible, access to essential medications in other countries.<sup>44</sup>

While much of the above commentary is directed at states, human rights bodies have also addressed the obligations directly owed by intergovernmental organizations in general, and the WTO specifically, requesting that they “integrate into their policies, practices and operations,” provisions that “protect the social

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[hereinafter Commission on Human Rights 2004] (calling on states “[t]o ensure ... the application of international agreements is supportive of public health policies that promote broad access to safe, effective and affordable preventive, curative or palliative pharmaceutical products and medical technologies).

<sup>42</sup> See, e.g., ECOSOC, Sub-Commission on the Promotion and Protection of Human Rights, *Intellectual Property and Human Rights*, Res. 2001/21, U.N. Doc. E/CN.4/Sub.2/RES/2001/21 (Aug. 16, 2001) [hereinafter Sub-Commission 2001], ¶ 6 (urging “all Governments to take fully into account existing State obligations under international human rights instruments in the formulation of proposals for the ongoing review of the TRIPS Agreement,”); Commission on Human Rights 2004, *supra* note 41, ¶ 10(b) (calling on states “To ensure that their actions as members of international organizations take due account of the right of everyone to the enjoyment of the highest attainable standard of physical and mental Health...”; OHCHR and UNAIDS, *HIV/AIDS and Human Rights: Guideline 6*, HR/PUB/2002/1 (2002), ¶ z (“States should, in light of their human rights obligations, ensure that bilateral, regional and international agreements, such as those dealing with intellectual property, do not impede access to HIV/AIDS prevention, treatment, care and support, including access to antiretroviral and other medicines, diagnostics and related technologies.”).

<sup>43</sup> Special Rapporteur on the Right to Health 2006, *supra* note 9, ¶ 64 (asserting that “no rich State should encourage a developing country to accept intellectual property standards that do not take into account the safeguards and flexibilities included under the TRIPS Agreement”).

<sup>44</sup> Commission on Human Rights 2001, *supra* note 7, ¶ 4(a) (calling on states to “facilitate, wherever possible, access in other countries to essential preventive, curative or palliative pharmaceuticals or medical technologies ... as well as to extend the necessary cooperation, wherever possible, especially in times of emergency;”); Commission on Human Rights 2002, *supra* note 7, ¶ 6(a); Commission on Human Rights 2004, *supra* note 41, ¶ 10(a).

function of intellectual property” in accordance with international human rights law.<sup>45</sup>

*c. The Private Sector*

The private sector is also increasingly being addressed by human rights actors. In 2008, the Special Rapporteur on the right to health issued human rights guidelines addressed directly to pharmaceutical companies calling on them, *inter alia*, to: respect the right of countries to use to the fullest extent possible the flexibility afforded by TRIPS; make and respect a public commitment not to lobby for more demanding intellectual property protections than those required by TRIPS;<sup>46</sup> and respect the Doha Declaration on the TRIPS Agreement and Public Health (2001).<sup>47</sup>

While we may seem far off from being able to enforce company compliance with these guidelines, the idea that businesses should at the very least respect human rights is gaining traction at the U.N. Although TNCs have not traditionally been viewed as directly bound by international human rights law, support has recently emerged for the “Protect, Respect, Remedy” framework, a set of obligations which, if fully embraced, would impose some international human rights obligations directly on businesses. Originally proposed by the U.N. Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie—and approved by the Human Rights Council in 2008<sup>48</sup>—the Framework states that corporations and

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<sup>45</sup> Sub-Commission 2000, *supra* note 41, ¶ 6, 8; CESCR 2001, *supra* note 6 (noting that realms of trade, finance and investment are in no way exempt from human rights principles and that “international organizations with specific responsibilities in those areas should play a positive and constructive role in relation to human rights.”)

<sup>46</sup> Special Rapporteur on the Right to Health 2008, *supra* note 9, ¶ 26.

<sup>47</sup> *Id.* ¶ 27. The Declaration recognizes states’ “right to protect public health and, in particular, to promote access to medicines for all.” World Trade Organization, Ministerial Decision of 14 November 2001, WT/MIN(01)/DEC/1.41 I.L.M. 746 (2002), ¶ 4 [hereinafter Doha Declaration].

<sup>48</sup> UNHRC, 8<sup>th</sup> Session, Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, ‘Protect, Respect and Remedy: A Framework for Business and Human Rights’ (Apr. 7, 2008) A/HRC/8/5, available at <http://www.reports-and-materials.org/Ruggie-report-7-Apr-2008.pdf> [hereinafter

other business enterprises must, as a baseline expectation, *respect* human rights.<sup>49</sup> This responsibility to respect means that businesses should “avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved.”<sup>50</sup> Businesses should also “[s]eek to prevent or mitigate adverse human rights impacts that are directly linked to their operations, products or services by their business relationships, even if they have not contributed to those impacts.”<sup>51</sup> To meet these requirements, businesses must exercise due diligence to “become aware of, prevent and address adverse human rights impacts.”<sup>52</sup>

In 2011, the U.N. Human Rights Council unanimously approved a set of Guiding Principles that offer a set of practical recommendations for operationalizing the “Protect, Respect and Remedy” framework.<sup>53</sup> Advocates are now beginning to consider how to hold pharmaceutical companies directly accountable for their impact on human rights, and are starting to make use of the Ruggie standards to evaluate corporate conduct.<sup>54</sup>

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Protect, Respect and Remedy].

<sup>49</sup> See Protect, Respect and Remedy, *supra* note 48, ¶¶ 9, 54-55.

<sup>50</sup> UNHRC, 17<sup>th</sup> Session, Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, ‘Guiding Principles on Business and Human Rights: Implementing the United Nations “Protect, Respect and Remedy”’, (Mar. 21, 2011) U.N. Doc. A/HRC/17/31 [hereinafter *Guiding Principles*], available at <http://www.businesshumanrights.org/media/documents/ruggie/ruggie-guiding-principles-21-mar-2011.pdf>, ¶ 6, Annex ¶ 11.

<sup>51</sup> *Id.* Annex ¶ 13.

<sup>52</sup> Protect, Respect and Remedy, *supra* note 48, ¶ 56. Furthermore, “[f]or the substantive content of the due diligence process, companies should look, at a minimum, to the international bill of human rights [i.e. the Universal Declaration of Human Rights, as well as the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights] and the core conventions of the ILO, because the principles they embody comprise the benchmarks against which other social actors judge the human rights impacts of companies.” *Id.* ¶ 58. Businesses’ obligations extend both to the effects of direct activities as well as, sometimes, to the conduct of actors over whom the business has leverage. *Id.* ¶¶ 68, 72.

Additionally, corporations cannot act in complicity with third parties, whether state or non-state actors, who are committing human rights violations. *Id.* ¶ 73.

<sup>53</sup> See generally *Guiding Principles*, *supra* note 50.

<sup>54</sup> See, e.g., Sofia Gruskin and Zyde Read, *Are Drug Companies Living Up to Their Human Rights Responsibilities? Moving Toward Assessment*, 7 PLOS MEDICINE 1 (2010) (suggesting three approaches to concretely assesses drug

Attempts to lasso the big private actor into the human rights conversation must of course contend with the significant power dynamics that are at play. These and other obstacles to implementing a rights-based approach to access to medicine are described in Part II.

## **B. Reconciling the Right to Health with Intellectual Property Rights**

There are multiple ways of addressing the interaction between international human rights law and international and domestic intellectual property regimes. Several trends emerge among the human rights bodies that have addressed access to medicines from a right to health perspective.

First, human rights bodies must address the apparent protection for intellectual property within human rights instruments. Both the Universal Declaration of Human Rights and the ICESCR guarantee the right of everyone to “enjoy the benefits of scientific progress and its applications”<sup>55</sup> and the right to benefit from “the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”<sup>56</sup> Such protections can also be found in regional instruments.<sup>57</sup> Human rights bodies such as the Committee on

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companies’ compliance with human rights responsibilities); Paul Hunt and Rajat Khosla, *Are Drug Companies Living Up to Their Human Rights Responsibilities? The Perspective of the Former United Nations Special Rapporteur (2002-2008)*, 7 PLOS MEDICINE (2010) (suggesting that pharmaceutical companies are not living up to their human rights responsibilities, and suggesting the contours and participants of an international institution to serve as an “effective right-to-health accountability mechanism[]” to confirm whether or not allegations of failure are well founded, and to make sensible practical recommendations for all parties).

<sup>55</sup> ICESCR, *supra* note 13, at art. 15(b). The corollary to this right in the UDHR is framed as the right to “share in scientific advancement and its benefits.” Universal Declaration of Human Rights [hereinafter UDHR], art. 27(1), G.A. res. 217A (III), U.N. Doc A/810 at 71 (1948).

<sup>56</sup> ICESCR, *supra* note 13, at art. 15(c); UDHR, *supra* note 55, art. 27(2).

<sup>57</sup> See, e.g., Charter of Fundamental Rights of the European Union, 2000 O.J. (C 364) 1, Art. 17 (“Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. . . . Intellectual property shall be protected.”). American Declaration of the Rights and Duties of Man, OEA/Ser.L./V.II.23, doc. 21, rev. 6 (1948), Art. 13 (giving every person the “the

Economic, Social and Cultural Rights and the Sub-Commission on the Promotion and Protection of Human Rights have sought to distinguish the protection of intellectual property as a human right from intellectual property regimes that protect broader commercial interests, arguing that, as framed in human rights law, concerns the relationship of individuals to their creation and is not one that corporations can avail themselves of to protect corporate interests.<sup>58</sup> The “social function” of intellectual property, they add, must be protected.<sup>59</sup>

Having outlined this distinction, human rights bodies go on to assert the primacy of human rights over economic policies and agreements.<sup>60</sup> The “first responsibility” of states, it is argued, is to attend to human rights.<sup>61</sup> As the argument goes, human rights take precedence over economic policies and agreements. They are of a higher order.

Such an approach may suggest a conflict between human rights and intellectual property regimes. But according to key

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right to the protection of his moral and material interests as regards his inventions or any literary, scientific or artistic works of which he is the author.”).

<sup>58</sup> General Comment No. 17, *supra* note 6, ¶ 2, 7. Specifically, the right protects the “moral interest” of authors to be “recognized as the creators” of their work, and to “object to any distortion, mutilation or other modification of, or other derogatory action in relation to, such productions, which would be prejudicial to their honour and reputation.” *Id.* at 13. The right also protects the author’s “material interests,” which can be linked to other human rights such as the rights to own property, to adequate remuneration, and to an adequate standard of living. *Id.* at 15.

<sup>59</sup> CESCR 2001, *supra* note 6, ¶ 4 (“Ultimately, intellectual property is a social product and has a social function. The end which intellectual property protection should serve is the objective of human well-being, to which international human rights instruments give legal expression.”).

<sup>60</sup> *See, e.g.*, Sub-Commission 2000, *supra* note 41 (criticizing the implementation of the TRIPS agreement and “remind[ing] all Governments of the primacy of human rights obligations over economic policies and agreements”).

<sup>61</sup> Report of the High Commissioner 2001, *supra* note 8, ¶ 60: “Out of the 141 members of WTO that have undertaken to implement the minimum standards of IP protection in the TRIPS Agreement, 111 have ratified ICESCR. Members should therefore implement the minimum standards of the TRIPS Agreement bearing in mind both their human rights obligations as well as the flexibility inherent in the TRIPS Agreement, and recognizing that ‘human rights are the first responsibility of Governments’.”

commentators<sup>62</sup> and human rights actors, the issue is not so simple; there exist other approaches as well. The “coexistence” approach, for example, sees “human rights law and intellectual property law as essentially compatible but as in tension over where to strike the balance between incentives [to innovate] on the one hand and access [to the public] on the other.”<sup>63</sup>

No matter the theoretical approach adopted by human rights bodies, there exist significant obstacles to implementing a rights-based approach in practice. Implementation difficulties arise not only in the context of transnational corporations and IFIs, as mentioned above, but also in the operationalization of more settled legal frameworks such as states’ international and even national duties towards their own populations, as described below.

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<sup>62</sup> See HELFER AND AUSTIN, *supra* note 1, at 65- 67, arguing that “although the conflicts approach appears conceptually straightforward, in fact it masks a number of embedded assumptions and ambiguities. Among the most important of these are (1) identifying the nature of the conflict that must exist before a state’s human rights obligations supersede its intellectual property commitments, and (2) analyzing the legal justification for giving primacy to human rights over other international rules.”

<sup>63</sup> HELFER AND AUSTIN, *supra* note 1, at 73. For alternative visions of interaction between the two fields see: Peter K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039, 1044 (2007) (suggesting that two different approaches are needed to resolve distinct areas of conflicts between human rights and intellectual property: “external conflicts (conflicts at the intersection of the human rights and intellectual property regimes) and internal conflicts (conflicts between rights within the human rights regime)”; Laurence R. Helfer, *Toward a Human Rights Framework for Intellectual Property*, 40 U.C. DAVIS L. REV. 971 (2007) (emphasizing the need for a more comprehensive human rights approach to intellectual property, and mapping three potential directions which the interface between the two fields could follow which include the possibility of using intellectual property to achieve human rights goals); and Ruth Okediji, *Securing Intellectual Property Objectives: New Approaches to Human Rights Considerations*, in CASTING THE NET WIDER: HUMAN RIGHTS, DEVELOPMENT AND NEW DUTY-BEARERS 211 (Margot E. Salomon et al. eds., 2007) (arguing that “human rights should be viewed as a means of preserving the objectives of intellectual property using existing intellectual property tools” and that “[a]t the very least, human rights justify the objectives of intellectual property and could be used to impose an internal constraint within the intellectual property system so that those objectives remain critical to the legitimacy of the system”).

## II. OBSTACLES TO IMPLEMENTING A RIGHTS-BASED APPROACH

The field of international human rights law, and its ability to influence developments in parallel legal realms, has developed significantly over the past several decades. Despite these developments, a number of obstacles remain to implementing a rights-based approach to access to medicine and to effectively asserting the primacy of human rights in the context of international financial agreements. These obstacles arise in connection to key inter-related deficits in international human rights law around the issues of legitimacy, accountability, and domestic capacity.

### A. The Legitimacy Deficit

Human rights norms enjoy varied levels of credibility and institutional backing, which in turn influence their domestic implementation. Despite significant developments in the field of economic, social and cultural rights (of which the right to health is one), this sub-set of human rights is still playing catch up to civil and political rights. Though economic, social and cultural rights formed a core part of the post-World War II body of human rights doctrine, they were soon unlinked from civil and political rights. The drafters of the Universal Declaration of Human Rights (UDHR) had intended it to be the precursor of a single Human Rights Covenant that would make the principles of the Declaration binding on ratifying states.<sup>64</sup> But Cold War politics resulted in the creation of two Covenants instead of one:<sup>65</sup> the ICESCR and the International Covenant on Civil and Political Rights (ICCPR).<sup>66</sup> In so doing, economic, social and cultural rights were essentially subordinated to their civil and political counterparts,<sup>67</sup> despite the obvious interdependence and indivisibility of the two sets of

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<sup>64</sup> U.N. GAOR, *Annotations on the text of the draft International Covenants on Human Rights*, 10th Sess., pt. 2, U.N. Doc. A/2929 (1955), at 7.

<sup>65</sup> Beth Lyon, *Discourse in Development: A Post-Colonial "Agenda" for the United Nations Committee on Economic, Social and Cultural Rights*, 10 AM. U.J. GENDER SOC. POL'Y & L. 539-41 (2002).

<sup>66</sup> ICCPR, *supra* note 31, at 171.

<sup>67</sup> Attempts to include economic, social and cultural rights in the UDHR also faced strong opposition. See Henry J. Steiner, Philip Alston & Ryan Goodman, *Economic and Social Rights*, in INTERNATIONAL HUMAN RIGHTS IN CONTEXT: LAW, POLITICS, MORALS 271 (3d ed. 2008).

rights.<sup>68</sup>

Much has changed in the decades since the promulgation of the ICCPR and ICESCR to push economic, social and cultural rights to the front of the human rights agenda, and navigate their salience in the context of economic globalization.<sup>69</sup> But economic, social and cultural rights still lack the normative pull and moral cachet that is enjoyed by civil and political rights. Advocates seeking to ensure that states are held accountable to these obligations therefore face this additional hurdle on top of navigating an already complex field.

### **B. The Accountability Deficit**

International human rights law embodies a set of hard obligations that states must live up to as States parties to various human rights treaties. But what does it mean to have hard obligations without accompanying mechanisms to ensure enforcement? International human rights law suffers from a case of primacy without enforceability leading to a significant accountability deficit. While the normative content of right to health and access to medicines may enjoy greater clarity, the ability to enforce these rights or effectively reconcile them with international financial obligations remains relatively weak.

This is especially so in the context of intellectual property law, which embodies a highly developed transnational regulatory framework. The TRIPS Agreement “contains detailed,

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<sup>68</sup> See generally Craig Scott, *The Interdependence and Permeability of Human Right Norms: Towards a Partial Fusion of the International Covenants on Human Rights*, 27 OSGOODE HALL L.J. 769 (1989); see also CHR Res. 2001/30, *Question of the realization in all countries of the economic, social and cultural rights contained in the Universal Declaration of Human Rights and in the International Covenant on Economic, Social and Cultural Rights, and study of special problems which the developing countries face in their efforts to achieve these human right*, ¶ 4(d), U.N. Doc. E/CN.4/RES2001/30 (Apr. 20, 2001) (Comm’n on Hum. Rts. reaffirming “the universality, indivisibility, interdependence and interrelatedness of all human rights and fundamental freedoms . . . promoting and protecting one category of rights should therefore never exempt or excuse States from the promotion and protection of other rights.”).

<sup>69</sup> See, e.g., Smita Narula, *The Right to Food: Holding Global Actors Accountable Under International Law*, 44 COLUM. J. TRANSNAT’L L 691 (2006).

comprehensive substantive rules and is linked to the WTO's comparatively hard-edged dispute settlement system in which treaty bargains are enforced through mandatory adjudication backed up by the threat of retaliatory sanctions."<sup>70</sup> Where human rights obligations come into conflict with WTO obligations, the pressure to adhere to WTO rules is far stronger than is the pressure to uphold human-rights; countries may be punished for failing to follow WTO rules but not for ignoring the recommendations of U.N. human rights treaty bodies. Violating human rights may lead to swift condemnation by civil society groups, but these protests do not generate the same level of pressure as is imposed by the market and domestic financial actors to stay the course with economic policy rules.

States are also not the only actors at play. Both intergovernmental organizations and non-state actors such as big pharmaceutical companies play a significant role in shaping and determining access to medicine globally. Yet despite significant efforts to broaden the scope of human rights duty-bearers to include other actors, as briefly described in Part I, international human rights law remains a very state-centric enterprise. The majority of human rights adjudicative decisions limit states' obligations to respecting, protecting, and fulfilling the rights of individuals in their territory or under their jurisdiction, and the foundational human rights documents do not adequately address the obligations of trans-national corporations and international financial institutions.<sup>71</sup> Powerful foreign states are increasingly urged to take cognizance of their extra-territorial obligations. While the idea is gaining force, it is still a relative newcomer to the scene.<sup>72</sup>

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<sup>70</sup> Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 *YALE J. INT'L L.* 1 (2006) 2.

<sup>71</sup> Smita Narula, "International Financial Institutions, Transnational Corporations and the Duties of States," in *GLOBAL JUSTICE, STATE DUTIES: THE EXTRA-TERRITORIAL SCOPE OF ECONOMIC, SOCIAL AND CULTURAL RIGHTS IN INTERNATIONAL LAW* (Malcolm Langford, Martin Scheinin, Wouter Vandenhole, and Willem van Genugten eds.) (New York: Cambridge University Press, forthcoming 2012).

<sup>72</sup> See generally *GLOBAL JUSTICE, STATE DUTIES: THE EXTRA-TERRITORIAL SCOPE OF ECONOMIC, SOCIAL AND CULTURAL RIGHTS IN INTERNATIONAL LAW* (Malcolm Langford, Martin Scheinin, Wouter Vandenhole, and Willem van Genugten eds.) (New York: Cambridge University Press, forthcoming 2012).

There remains of course the problem of a lack of political will on the part of states. In many cases, the issue is not that IFIs and corporations are not accountable to international human rights law; it is that states are not accountable to their citizens, allowing them to selectively implement only those obligations that favor members of the domestic elite.

Given the difficulties outlined above, how and whether these obligations and norms translate in-country can depend greatly on the capacity and political inclination of domestic actors, as well as the extent to which domestic agendas align with the goals of transnational networks.

### **C. The Capacity Deficit**

In the absence of an effective international regulatory framework for human rights, domestic actors and mechanisms act as the enforcers of human rights obligations.<sup>73</sup> The extent to which international pronouncements and norms find coherence domestically and effectively overcome both legitimacy and accountability deficits therefore depends on a number of factors: Does civil society have the capacity and inclination to play an active role?; Is there legislative and judicial support to translate and implement human rights obligations?; How robust is the support and pressure exerted by other global actors, including transnational advocacy networks?

A number of domestic actors can potentially play a role in successfully giving domestic traction to international norms and agreements. Yet these actors may lack the capacity to effectively take on this critical role. For one, if both the state's and civil society's engagement with human rights have largely been framed in civil and political rights terms, as is the case for a number of countries that are the subject of this volume, then the capacity or even political inclination of domestic actors to engage with

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<sup>73</sup> Indeed, as part of their duty to fulfill and facilitate human rights, states must undertake legislative, administrative, budgetary, and judicial action in order to create a general framework in which these rights may be realized. General Comment No. 14, *supra* note 14, ¶ 33.

economic and social rights—which engage broad-based macro-economic and public health frames—may be severely limited.

These actors also do not benefit from sufficient guidance from human rights treaty bodies set up to monitor states' implementation of their human rights obligations. A number of countries that are the subject of cases studies in this volume have appeared before treaty bodies as part of a periodic review of their human rights performance. Guidance offered to these states and domestic actors therein comes in the form of concluding observations and recommendations but is not laid out in great detail.<sup>74</sup> The reason, in part, is the significant leeway and deference given to states to tailor their approaches as they see fit taking into consideration the contextual specificity of conditions in-country.

Litigation has played a key role in the enforcement of rights.<sup>75</sup> A great deal of advocacy is, for example, occurring in national courts in Central and South America.<sup>76</sup> But litigation has its limits. In Brazil, for example, even though the constitutional recognition of the right to health has been broadly interpreted to mean an individual right to the best treatment—leading to a large tide of access to medicines litigation—the benefits of litigation have not been equally distributed across the population and seem

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<sup>74</sup> See, e.g., CESCR, *Concluding Observations of the Committee on Economic, Social and Cultural Rights: Chile*, ¶ 60, U.N. Doc. E/C.12/1/Add/105 (Nov. 26, 2004) (concluding that “[t]he Committee encourages the State party to provide greater access to generic medicine making use of the flexibility clauses permitted in the World Trade Organization on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement).”).

<sup>75</sup> See, e.g., cases cited in *supra* note 12. See also, Lisa Forman, “Rights” and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines?, 10 HEALTH & HUM. RTS. 37 (2009) (arguing that “the AIDS medicine experience and the seminal corporate litigation in South Africa in 2001, in particular, point to the transformative potential of the right to health to raise the priority of public health needs in trade-related intellectual property rights, and to advance access to critical health interventions in resource-poor settings.”)

<sup>76</sup> HELFER AND AUSTIN, *supra* note 1, at 152, citing Alicia Ely Yam & Oscar Parra-Vera, *How Do Courts Set Health Policy? The Case of the Colombian Constitutional Court*, 6 PUB. LIBRARY OF SCIENCE MED. 147, 149 (2009) (stating that Central and South America are “characterized by rights-rich constitutions, high social exclusions, and systemic failures of representation by the political branches of government.”).

to have been captured by those who can already afford to adjudicate their claims.<sup>77</sup> The ability of these cases to affect broader systemic reform has also come into question.<sup>78</sup>

Difficulties also arise in the very act of adjudicating the right to access to medicine. States and corporations could effectively argue that intellectual property laws fulfill these rights obligations in the long term by fostering innovation, even if they hamper access in the short term. Unless legislatures take on the role of providing strong direction regarding the primacy of human rights, judicial pronouncements will likely be weak.

Even when domestic actors succeed in incorporating human rights elements into agreements, domestic implementation may fall far short of expectations due to structural impediments and institutional problems. India's experience is a case in point. When India signed TRIPS in 1995, the country's large generic drug manufacturing sector and active civil society were already alert to the possible implications for the right to health and access to essential medicines.<sup>79</sup> Despite intense domestic and international advocacy, and a relatively successful campaign to incorporate public health flexibilities into national implementing legislation, research has shown that it has been difficult to make use of the existing legal flexibilities. Limits on administrative resources limit patent offices' abilities to rigorously impose existing standards and impede the ability to find out about, and therefore contest, problematic patent claims.<sup>80</sup> The transnational legal expertise that often accompanies intellectual property advice and litigation tends to gloss over unique elements in the Indian law, exerting a harmonizing effect with more restrictive standards from other jurisdictions.<sup>81</sup> Finally, there is always the threat that

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<sup>77</sup> Octavio Luiz Motta Ferrz, *The Right to Health in the Courts of Brazil: Worsening Health Inequities?*, 11 HEALTH AND HUMAN RIGHTS 33, 34 (2009).

<sup>78</sup> *Id.*

<sup>79</sup> Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571 (2009).

<sup>80</sup> Kapczynski, *supra* note 79, at 1617-1618; Sudip Chaudhuri, Chan Park and K.M. Gopakumar, *Five Years into the Product Patent Regime: India's Response*, (United Nations Development Programme 2010) at 16

<sup>81</sup> Kapczynski, *supra* note 79, at 1622.

jurisdictions offering a high amount of patent protection will unilaterally retaliate if flexibilities are too liberally implemented.<sup>82</sup>

The extent to which domestic agendas are able to link up with global advocacy priorities also seems to be a critical factor for other countries. In South Africa, for example, the domestic generic pharmaceutical industry played a key role in bringing forward a lawsuit that eventually authorized the use of key public health flexibilities in TRIPS. The first round of litigation brought by the domestic industry representatives focused on the provisions of the TRIPS Agreement itself and South Africa's constitutional protections for property.<sup>83</sup> It was not until the appellate stages of litigation that civil society organizations became involved, pushing their arguments using a right to health framework that drew from international and domestic law and allowed them to argue that the right to health should have primacy over corporate property rights.<sup>84</sup> South African human rights groups were also able to coordinate with a large international advocacy community, creating an international day of action spanning thirty cities on the day the case was heard, and obtaining statements of support from the European Union, Holland, Germany, France and the World Health Organization.<sup>85</sup>

As the above makes clear, there are significant obstacles to implementing the rights-based approach to intellectual property and access to medicines. These obstacles emerge in the context of both horizontal and vertical fragmentation in the realm of international law. Horizontally, states' human rights obligations may not cohere with their financial commitments, despite calls for such coherence by numerous human rights actors. Vertically, international norms may not translate into domestic implementation. As briefly described below, such fragmentation has already rolled back some hard fought civil society gains.

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<sup>82</sup> Kapczynski, *supra* note 79, at 1627.

<sup>83</sup> Forman, *supra* note 75, at 42.

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

<sup>85</sup> *Id.*

### III. CONCLUDING OBSERVATIONS

The past decade has witnessed immense developments in international human rights law on the issue of intellectual property and access to medicines. The significant and enduring involvement of a number of human rights and civil society actors has led to the development of principles and guidelines that have kept pace with the globalization of international trade rules and have sought to respond to the urgency of ensuring access to medicines in the context of global pandemics.<sup>86</sup> Advocacy by international human rights and global health advocates has also secured important TRIPS-related flexibilities and has raised awareness of these issues within the WTO. Health activists' engagement with the WTO was most extensive in 2001, when NGOs and developing countries worked in tandem to push through the Doha Declaration on TRIPS and Public Health.<sup>87</sup>

More recent negotiations in the WTO have stalled, however, perhaps leading to an increased focus on human rights bodies on the one hand, and bilateral or multilateral regional trade agreements on the other.<sup>88</sup> Hard-won TRIPS flexibilities are turning out to be quite cumbersome, making people rethink the "win."<sup>89</sup> Countries have also been pressured to sign TRIPS Plus

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<sup>86</sup> Kapczynski, *supra* note 79, at 1584-85 (noting that the HIV/AIDS crisis provided a focal point for access to medicines campaigners, who articulated TRIPS as a key barrier to affordable generic AIDS medicines in developing countries).

<sup>87</sup> *Id.* at 1585-86 ("The Declaration extended the transition period afforded to least-developed countries with regard to pharmaceuticals, addressed certain limitations on the export of generic medicines under compulsory license, and affirmed unequivocally that TRIPS 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.'").

<sup>88</sup> Helfer, *supra* note 63 at 973-975.

<sup>89</sup> HELFER AND AUSTIN, *supra* note 1, at 124, *citing* Frederick M. Abbott & Jerome H. Reichman, *Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L., 921, 921, 932 (2007); the TRIPS waiver and amendment are "saddled with unnecessary administrative hurdles" that make the export of generic versions of patented drugs neither "simple [n]or expeditious"; and Jessica L. Greenbaum, *TRIPS and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication in the Wake of the Paragraph 5 Waiver*, 25 J. CONTEMP. HEALTH L. & POL'Y 142, 151-152 (2008) (commenting that there are numerous practical obstacles outside the intricacies of the formal

regional or bilateral treaties, with patent protection rules that may go beyond TRIPS.<sup>90</sup>

Although it may be that “in this maelstrom of reaction, resistance, and regime shifting, international human rights law is poised to become an increasingly central subject of contestation,”<sup>91</sup> it is not clear how effective the pronouncements of human rights bodies are or will be. Ongoing problems remain with implementation of the hard-won TRIPS flexibilities and of recommendations made by UN human rights bodies and Special Rapporteurs. Even the most robust articulations of human rights domestically or the most significant victories internationally do not necessarily translate into a bottom up realization of rights.

Ultimately the full and equitable realization of the right to adequate health depends greatly on the capacity and political inclination of domestic actors to ensure that international norms enjoy local traction. Conclusions regarding the extent to which human rights primacy can be realized in the realm of access to medicines are therefore highly country and context-specific. A key contribution of the case studies in this volume will be to provide the specificity needed to draw such conclusions and press critical rights claims.

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legal system that stand in the way of effectively utilizing the flexibilities. See also HELFER AND AUSTIN, *supra* note 1, at 127-43, detailing individual countries’ difficulties in implementing compulsory license flexibilities.

<sup>90</sup> See Abbott & Reichman, *supra* note 89.

<sup>91</sup> Helfer, *supra* note 63, at 975.