

# **Global Health Governance, Intellectual Property and Access to Essential Medicines: Opportunities and Impediments for South-South Cooperation**

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*Intellectual property “rights,” in many complex ways, impede access to Anti-Retroviral (ARV) drugs in most developing countries with heavy burdens of AIDS-related mortality and morbidity. This article argues that developing countries that lack the necessary pharmaceutical capacity should exploit emerging opportunities for South-South cooperation. While countries like Brazil and India have produced generic ARV drugs, most developing countries either do not have the technology to do so or they are “pressured” against doing so because of the consequences of violation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) enforced by the World Trade Organization. Most recently, Uganda entered into an agreement with Cipla, an Indian generic manufacturer of ARV drugs to open a drug plant in Uganda. Because such opportunities for South-South cooperation abound in contemporary global AIDS diplomacy, developing countries should ingeniously exploit them in ways that do not violate TRIPS. The impediments to this framework would include circumventing the hurdles posed by TRIPS as well as the pressure by global pharmaceutical corporate giants against such initiatives.*

## **PROLOGUE: THE CRUX OF THE ARGUMENT**

*Our response to AIDS has so far been a failure. There has been scientific progress, but with few dividends for people living with poverty as well as HIV – Paul Farmer<sup>1</sup>*

It is now widely accepted within global health governance communities that HIV and AIDS pose enormous challenges for what international scholars refer to as the governance architecture of the international system.<sup>2</sup> In well over two decades since the emergence of AIDS as a global health and developmental challenge, it appears that, as Paul Farmer put it in 2003, global policy initiatives and governance responses to the disease have “so far been a failure.”<sup>3</sup> Farmer’s allusion to “failure” is reinforced by the paradox of mass misery in the midst of plenty – the “few dividends” that vulnerable people living with the double burdens of HIV and poverty have derived from the enormous progress so far made by the global scientific community on AIDS treatment. Farmer’s assertion should be understood and situated within the facts and challenges of access to antiretroviral drugs by people living with poverty as well as HIV, especially in sub-Saharan Africa as of 2003. Since then, there has been a tremendous increase, almost twelve-fold from 2003-2009, in the numbers of people living with HIV and AIDS with access to antiretroviral treatment to reach 5.25 million people today. The vast majority of these individuals receive treatment with generic

drugs, which has been possible because many developing country governments have made use of a range of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) enforced by the World Trade Organization (WTO). These TRIPS flexibilities include compulsory licensing,<sup>4</sup> parallel importation, government procurement/use, and the waiver granted the Least Developed Countries (LDCs) until 2016 to change their national legislation to become TRIPS-compliant.<sup>5</sup> In a 2009 study, Ellen 't Hoen found that since the 2001 WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health, “between 2001 and end of 2007, 52 developing and least-developed countries have issued post-Doha compulsory licenses for production or import of generic versions of patented medicines. ...Many countries have also used the flexibilities as leverage in price negotiations with patent-holding pharmaceutical companies.”<sup>6</sup> These authorizations based on TRIPS flexibilities have been applied primarily to anti-retroviral drugs for HIV and AIDS.

Although the tremendous increase in access to antiretroviral drugs by people living with HIV or AIDS marks a dramatic shift in the effectiveness of global health governance since 2003, there still exist glaring disparities in access to medicines for HIV and AIDS between people living with HIV in developed and developing (including the least-developed) countries. These disparities have continued to challenge global health (including AIDS) governance policies and frameworks. Commenting on these disparities, 't Hoen observed that:

[T]he magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines they need to treat disease or alleviate suffering. The high cost of AIDS medicines has focused attention on the relationship between patent protection and high drug prices.<sup>7</sup>

Although policy responses to HIV encompass prevention, treatment, care and support, this article offers a perspective that explores the opportunities and challenges for South-South cooperation that could facilitate increased access to AIDS medicines in the countries of the global South. Although the argument(s) canvassed in this article and the policy conclusions would have been strengthened by interviews with the key players and actors—civil society, advocacy groups, non-governmental organizations, government, industry and representatives of inter-governmental institutions—due to time and other constraints, the article rather deploys literature review as the primary methodology. Based on rigorous analysis of relevant academic literature, policy frameworks of international organizations, and research and information generated by civil society groups, this article highlights the opportunities and impediments for South-South cooperation, and draws policy conclusions on the linkages between intellectual property and access to medicines for HIV and AIDS in developing countries.

## **MEDICINES AND INTELLECTUAL PROPERTY: WHERE ARE THE LINKAGES?**

The disproportionate distribution of the mortality and morbidity burdens of AIDS between the poorer and industrialized regions of the world reinforces the “Life vs. Profit” debate.<sup>8</sup> This discourse is important because it pitches the huge profit by pharmaceutical corporate actors against access to essential medicines by vulnerable populations in developing and least-developed countries, and the right to health against intellectual property protection.<sup>9</sup> Since AIDS is an incurable but treatable disease, the impediments to accessing antiretroviral drugs (ARVs) by people living with HIV in poor countries are compelling factors that demand a reassessment of the policy framework for emergent South-South cooperation.

This framework would inevitably engage with, and confront the normative architecture of global intellectual property regimes, especially the WTO’s TRIPS Agreement. TRIPS – an agreement that emerged with the WTO at the end of the Uruguay Round of trade negotiations in 1995 – has been the subject of insightful analytical inquiry.<sup>10</sup> In summary, TRIPS seeks to harmonize certain aspects of intellectual property globally by setting a minimum level of intellectual property protection for all WTO member-states in their national legislation. Although TRIPS “codified flexibilities found on age-old practices of parallel imports and compulsory licensing in intellectual property law, legitimate efforts by a few developing countries to pursue these measures in the face of high prevalence of HIV/AIDS among their populations were either blocked or legally challenged by some industrialized member-states of the WTO.”<sup>11</sup>

It is not surprising therefore that within the first decade of the life of the TRIPS Agreement (1995-2005), initiatives aimed at balancing the imperatives of intellectual property “rights”, and access to life-saving pharmaceutical drugs such as the Doha Declaration on TRIPS and Public Health in 2001, and the WTO General Council Decision in 2003 emerged – in part due to civil society activism fuelled by a coalition of developing countries,. In the context of the Doha Declaration and the 2003 Decision, most scholars and commentators have rightly observed that difficult questions still linger on how and when to use TRIPS flexibilities, the impact of TRIPS-Plus obligations<sup>12</sup> on access to drugs, and how to reconcile “conflicting” provisions of intellectual property, and human rights treaties.<sup>13</sup> Balancing the imperatives of the preservation and promotion of health (including access to ARVs by people living with HIV—particularly the poor), and the entitlement of an inventor to the material benefits of a scientific innovation (which could be patents for pharmaceutical drugs like ARVs) poses a difficult challenge. At the global and regional levels, multilateral and bilateral trade agreements that often “midwife” and drive intellectual property norms seem to impede health “regimes” that promote universal access to “essential medicines.”<sup>14</sup> and the right of everyone to the highest attainable standard of physical and mental health.

In recent years, the “intellectual property versus access” discourse seems to have shifted from a trade-off between intellectual property and access towards “innovation-plus-access” - a more holistic framework championed and advocated by civil society and developing countries aimed at generating health-

driven research and development. This new framework would strike a delicate balance between promoting and protecting the basic right to health (access to medicines), and the “right” of an inventor to the fruits and rewards of an invention. This shift, which is captured in the 2008 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPoA), adopted at the 2008 World Health Assembly, is being led by health authorities under the auspices of the World Health Organization (WHO). Albeit innovative in many ways, the success and sustainability of the “innovation-plus-access” framework as embodied in the GSPoA will, as ‘t Hoen observed, “depend on WHO’s forcefulness and resolve.”<sup>15</sup> Given WHO’s past history, which often favors non-binding (soft-law) governance instruments as opposed to legally-binding norms,<sup>16</sup> and the perceived or actual trumping of health by trade and economic interests, it is open to debate whether WHO could be resolute enough to push the GSPoA framework to confront the normative architecture of the WTO to effectively satisfy public health, and trade-economic-intellectual property interests in a win-win scenario.<sup>17</sup>

### **OPPORTUNITIES AND IMPEDIMENTS FOR SOUTH-SOUTH COOPERATION TO INCREASE ACCESS TO ARVs**

Post-TRIPS debate on intellectual property versus access to ARV drugs has catalyzed the expansion of the opportunities for pragmatic uses of TRIPS flexibilities. The WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001, affirmed 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.” The Declaration also affirmed that WTO member-states (the least-developed and most developing countries) with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. The Doha Declaration was supplemented by the 2003 Decision of the General Council of the WTO on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The 2003 Decision provides criteria aimed at facilitating access to essential medicines, including ARVs, by vulnerable populations in the least developed and developing countries.

Both the 2001 Doha Declaration and the 2003 WTO General Council Decision were fraught with serious structural impediments. While the Doha Declaration offered an interpretive paradigm that raised the visibility of public health and universal access to medicines in international trading relations, it offered no concrete road-map for technologically-challenged WTO member-states whose pharmaceutical sectors are either dysfunctional or totally non-existent. This is complicated by two factors. First, past efforts by countries like South Africa and Brazil to deploy TRIPS flexibilities in the face of genuine AIDS “emergencies” in their populations were challenged by both the United States and global pharmaceutical corporations in different forums.<sup>18</sup> While these challenges and pressures by the “Big Powers” including the dreadful Special 301 Reports of the Office of the U.S. Trade Representative (USTR) have considerably reduced,

they have not been completely eliminated. Second, whatever progress made by the Doha Declaration, and the WTO General Council Decision towards expanding the TRIPS opportunities are now gradually being reversed globally by the proliferation of bilateral and regional Free Trade Agreements (FTAs) that impose TRIPS-Plus obligations on developing countries that are always the weaker partners in such bilateral agreements.<sup>19</sup> Although some scholars argue that U.S. FTAs with most developing countries, in particular, are either currently mostly on hold<sup>20</sup> or will not independently achieve the goal of strengthening plurilateral patent norms,<sup>21</sup> there is no evidence that these FTAs will not be resuscitated, re-designed or re-negotiated in the future to achieve that goal.

The objective of the 2003 WTO General Council Decision was to facilitate access to essential medicines (including ARVs), especially for the least-developed and developing countries with insufficient or no manufacturing capacities in the pharmaceutical sector. Many developing countries lack a viable pharmaceutical sector with a technological capacity for domestic production of generic ARVs for the treatment of HIV, AIDS or other opportunistic infections. These countries, therefore, cannot issue compulsory licenses for the production of generic ARV drugs simply because they lack the technological capacity to produce generic medicines. Faced with this technological incapacity, the only viable option for these countries is a process that involves importing generic versions of the drugs from an industrialized country that is willing to amend its patent legislation in order to produce those drugs exclusively for export to poor countries where they are most needed by people living with HIV. Although the 2003 General Council Decision provides an additional incentive to increase access to ARVs in developing countries, most countries have not had to resort to it because India, one of the big generic producers, has been able to export generic ARVs without issuing compulsory licenses. This has been possible because India, as a member-state of the WTO, did not adopt medicines product patents until 2005 to make its intellectual law TRIPS-compliant. Also, most ARVs currently recommended by the World Health Organization are not patented in India.<sup>22</sup> Looking into the future, many scholars have predicted that the Indian generic medicines sector will likely shift its business orientation away from supplying medicines to the developing world, and towards exporting off-patent generics to more affluent markets.<sup>23</sup>

Because of this trend in the Indian generic medicines sector, which could also be the case in other countries of the global South with a thriving generic sector, the framework offered by the 2003 Decision has to be assessed to make it more effective and sustainable. The 2003 Decision provides for key obligations on exporting and importing countries for these medicines. There is, for example, an obligation on countries to notify the WTO of an intention to become an eligible importing member, and specifically to identify the products and quantities. In the seven years since the 2003 WTO General Council Decision was adopted, Canada was the first and probably the only industrialized country that amended its patent laws - in what is now known as "Canada's Access to Medicines Regime" (CAMR) - to allow domestic production of generic drugs exclusively for export to a poor country hit by HIV that files a request at the WTO

for importation of such drugs.<sup>24</sup> Following the CAMR as well as the requirements of the 2003 WTO General Council Decision, Apotex, a leading Canadian generic pharmaceutical manufacturer – at the request of MSF – developed a new fixed-dose combination tablet that combines existing ARV drugs – zidovudine (AZT), lamivudine (3TC), and niverapine into a single tablet for the first time for export under compulsory license to developing countries.<sup>25</sup> In July 2007, Rwanda became the first country to initiate the use of a procedure under WTO Rules that allows developing countries to import low-cost, generic medicines produced in other countries under compulsory licenses. In a Notification deposited at the WTO, Rwanda notified the organization of its intention to use the 2003 procedure to import 15.6 million doses of the fixed-dose combination produced by Apotex in Canada.<sup>26</sup>

In the long process that eventually led to the production of the three drugs into one fixed-dose, Apotex held complex negotiations with three Canadian pharmaceutical companies that owned patent rights on the three drugs before it finally got the compulsory license issued on 19 September, 2007. Canada subsequently notified the WTO of this development as required by the 2003 WTO General Council Decision. At the time of export to Rwanda, this generic single fixed-dose combination cost about US\$0.40 per tablet as opposed to US\$20 per tablet in the U.S. using the patented brands.<sup>27</sup> Although the Canadian CAMR regime is commendable, it is fraught with serious administrative bottlenecks, especially the long and often frustrating procedure of negotiations between the patent holders and generic drug producers for compulsory licenses. Because these negotiations took years, there is little or no incentive for most generic drug companies to pursue such CAMR initiatives in the future. In a recent media report, Bruce Clark, the Vice-President of Apotex, stated that the steps needed to produce generic drugs for export under CAMR “are simply too difficult and complicated. As it is currently written, we will not use it again.”<sup>28</sup> Even for Canada and other industrialized countries that might contemplate amending their patent legislation to take advantage of 2003 WTO General Council Decision, the real question remains whether such countries could withstand the pressure and corporate lobbying by the powerful pharmaceutical industry. As one commentator observed, “corporate pressure is nothing new in WTO negotiations. Such pressure, largely exerted by U.S.-based firms, is widely acknowledged to have been a driving force in the negotiations.”<sup>29</sup>

The limits of the Canadian CAMR regime and the unwillingness of other industrialized countries to expand TRIPS flexibilities along the lines provided in the 2003 WTO General Council Decision will leave most developing countries with the only option of pursuing South-South cooperation as a way to increase access to ARVs for their HIV-positive populations. This could take the form of foreign direct investment (FDI)-driven joint ventures with countries like India and Brazil that have well-established pharmaceutical sectors for generic ARV drug production. In 2007, for instance, Uganda commissioned a facility to produce generic ARVs locally in Uganda based on a joint-venture with Cipla, an Indian generic producer. Available data from WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) suggest that about 41% of Ugandans who need ARVs receive those drugs mainly from programs funded by the Global Fund

to Fight AIDS, Tuberculosis and Malaria (Global Fund), and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Although the Cipla-Uganda venture is a notable development in South-South cooperation, it is not yet clear if locally-produced drugs in Uganda will be cost-competitive with generic imports from India. Should the locally-produced drugs in Uganda be cost-competitive with imports from India, this will significantly increase access to ARVs in Uganda. Some other African countries – Ghana, Tanzania, and Ethiopia - have started exploring the feasibility of local production of generic ARV drugs along the lines of the Uganda-Cipla venture. Whether these South-South initiatives for increased access to ARV drugs in developing countries are sustainable is open to debate. Nonetheless such initiatives have opened a new vista in the global governance of AIDS as countries like India and Brazil emerge as part of the “Southern” engines of growth and development. However, one major challenge for future South-South cooperation is the rapidly changing orientation of the pharmaceutical industry in the BRIC countries (including Brazil and India) towards strong patent regimes/protection driven by the WTO obligation on these countries to amend their intellectual property laws to become TRIPS compliant.

Beyond local production of pharmaceuticals, as exemplified by the Cipla-Uganda joint venture, there exists considerable South-South collaboration on the larger intellectual property and access to medicines policy issues. Such collaboration includes the formation of political alliances between governments and civil society to push for shared interests in global policymaking arenas such as WHO, WTO and WIPO, and direct civil society-to-civil society networks that share information, strategies, and other resources across national boundaries to push for greater policy space in implementing TRIPS.<sup>30</sup> Specifically on trade and intellectual property issues, South-South collaboration has been intensified by the actual and perceived impact of trade liberalization on the social policy agenda in most developing countries. As Westerhaus and Castro observed:

With both the intensification of trade negotiations and concern about the impact of trade liberalization on developing countries, it is vital to formulate alternative strategies that promise to mitigate the impact of strengthened [IP] law upon patients. One such example is the Technological Network on HIV/AIDS, a consortium including Brazil, Cuba, China, Nigeria, Russia, Thailand, and Ukraine, and potentially Uruguay, India, and South Africa, that aims to achieve self-sufficiency in the research, development, production, and distribution of ARVs and other related medications.<sup>31</sup>

In his work on access to medicines, BRIC alliances and collective action, Yu argued that:

[I]f less developed countries can use collective action to their advantage, they may be able to not only reduce the ongoing push by the European Communities and the

United States to ratchet up global intellectual property standards, but also will enlarge the policy space that can be used to develop their intellectual property, trade, and public health policies.<sup>32</sup>

This form of collective action would counterbalance the influence of the “Big Powers.” According to Yu:

[I]f less developed countries are to counterbalance the United States’ divide-and-conquer strategy, lest more TRIPs-plus standards be developed at both the multilateral and regional levels, they need to initiate a combine-and-conquer strategy. Simply put, they need to build more coalitions within the less developed world – such as the BRIC coalition, partial BRIC alliances, or various forms of South-South alliances.<sup>33</sup>

It must be noted that South-South cooperation and the formation of political alliances by developing countries is not new in the history of international relations and inter-governmental institutions. Post-World War II, the international system, especially since the establishment of the United Nations, has witnessed such alliances including the Group of 77 developing countries at the UN (“G-77”), South Commission, Non-Aligned Movement, and many others. While the earlier South-South alliances and strategies focused mainly on governmental interactions, the latter day coalitions and alliances have gone beyond the governmental level to focus on direct civil society-to-civil society networks and coalitions, and even in some instances civil society-to-government alliances. These networks are simply a phenomenon of contemporary global health governance which, as Zacher and Keefe observed, “is complicated and messy; ...comprised of numerous and varied actors with competing values, interests and motivations.”<sup>34</sup> These civil society networks come within the rubric of what global governance experts explore as the “cognitive” dimension of globalization – “that affects the creation and exchange of knowledge, ideas, beliefs, values, cultural identities, and other thought processes”<sup>35</sup> across transcontinental distances in an interdependent world.

With thousands of civil society organizations (CSOs) across the world now directly operating in the health sector, “CSOs interact with other CSOs, governments and bureaucracies of nation-states both in the North and the South, bilateral donors, international governmental organizations (IGOs) and transnational corporations in the newly emerging structures of global health governance.”<sup>36</sup> There are numerous examples of how global civil society networks have produced tangible results in the fight for access to essential medicines for HIV and AIDS. These examples range from the campaigns led by *Medecins Sans Frontieres* (“Doctors Without Borders”) in the 1990s advocating and campaigning for access to ARVs for the poor<sup>37</sup> to the advocacy and “public interest” litigation in South Africa championed by the Treatment Action Campaign (TAC) and other groups.<sup>38</sup> These and many other models are now

being “globalized” and replicated in many developing countries with high numbers of people living with AIDS. To paraphrase James Orbinski, if global health is best conceptualized as the pursuit of equity, justice and fairness, and as fundamentally considering public health measures and access to health care and healthcare technologies, such as drugs, as a basic human entitlement, then “social movements matter, and matter a lot.”<sup>39</sup>

### **EPILOGUE: TOWARDS HUMANE GOVERNANCE OF AIDS**

Global governance of AIDS is a complex phenomenon in an asymmetric international system with inequalities and disparities between under-developed, developing, and industrialized countries as well as divergent interests between nation-states and transnational corporate actors. While these disparities and divergent interests are not peculiar to AIDS diplomacy, as they are embedded in the orthodoxy of global governance architecture as a whole, they nonetheless raise complicated questions for policy coherence within the mandates of multilateral institutions like the World Health Organization and the WTO. To what extent are the goals and objectives of the WHO that are oriented towards ‘universal access to drugs’, and the right to “the enjoyment of the highest attainable standard of health.”<sup>40</sup> either undermined or supported by the intellectual property regime enforced by the WTO? While the perspective offered by this article does not exhaustively answer this complex question, it is important to point out that the “trade versus health” tensions in global health governance require the creation of sufficient policy space to enable weaker nation-states to strengthen their institutional capacity to generate and promote public goods, taking into account each country’s specific socio-economic context.<sup>41</sup> This is feasible even in multilateral settings like the WTO. This is what the flexibilities codified in the TRIPS Agreement are meant to achieve. Within this framework, the emergent “Southern” global economic players with thriving pharmaceutical sectors, such as Brazil and India, would partner with developing countries to boost access to ARVs for HIV. The operational framework for this South-South cooperation should be pursued in ways that are TRIPS compliant because, as the Doha Declaration provided, TRIPS and public health are not mutually exclusive.

Finally, a South-South cooperative framework to boost access to ARVs in developing countries should be subject to one important caveat: the solution to the AIDS crisis in most developing countries is not just access to drugs. The health care infrastructure and health systems in most developing countries are dysfunctional, and as such, may not sustain life-long ARV therapies. Availability of drugs without a functioning health care system to administer them effectively does not offer a sustainable solution to the HIV crisis in most of the least-developed and developing countries.<sup>42</sup> While access to ARV drugs must be actively promoted and pursued as an indispensable component of the global governance of AIDS, it is also urgent to address the equally important and related issue of health care reform and financing in order to sustain treatment therapies.

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<sup>1</sup> Paul Farmer, "AIDS as a Global Emergency", *Bulletin of the World Health Organization*, 81, no. 10, (2002): 699.

<sup>2</sup> Andrew F. Cooper, John J. Kirton and Ted Schrecker, eds., *Governing Global Health: Challenges, Response, Innovation* (Aldershot, UK: Ashgate, 2007); Obijiofor Aginam, *Global Health Governance: International Law and Public Health in a Divided World* (Toronto: University of Toronto Press, 2005); Mark W. Zacher and Tania J. Keefe, *The Politics of Global Health Governance: United By Contagion* (New York: Palgrave Macmillan, 2008); David P. Fidler, *SARS, Governance and the Globalization of Disease* (London: Palgrave Macmillan, 2004).

<sup>3</sup> Farmer, "AIDS as a Global Emergency," 699.

<sup>4</sup> Compulsory license enables a government authority to issue a license for the use of a patented invention to a third party or government agency without the consent of the patent-holder subject to payment of adequate compensation.

<sup>5</sup> Ellen F.M. 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* (Diemen, The Netherlands: AMB Publishers, 2009)

<sup>6</sup> Ibid, pXVI. On the links between drugs, policies, markets and prices, see Brenda Waning, et al, "Intervening in Global Markets to Improve Access to HIV/AIDS Treatment: An Analysis of International Policies and the Dynamics of Global Antiretroviral Medicines Markets," *Globalization and Health* 6,no.9 (2010):1-19.

<sup>7</sup> Ibid, p1

<sup>8</sup> Obijiofor Aginam, "Between Life and Profit: Global Governance and the Trilogy of Human Rights, Public Health and Pharmaceutical Patents," *North Carolina Journal of International Law & Commercial Regulation* 31, no 4, (2006): 901-921; Yves Beigbeder, *International Public Health: Patients' Rights vs. the Protection of Patents* (Aldershot, UK: Ashgate, 2004); Susan K. Sell, "The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive, and Institutional Dimensions," *Temple Law Review* 77, (2004): 363-399.

<sup>9</sup> Sarah Joseph, "Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Scrutiny," *Human Rights Quarterly* 25, (2003): 425-452; Caroline Thomas, "Trade Policy and the Politics of Access to Drugs," *Third World Quarterly* 23, (2002): 251-264; Michael A. Santoro and Thomas M. Gorrie, eds., *Ethics and the Pharmaceutical Industry* (New York: Cambridge University Press, 2005); Susan K. Sell, "The Quest for Global Governance in Intellectual Property and Public Health."

<sup>10</sup> Susan K. Sell, "The Quest for Global Governance in Intellectual Property and Public Health" citing Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy* (London: Earthscan, 2002); Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (London: Routledge, 2002).

<sup>11</sup> Obijiofor Aginam, "Between Life and Profit," 909.

<sup>12</sup> TRIPS-Plus refers to legal obligations in bilateral and regional free trade agreements that go beyond the already high standards of the WTO's TRIPS Agreement.

<sup>13</sup> James Thuo Gathii, "The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties", *Harvard Journal of Law and Technology*

15, (2002): 291-317; Steve Charnovitz, "The Legal Status of the Doha Declarations," *Journal of International Economic Law* 5, (2002): 207-211; Frederick M. Abbott, "The WTO Medicines Decision: Pharmaceutical Trade and the Protection of Public Health," *American Journal of International Law* 9 (2005): 317-358.

<sup>14</sup> The World Health Organization defines essential medicines as "those medicines that satisfy the health needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage form". See WHO, *Action Programme on Essential Drugs, Globalization, and Access to Drugs: Perspectives on the WTO/TRIPS Agreement* (Geneva: WHO, 1999), 10.

<sup>15</sup> Ellen 't Hoen, note 4, p93

<sup>16</sup> See generally, David P. Fidler, *International Law and Infectious Diseases* (Oxford: Clarendon, 1999); Obijiofor Aginam, *Global Health Governance*, note 2

<sup>17</sup> On recent perspectives that explore health and trade in foreign policy, see Obijiofor Aginam, "Health or Trade? A Critique of Contemporary Approaches to Global Health Diplomacy," *Asian Journal of WTO & International Health Law and Policy* 5, no.2 (2010):355-380; Ronald Labonte & Michelle L. Gagnon, "Framing Health and Foreign Policy: Lessons for Global Health Diplomacy," *Globalization and Health* 6, (2010): 1-19; David P. Fidler, "The Challenges of Global Health Governance," Working Paper for the Council on Foreign Relations, May 2010 .

<sup>18</sup> Ellen 't Hoen, "TRIPS, Pharmaceutical Patents, and the Access to Essential medicines: A Long Way from Seattle to Doha," *Chicago Journal of International Law* 3, (2002): 27-46.

<sup>19</sup> On TRIPS-Plus, see Chang-Fa Lo, *WTO-PLUS in Free Trade Agreements* (Taipei: Angle, 2010); Pedro Roffe, Johanna Von Braun and David Vivas-Eugui, "A New Generation of Regional and Bilateral Trade Agreements: Lessons from the US-CAFTA-DR Agreement", in *Trade and Health: Seeking Common Ground*, ed.C. Blouin, J. Heymann and N. Drager (Montreal & Kingston: McGill/Queen's University Press, 2007), 41-89.

<sup>20</sup> William H. Cooper, "Free Trade Agreements: Impact on US Trade and Implications for US Trade Policy," Congressional Research Service, Washington, DC, February 23, 2010.

<sup>21</sup> J. Morin, "Multilateralising TRIPS-Plus Agreements: Is the US Strategy a Failure?," *The Journal of World Intellectual Property* 12, no.3 (2009):175-197.

<sup>22</sup> 't Hoen, note 4, p37

<sup>23</sup> Ibid, p37 citing P.G. Sampath, "Economic Aspects of Access to Medicines After 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry," CPIH, 2005

<sup>24</sup> This section of the article draws from the concise but excellent review of Rwanda's request for generic ARVs under Canada's CAMR written by Richard Elliott of the Canadian HIV/AIDS Legal Network. See Richard Elliott, "First Test of WTO Mechanism for Procuring Generic Medicines under Compulsory License, via Canada's Access to Medicines Regime," *HIV/AIDS Policy & Law Review* (Canadian HIV/AIDS Legal Network) 12 no2/3, (2007): 23-25.

<sup>25</sup> Ibid

<sup>26</sup> Ibid

<sup>27</sup> Ibid

<sup>28</sup> Michael Fleshman, "A 'Crisis in Waiting' for AIDS Patients: Trade Rules Will Make it Harder to Get Cheap Generic Medicines," *Africa Renewal* 24, no.1 (2010):17.

<sup>29</sup> Scott Sinclair, *GATS: How the World Trade Organizations New Services Negotiations Threaten Democracy* (Ottawa: Canadian Centre for Policy Alternatives, 2000): 22. On the pressure exerted by the "Big Powers" against the weak states in trade negotiations, see Fatoumata Jawara and Aileen Kwa, *Behind the Scenes at the WTO: The Real World of International Trade Negotiations: the Lessons of Cancun* (London/New York: Zed Books, 2003)

<sup>30</sup> R. Reis; V. Terto Jr & M.C. Pimenta, "Intellectual Property Rights and Access to ARV medicines: Civil Society Resistance in the Global South," Brazilian Interdisciplinary AIDS Association (ABIA), Rio de Janeiro, Brazil, 2009.

<sup>31</sup> M. Westerhaus & A. Castro, "How Do Intellectual Property Law and International Trade Agreements Affect Access to Antiretroviral Therapy?," *PLoS Medicine* 3, no.8 (August, 2006): 1230-1236 citing C.M Morel, et al, "Health Innovation Networks to Help Developing Countries Address neglected Diseases," *Science* 309, (2005):401-404.

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<sup>32</sup> Peter K. Yu, "Access to Medicines, BRICS Alliances, and Collective Action," *American Journal of Law and Medicine* 34, (2008):345-394, at 347. In Yu's work, the acronym BRICS stands for Brazil, Russia, India, China, and South Africa.

<sup>33</sup> *Ibid*, 372-373.

<sup>34</sup> Mark W. Zacher and Tania J. Keefe, *The Politics of Global Health Governance*, note 2, p135

<sup>35</sup> Kelley Lee and Richard Dodgson, "Globalization and Cholera: Implications for Global Governance," *Global Governance* 6, no.2 (2000):213-236, at 215.

<sup>36</sup> Sonja Bartsch and Lar Kohlmorgen, "The Role of Civil Society Organizations in Global Health Governance", in *Global Health Governance and the Fight Against HIV/AIDS*, ed. W. Hein, S. Bartsch and L. Kohlmorgen (New York: Palgrave MacMillan, 2007): 92.

<sup>37</sup> Bartsch and Kohlmorgen, *Ibid*, documented 3 case studies on the successes and challenges of these networks on global health issues, pp104-113.

<sup>38</sup> On the struggle for access in South Africa and the influence of civil society groups, see generally Adila Hassim, Mark Heywood and Jonathan Berger, *Health and Democracy: A Guide to Human Rights, Health Law and Policy in Post-Apartheid South Africa* (Cape Town: Siber Ink, 2007).

<sup>39</sup> James Orbinski, "Global Health, Social Movements, and Governance", in *Governing Global Health*, ed. Andres F. Cooper, John J. Kirton, and Ted Schrecker, note 2:29-40, at 30.

<sup>40</sup> Constitution of the World Health Organization (Preamble), World Health Organization: *Basic Documents* (Geneva: WHO, 2001): 1-21.

<sup>41</sup> Obijiofor Aginam, "Between Life and Profit" note 8 ; Obijiofor Aginam, "The Rights to 'The Highest Attainable Standard of Health': Trade Agreements and the Right to Health in Africa," *African Yearbook of International Law* 15, (2007): 223-235.

<sup>42</sup> WHO Commission on Macroeconomics and Health, *Macroeconomics and Health: Investing in Health for Economic Development*, Report of the Commission on Macroeconomics and Health (Geneva: WHO, 2001).