

## COMMENTARY I

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### Comment: access to essential medicines – promoting human rights over free trade and intellectual property claims

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#### 1. Introduction

Over the past five years, there has been an intense international debate, negotiations at the World Trade Organization (WTO) and a variety of political and legal struggles in various jurisdictions over access to affordable medicines in developing countries. Until recently, the debate focused on the ability of the existing medical infrastructure to address the HIV/AIDS pandemic; but more recently the focus has shifted to questioning whether the heightened patent protection of the TRIPS Agreement<sup>1</sup> allows countries sufficient flexibility to deal with domestic health crises.<sup>2</sup> This question has been increasingly driven by the impact of the global HIV/AIDS pandemic and the threat it poses to economic and political stability, particularly in Africa,<sup>3</sup> and it has motivated two new WTO agreements – at Doha and just before Cancun – aimed at providing flexibility under the terms of the TRIPS Agreement.<sup>4</sup> Most recently, the World Health Organization (WHO), which has been on the forefront of these negotiations, declared that the “failure to deliver

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<sup>1</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 Apr. 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

<sup>2</sup> Carlos Correa, *Implementing the TRIPS Agreement in the Patents Field – Options for Developing Countries*, 1 J. World Intell. Prop. 75 (1998); C. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books 2000). See also Frederick Abbott, *Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines* [this volume].

<sup>3</sup> A. De Waal, *Why the HIV/AIDS Pandemic is a Structural Threat to Africa's Governance and Economic Development*, 27 FLETCHER F. WORLD OF WORLD AFF. 6 (2003).

<sup>4</sup> WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (14 Nov. 2001) [hereinafter Declaration on TRIPS and Public Health]; WTO Council for TRIPS, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W/405 (30 Aug. 2003) [hereinafter WTO, Implementation of Paragraph 6].

AIDS drugs to impoverished people is so grave that it has become a global health emergency.<sup>5</sup> With thousands of people dying each day, the question of access to affordable medicines can no longer be treated as a predominately intellectual property or trade-related issue. Rather, it requires the assertion of a human rights perspective to facilitate access to public goods, particularly when dealing with rights to the knowledge required to produce medicines that combat life-threatening diseases.<sup>6</sup>

Placing public health – in this case the global HIV/AIDS pandemic – at the center of this debate exposes the inherent tensions between the law and policies affecting free trade, intellectual property rights, development, and public health. Instead of debating whether the protection of intellectual property rights (IPRs) will eventually lead to increased innovation and foreign investment in developing countries,<sup>7</sup> or whether current drug prices are justified by the need for future research and development,<sup>8</sup> issues which presuppose a hierarchy of values dominated by free trade and IPRs, advocates of a human rights approach insist on the primacy of public health concerns. This position is supported by an approach to interpreting international agreements that takes the broad goals of the post-World War II United Nations system, particularly the emphasis on human rights reflected in the Universal Declaration,<sup>9</sup> as guiding principles. While this approach does not resolve the real policy debates over economic development, trade and the protection of intellectual property, it does raise questions about the relative importance of the so-called “soft law” set out in the preambles and general principles clauses of relevant treaties as opposed to the so-called “hard law” of specific treaty provisions that purport to guarantee free trade and protect the rights of property claimants against attempts by national governments to address pressing social needs.<sup>10</sup>

<sup>5</sup> Press Release, WHO, World Health Organization Says Failure to Deliver AIDS Medicines is a Global Health Emergency: Global AIDS Treatment Emergency Requires Urgent Response – No More Business as Usual (2003), available at <http://www.who.int/mediacentre/releases/2003/pr67/en/print.html> (visited 26 Sept. 2003).

<sup>6</sup> See I. Kaul & R.U. Mendoza, *Advancing the Concept of Public Goods*, in PROVIDING GLOBAL PUBLIC GOODS: MANAGING GLOBALIZATION 78, 84 (Inge Kaul et al. eds., Oxford 2003).

<sup>7</sup> Robert. Sherwood, *A Larger Context for Considering Pharmaceutical Patents in Developing Countries*, 15 WORLD BULL. 76 (Jan.-Dec. 1999) (Institute of International Legal Studies, University of Philippines Law Center).

<sup>8</sup> H.E. Bale, *Patent Protection and Pharmaceutical Innovation*, 29 N.Y.U. J. INT'L L. & POL. 95 (1997); International Federation of Pharmaceutical Manufacturers Associations (IFPMA), *TRIPS, Pharmaceuticals and Developing Countries: Implications for Health Care Access, Drug Quality and Drug Development* (2000), available at [http://www.ifpma.org/admin/MediaServer.jsr?@\\_ID=431&@\\_MODE=GLB%20\(2000\)](http://www.ifpma.org/admin/MediaServer.jsr?@_ID=431&@_MODE=GLB%20(2000)). See also Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals* [this volume].

<sup>9</sup> Universal Declaration of Human Rights, G.A. Res. 217A (III), U.N. GAOR, UN Doc A/810, at 71 (10 Dec. 1948).

<sup>10</sup> See generally, Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1 (2004).

International law, however, provides no institutional mechanism for resolving these tensions. Instead, this failure in global governance leaves each negotiating or interest community to rely upon its own expertise and assumptions about subject matter and priority to define the parameters of its debate and feasible outcomes. Trade negotiators and their allied professionals, including some economists and trade lawyers, balance and barter concessions – greater IP protection for increased access to agricultural and textile markets<sup>11</sup> – while IP lawyers and other economists focus on increasing the likelihood of innovation and foreign investment.<sup>12</sup> While each arena is guided by its own constituting principles, the range of fora provides opportunities for powerful interests to shape the terrain upon which the rules governing particular issues, such as intellectual property, are formed.<sup>13</sup> However, the emergence of non-government organizations (NGOs) operating within the global system as observers and activists is providing a counter-weight to organized business, particularly in the context of the HIV/AIDS pandemic; NGOs have been campaigning and vocally raising concerns about the impact that policies tailored to suit organized business might have on the health of marginalized populations.<sup>14</sup> Furthermore, so long as the ministries of trade, industry and commerce were the only national authorities conducting the negotiations – whether at the WTO or World Intellectual Property Organization (WIPO) – the relationship between the exploding HIV/AIDS pandemic, access to essential medicines and the developing global trade regime remained in the background.

An effective human rights approach must not, however, be limited to the mere counter-assertion of rights – especially if it takes the form of a simple recitation of the long list of United Nations resolutions or other formal commitments to improving health in general, or even statements and resolutions specifically designed to address the HIV/AIDS pandemic. Rather, it should begin by defining the legal and institutional terrain on which multiple claims, norms and strategic interventions accumulate, with a view to either facilitating or hindering attempts to make public health the first level of concern. Such an approach must also recognize the ways in which different fora have provided alternative loci for competing normative and strategic interventions. These have ranged from the international to the domestic; from WIPO and the WTO to WHO, UNAIDS and the United Nations Conference on the Trade and Development (UNCTAD); from national trade offices to domestic courts. These fora have been used by all sides: those

<sup>11</sup> JAYASHREE WATAL, *INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES* (Kluwer Law International 2001).

<sup>12</sup> *INTELLECTUAL PROPERTY RIGHTS IN EMERGING MARKETS* (Clarisa Long ed., AEI Press 2000).

<sup>13</sup> Peter Drahos & John Braithwaite, *INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?* (New Press 2002). *See also* SUSAN SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* (Cambridge University Press 2003).

<sup>14</sup> *See, e.g.*, Helfer, above n. 10; Abbott, above n. 2.

attempting to protect intellectual property, those working to facilitate the transfer of technology, and those trying to ensure affordable access to essential medicines. Although there have been formal links between some of these fora – with UNCTAD and WHO being invited to attend TRIPS Council meetings on the subject – and even more intensive informal interactions involving negotiators, drug companies, experts and NGOs, so long as these have remained within the rubric of trade negotiations and intellectual property rights, the legal framework has remained dominated by the prerogatives of the WTO agreements.

Focusing on the different sources of law governing human rights, trade, and intellectual property rights, I will argue that, in the debate over access to medicines, there is a need to view the relationship between them in terms of the broader normative goals of the international legal order, rather than simply treating them as bases for contending claims.<sup>15</sup> To do this, it is important to understand the recent and socially-constructed nature of the system of intellectual property rights guaranteed by the TRIPS Agreement and to recognize the implications of characterizing the rules as more or less flexible, or as subject to determination under a particular international or national regime. While much of the excellent academic work on this issue has focused on the construction of the TRIPS Agreement, its implementation, interpretation, or even the growing opposition to it, little attention has been paid to the legal assumptions and implications of the different sources and forms of rights and obligations being deployed by the different participants. Finally, I will focus primarily on the implications of choosing particular legal tools or approaches and the impact these choices have on the question of access to medicines and public health more generally.

### Public health and access to medicines

Until recently, public health has been understood only in terms of measures that are necessary to prevent large-scale epidemics. This preventive approach is evident in the development of the idea of primary health care which “is a blend of essential health services, personal responsibility for one’s own health and health-promoting action taken by the community.”<sup>16</sup> The most effective means for achieving these goals have been the provision of clean water, good sanitation and more recently, widespread vaccination. While these remain the most cost effective and broadly applicable ways to protect public health, the revolution in pharmaceuticals during the twentieth century has blurred the line between treatment and prevention. In the context of the HIV/AIDS pandemic,

<sup>15</sup> Cf. JOOST PAUWELYN, *CONFLICT OF NORMS IN PUBLIC INTERNATIONAL LAW: HOW WTO LAW RELATES TO OTHER RULES OF INTERNATIONAL LAW* 158–236 (2003).

<sup>16</sup> World Health Organization (WHO), *Concepts of Health Development*, WHO 50TH (1998), at [www.who.int/archives/who50/en/concepts.htm](http://www.who.int/archives/who50/en/concepts.htm).

where prevention on its own has proven extremely difficult, the most effective approach seems to lie in the combination of preventive education, treatment, and the lowering of individuals' viral loads. Effective prevention must include treatment and today, particularly in developing countries, this requires access to affordable medicines, which are now understood to be integral to the achievement of public health goals.

At the beginning of the twentieth century, "aspirin was the only widely available modern medicine,"<sup>17</sup> but by the 1970s modern pharmaceuticals existed for nearly every major illness known to medical science. The problem was clearly one of access. According to Dr. Michael Scholtz, WHO's Executive Director of Health Technology and Pharmaceuticals, "one third of the world's population still lacks access to essential drugs while in the poorest parts of Africa and Asia, over fifty percent of the population do not have regular access to the most vital essential drugs."<sup>18</sup> It was in response to this situation that the idea of identifying a list of essential medicines arose and led to the launch of the WHO's essential medicines program in 1977. The program produced model lists of essential drugs that national governments use to make their own local lists; these lists make the task of providing prescribed medications more manageable by limiting the thousands of available medicines to approximately 200 essential ones.

By the turn of the century, over 160 countries had adopted essential drug lists and clinical treatment guidelines based on the WHO's model lists and selection criteria, which effectively doubled access to essential medicines. The criteria laid out for compiling these lists reflect a synergetic amalgam of public health and human rights concerns, with an emphasis on equal access and medical effectiveness. Drugs chosen for an essential medicines list must "satisfy the health needs of the majority of the population; be available at all times in adequate amounts and appropriate dosage forms; and be available at a price that individuals and the community can afford."<sup>19</sup> When it comes to choosing between different available drugs there are five key criteria: relative efficacy, safety, quality, price and availability. Reliance on these criteria has led to an emphasis on off-patent or generic drugs, which still comprise more than 90 percent of the medicines included on the model list.<sup>20</sup>

<sup>17</sup> Dr. M. Scholtz, International Trade Agreements and Public health: WHO's Role, Paper Presented at the Conference on Increasing Access to Essential Drugs in a Globalized Economy, at 1 (Amsterdam, 25–26 Nov. 1999), available at [http://www.who.int/medicines/docs/WTO\\_Public\\_Health\\_Amsterdam\\_MS.html](http://www.who.int/medicines/docs/WTO_Public_Health_Amsterdam_MS.html).

<sup>18</sup> *Id.*

<sup>19</sup> World Health Organization, WHO 50th: Concepts of Health Development (1998), at [www.who.int/archives/who50/en/concepts.htm](http://www.who.int/archives/who50/en/concepts.htm) (last visited 3 Oct. 2003).

<sup>20</sup> World Health Organization, The Use of Essential Drugs, Ninth Report of the WHO Expert Committee (including the Tenth Model List of Essential Drugs), Technical Report Series, No. 895 (2000).

While the price of pharmaceuticals varies significantly between different markets,<sup>21</sup> the cost of most patented medicines remains beyond the reach of the bulk of the population in developing countries. This reality is starkly evident in the case of HIV/AIDS, where the emergence of drug regimes to manage the disease in the mid-1980s created a bifurcated epidemic. Opening the Thirteenth International AIDS Conference in Durban, South African High Court Judge Edwin Cameron claimed to embody “the injustice of AIDS in Africa because, on a continent in which 290 million Africans survive on less than one US dollar a day, I can afford medication costs of about \$400 per month.”<sup>22</sup> Accusing manufacturers of imposing prices that made drugs “unaffordably expensive,” Cameron argued that the international patent and trade regime prevents the production and marketing of affordable drugs, despite earlier experience in India, Thailand and Brazil, that demonstrates the feasibility of producing key drugs at costs within reach of the developing world.<sup>23</sup>

Still today, despite a dramatic drop in the price of antiretrovirals, victims of the HIV/AIDS pandemic may be divided into those for whom contraction of HIV remains a death sentence and those for whom the disease is a chronic illness they are able to manage. The disparity in access to antiretrovirals that creates this divide is heightened by the lack of generic alternatives, which has fueled the demand for access to medicines in general and generic drugs in particular. Using affordability as one of the relevant criteria, the essential drug program promoted the use of generic drugs, a strategy which allowed the program to both limit costs and reduce conflict with the global patent-based pharmaceutical industry, which opposes generic substitution (particularly for products originating from countries that did not recognize the companies product patents). The inclusion of twelve antiretrovirals on the WHO’s model essential medicines list in 2002<sup>24</sup> brought this tension to the fore and made it clear that the program’s primary reliance on generics for the effective delivery of affordable drugs was no longer tenable.

Research-oriented pharmaceutical manufacturers are involved in a relatively risky business, in which an average of only one “commercially viable drug emerges from every 4,000 to 10,000 compounds screened in a development process that may involve ten years of testing and clinical trials for efficacy

<sup>21</sup> See, e.g., Danzon & Towse, *Theory and Implementation of Different Pricing for Pharmaceuticals* [this volume].

<sup>22</sup> Justice Edwin Cameron, First Jonathan Mann Memorial Lecture: The Deafening Silence of AIDS, XIIIth International AIDS Conference, Durban, South Africa, 9–14 July 2000, available at <http://www.tac.org.za/newsletter/2000/ns000717.txt>

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

<sup>24</sup> WHO, Department of Essential Medicines, Updating and Disseminating the WHO Model List of Essential Drugs: The Way Forward, draft (22 June 2001), available at <http://www.who.int/medicines/organization/par/edl/orgedldev.html>. See also WHO, Essential Drugs and Medicines Policy Department, WHO Medicines Strategy: 2000–2003, WHO Policy Perspectives on Medicines, No. 1 (Dec. 2000). Geneva.

and safety.”<sup>25</sup> Compounding the high costs of development, however, are the relatively low costs of product imitation – through reverse engineering – and production, which creates what economists refer to as the appropriability problem. Patent law, which aims to reward innovation by providing a limited monopoly to the patent holder, provides intellectual property-intensive industries, such as the pharmaceutical industry, with one means of attaining profitability. But the fruits of medical innovation raise questions that go beyond profitability. As the WHO points out, medicines are “not simply just another commodity,” but rather a public good.<sup>26</sup>

Access to essential drugs, from this perspective, becomes a critical part of the fundamental human right to health.<sup>27</sup> While WHO accepts that “patent protection stimulates development of needed new drugs,” it argues that “countries must ensure a balance between the interests of the patent holders and the needs of society.”<sup>28</sup> Advocating that “generic competition should begin promptly upon patent expiration” and that “preferential pricing is necessary for lower-income countries and should be actively pursued,”<sup>29</sup> WHO also argues that because the research and development priorities of the pharmaceutical industry do not necessarily respond to the needs of the bulk of the world’s population, there should be public involvement to “ensure development of new drugs for certain priority health problems.”<sup>30</sup> Thus, although WHO does not reject the idea of pharmaceutical patents, its position seems to question the unbridled power of private decision-making in the research effort and to claim some level of exception to the rights of patent holders for essential drugs. This prioritization of health over specific property rights becomes the key to a human rights approach.

### **Towards a legal regime that promotes public health**

Since the Second World War, it may have been assumed that public health issues, particularly those with transnational effects, would be coordinated by WHO as the relevant body within the United Nations system. The WHO constitution empowered the organization’s governing body, the World Health Assembly, to adopt conventions as well as other international legal instruments, including binding regulations.<sup>31</sup> In practice, however, WHO has, until very recently relied

<sup>25</sup> M. RYAN, *KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY* 5 (Brookings Institution 1998). See also Grabowski, above n 8.

<sup>26</sup> Dr. G.H. Brundtland (Director-General of the WHO), *International Trade Agreements and Public Health: WHO’s Role*, presented by video at the Conference on Increasing Access to Essential Drugs in Globalized Economy (Amsterdam, 25–26 Nov. 1999), at 1, available at [http://www.who.int/medicines/docs/WTO\\_Public\\_Health\\_Amsterdam\\_GHB.html](http://www.who.int/medicines/docs/WTO_Public_Health_Amsterdam_GHB.html).

<sup>27</sup> See Jonathan Mann et al., *Health and Human Rights*, in *HEALTH AND HUMAN RIGHTS* 7 (J. Mann et al. eds., Routledge 1999). See also Rebecca Cook, *Gender, Health and Human Rights*, in *HEALTH AND HUMAN RIGHTS* 262 (J. Mann et al. eds., Routledge 1999).

<sup>28</sup> Scholtz, above n. 17, at 3. <sup>29</sup> *Id.* <sup>30</sup> *Id.*

<sup>31</sup> D. FIDLER, *INTERNATIONAL LAW AND PUBLIC HEALTH: MATERIALS ON AND ANALYSIS OF GLOBAL HEALTH JURISPRUDENCE* 118 (Transnational Publishers 2000).

more on the adoption of standards, principles and models supplemented by the body's annual reports and occasional declarations such as the Alma-Ata Declaration, which called upon countries and international organizations to adopt a system of primary health care.<sup>32</sup> When it came to the regulation of pharmaceuticals, the essential medicines program exemplified WHO's choice of standards rather than rules. Any binding legal rules controlling the availability of medicines remained rooted in two independent legal processes within national jurisdictions, one regulatory and the other based on the laws of the market, including the relevant intellectual property rules of each country.

Despite a long history of the international regulation of drugs,<sup>33</sup> the availability of any particular medicine still depends on its registration by the health authorities or other agencies empowered to decide which products meet the required standards of safety and effectiveness. Even after registration, access to these drugs depends on their affordability in the market and, for the vast majority of patients in the developing world, on whether the state is able to make the drug available through the public health system. In this latter case, states have mostly relied on the availability of generic substitutes or used their relative market power to bargain for sustainable public sector prices. Despite the state's formal status as sovereign power, many developing countries, particularly in Africa, in the era of structural adjustment and neoliberal fiscal constraints, have lost the capacity to keep their public hospital dispensaries well stocked. The implementation of national essential drugs programs that rely to a large extent on the model lists produced by WHO had provided one mechanism for governments to manage the supply, use and cost of pharmaceuticals.

By the 1990s, however, initiatives affecting health care, particularly within individual nations, seemed to have shifted away from reliance on WHO standards and towards incorporation of decisions made by a range of other international bodies, including the World Bank and the WTO.<sup>34</sup> Fueled by the debate over access to medicines in the context of the HIV/AIDS pandemic, the question of the relationship between health and trade policies began to complicate the WTO's trade agenda in the late 1990s. The adoption of the TRIPS Agreement as part of the world trade regime in 1994 fundamentally changed the global legal environment for the production and supply of medicines.<sup>35</sup>

<sup>32</sup> WHO & UNICEF, Declaration of Alma-Ata, Report of the International Conference on Primary Health Care (1978).

<sup>33</sup> J. BRAITHWAITE & P. DRAHOS, GLOBAL BUSINESS REGULATION 360–98 (Cambridge University Press 2000).

<sup>34</sup> G. WALT, HEALTH POLICY: AN INTRODUCTION TO PROCESS AND POWER (University of the Witwatersrand Press 1994); G. Walt, *Globalization of International Health*, 351 LANCET 434 (7 Feb. 1998).

<sup>35</sup> See, e.g., Abbott, above n. 2. At the GATT Ministerial Meeting in 1982, intellectual property rights were discussed in the context of international trade relations for the first time. This was an early indication of the impact of a group of United States corporate leaders who, in the late 1970s, had “devised a strategy to improve intellectual property protection

Despite these and other successes, the pharmaceutical industry's goal of having intellectual property rights enforced through the international trade regime continued to face strong opposition, especially from developing and newly industrialized countries.<sup>36</sup> Launching the Doha Round of Multilateral Trade Negotiations in November 2001 was made possible only after Members agreed to adopt the Doha Declaration on the TRIPS Agreement and Public Health.<sup>37</sup> Despite concerted opposition from multinational pharmaceutical corporations and a group of developed countries led by the United States, Switzerland and Japan, the 140 trade ministers gathered in Doha, Qatar, agreed that the TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health . . . [and] that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health and, in particular, to promote access to medicines for all."<sup>38</sup>

At first blush, this seemed to be a major negotiating success for the developing world. Not only was this interpretation extended to all aspects of public health, not just pharmaceuticals, but it also emphasized the need to interpret the WTO agreements in more holistic ways. In essence, it accepted that an interpretation reducing barriers to free trade is not automatically the sole or correct understanding of the relevant agreements.

Despite opposition by the United States and Canada to any broad public health exception, their own threats to override Bayers' Cipro patent – in response to the mailed Anthrax attacks<sup>39</sup> – weakened their official claims that the strong protection of patents was the most effective means of securing access to required medicines. The Doha Declaration specifically recognizes the right of a Member to grant compulsory licenses, to determine what constitutes a national emergency or other circumstance of extreme urgency, and to establish its own regime for the exhaustion of intellectual property rights.<sup>40</sup> It also encourages developed countries to promote technology transfer to the least developed countries, and it extends the initial transition period, with respect to pharmaceutical products,

internationally until American standards became the international norm, especially in developing countries." RYAN, above n. 28, at 68. See also THE PHARMACEUTICAL CORPORATE PRESENCE IN DEVELOPING COUNTRIES 198 (L.A. Travis & O.P. Williams eds., University of Notre Dame Press 1993).

<sup>36</sup> See Abbott, above n. 2. See also Ruth Gana, *Prospects For Developing Countries Under the TRIPS Agreement*, 29 VAND. J. TRANSNAT'L L. 735 (1996); M. Adelman & S. Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507 (1996).

<sup>37</sup> Declaration on TRIPS and Public Health, above n. 4. <sup>38</sup> *Id.* para. 4.

<sup>39</sup> See Paul Blustein, *Drug Patents Dispute Poses Trade Threat; Generics Fight Could Derail WTO Accord*, WASH. POST, 26 Oct. 2001, Sec. F, at E1. See also, Kavaljit Singh, *Anthrax, Drug Transnationals and TRIPS: Profits Before Public Health*, Z Magazine (December 2001) pp39–42.

<sup>40</sup> Doha Declaration, above n. 37, para. 5.

until 1 January 2016.<sup>41</sup> The understanding of the TRIPS Agreement reached in Doha constituted a major shift in the rhetoric about the protection of intellectual property rights; yet, given the realities of pharmaceutical production and distribution, little progress has been made towards actually ensuring access to urgently needed HIV/AIDS related medications.<sup>42</sup>

Despite acknowledging that many countries have “insufficient or no manufacturing capacities in the pharmaceutical sector” and thus cannot make effective use of compulsory licensing,<sup>43</sup> the declaration failed to accept the developing countries’ claim that they have the right to grant compulsory licenses to producers in countries with greater manufacturing capacity in order to gain access to medicines. Instead, the declaration instructed the TRIPS Council to find a solution and to report to the WTO General Council by the end of 2002. Without the capacity to produce under compulsory licenses or to import generic equivalents of necessary medications, the problem of access for the millions infected with or suffering from life-threatening diseases in developing countries remained unresolved.

It took the TRIPS Council twenty one more months to finally reach agreement in late August 2003 on the problem of access to medicines for countries that lack manufacturing capacity.<sup>44</sup> Heralded at first as the solution to the problem of lack of capacity, the pre-Cancun agreement has since been criticized as being unworkable for placing so many prerequisites on its implementation.<sup>45</sup> Before it can benefit from the decision, a country must prove that it lacks production capacity and access to affordable medicines, and that it has an existing health emergency. While the Canadian government has taken steps to change Canadian law to make the export of medicines produced under these compulsory licenses possible, the international brand-name pharmaceutical industry has begun to raise questions about whether the NAFTA Agreement precludes Canada from supplying these medicines. Even the Canadian government itself seems to be limiting its proposals to drugs designed to address HIV/AIDS, malaria and Tuberculosis, a restriction rejected by the developing countries and the pre-Cancun agreement.<sup>46</sup>

Once again, it seems that the question of access to essential medicines is being displaced by an assertion of prior legal commitments. The uncompromising

<sup>41</sup> *Id.* para. 7.   <sup>42</sup> See, e.g., Abbott, above n. 2.   <sup>43</sup> *Id.* para. 6.

<sup>44</sup> WTO, Implementation of Paragraph 6, above n. 4.

<sup>45</sup> See Carlos M. Correa, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Draft, December 2003). See also, Carlos M. Correa, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, Health Economics and Drugs, EDM Series No. 12, WHO/EDM/PAR/2002.3 (WHO June 2002).

<sup>46</sup> See, Press Release, 28 Apr. 2004, Canada Proceeds with Bill C-9 on Cheaper Medicines Exports: NGOs Say Initiative is Important, and Urge Other Countries to Avoid the Flaws in the Canadian Model, available at [www.aidslaw.ca/Media/press-release/e-press-apr2804.pdf](http://www.aidslaw.ca/Media/press-release/e-press-apr2804.pdf).

principle of *pacta sunt servanda* that is used to elevate notions of unrestricted trade above the health needs of millions of people around the world. While all participants in the debate deny any intention to restrict access or even to indirectly create such an effect,<sup>47</sup> it seems hard to deny that the failure to resolve the issue of compulsory licensing, since it was first raised by the international pharmaceutical industry in its 1997 case against the South African law implementing an essential drugs program, has in fact frustrated attempts to broaden access.

Even if it is accepted that the TRIPS Agreement was initially unsuited to accommodating the complexities of a global health emergency such as HIV/AIDS, it is hardly unreasonable to suggest that, in light of both new understanding of the magnitude of the pandemic and the emergence of effective medicines to address it, the principle of adapting to changed circumstances – or *rebus sic stantibus* – should have been applied to interpretations of the Agreement in order to facilitate attempts to address this exploding crisis. At the least, such an approach would justify the assertion of an article 30 exception under the TRIPS Agreement.<sup>48</sup> Instead, there has been a constant emphasis on the rather unique protection of private rights contained in the TRIPS Agreement and a denial of the legal effect of the so-called soft-law exceptions and principles of interpretation, which are also part of international trade law and essential to realizing public health goals.

### Conclusion

After twenty years, the HIV/AIDS pandemic has finally been recognized as a global health crisis, yet the debates over access to public goods that are essential to defeating this scourge continue to be shaped less by concerns about public health than by principles of unrestricted trade and intellectual property rights protection. Within the legal field, the claims of the international patent-based pharmaceutical corporations are framed as rights to property, while the claims of NGOs and developing country governments seeking access to affordable medicines are characterized as legal exceptions to free trade or as the soft law principles contained in general preambular statements. These formal legal distinctions, based upon the interpretation of international agreements created in a context of asymmetrical power, are now relied upon to delay and avoid recognizing the urgent needs of those whose lives and futures are at stake.

Asserting a human rights perspective, from which the health impact of any particular interpretation is seen as an equally legitimate consideration in evaluating the validity of any particular legal option, could dissolve the stifling

<sup>47</sup> International Intellectual Property Institute, Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa, Report prepared for WIPO (2000).

<sup>48</sup> See TRIPS Agreement, above n. 1, art. 30.

distinction between so-called hard law obligations and soft law principles or commitments. Introducing such a perspective might facilitate access to medicines by encouraging private investors to reconcile the need for compulsory licenses or other exemptions with their own investment calculus, including investments in generic production. It could also provide developing countries with a means to justify decisions to privilege policies securing access to medicines over concerns about their international trade commitments or threats from patent holders. Instead of relying on thin strands of legal flexibility, NGOs, international organizations, countries and governments attempting to address the global HIV/AIDS pandemic should promote a human rights-based interpretation that places public health ahead of economic claims.