

---

---

## Essay

# **Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil**

**Zita Lazzarini<sup>†</sup>**

*The HIV/AIDS epidemic has made the problem of access to pharmaceuticals in developing countries a subject of intense public debate. This Essay contends that tensions between intellectual property rights and human rights are largely resolvable through the full utilization of exceptions under new international trade and intellectual property rules. Rather than undermining these regimes, the approach laid out in this Essay was anticipated by the international forum that established the World Trade Organization and issued the Trade-Related Aspects of Intellectual Property Agreement (TRIPS). Brazil's experience illustrates possible strategies, relevant to developing countries, which can be used to strike a balance between respect for public health and human rights and protection of intellectual property rights.*

### I. INTRODUCTION

Extreme disparities in access to pharmaceuticals for life-threatening

---

<sup>†</sup> Director, Division of Medical Humanities, Health Law and Ethics, University of Connecticut Health Center; B.A. 1979, University of California – Berkeley; J.D. 1983, University of California – Hastings College of Law; M.P.H. 1991, Harvard University School of Public Health. The author would like to thank Scott Curris and Bebe Loff for their help in early discussion of the topic and acknowledge the assistance of Jon Von Kohorn, Lorilyn Rosales, Sarah Sia, Amy Hozer, Jennifer McSweeney, and Theo Ungewitter in preparation of this Essay.

---

---

diseases are not new. Although much of the world has always lacked access to new and expensive drugs, only now are we seriously discussing these disparities. Spurred by the growing HIV/AIDS epidemic as well as the globalization of international trade, these questions have landed squarely in the public arena.

This Essay will investigate the problem of access to pharmaceuticals in the context of intellectual property rules and human rights. As long as concepts like sharing equitably in the benefits of science and technology, safeguarding the rights of indigenous peoples, and protecting “authors’ rights” remain unrealized and unreconciled, access to pharmaceuticals will continue to be an issue of charity rather than of rights, and good health will remain beyond the grasp of most of the world. In this Essay, I will not venture an exhaustive exploration of the empirical evidence related to drug pricing or a detailed examination of the legal mechanisms available to facilitate access in all countries. Instead, I will lay the groundwork for possible ways to resolve the tension between intellectual property rights and human rights in the effort to guarantee access to pharmaceuticals.

This Essay suggests that many middle-income countries could provide wider access to pharmaceuticals by fully utilizing the exceptions permitted under new international trade and intellectual property rules. For the poorest nations, however, these rules as written do not offer easy solutions. Moreover, rich nations have been slow to recognize—and poor nations have been slow to use—the potential exceptions within the existing regime. This Essay will draw on the recent experience of Brazil to illustrate possible strategies and several notable trends.

Part I briefly describes global disparities in health and access to pharmaceuticals. Part II sheds light upon some of the barriers to wider access to pharmaceuticals related to HIV/AIDS and reviews the basic structure of international intellectual property law. Part III characterizes access to pharmaceuticals as a human right. Part IV considers ways to reconcile the existing tension between intellectual property rules and human rights. Part V presents Brazil as a case study, considering the relevance of its experience for other developing countries. Finally, Part VI concludes with proposed directions for further inquiry.

## II. DISPARITIES IN HEALTH AND DISPARITIES IN ACCESS

If you live in a poor country, you are much more likely to suffer early sickness, disability and death than if you live in a rich country. The World Health Organization (WHO) reports that such glaring disparities in health conditions, incidence and prevalence of disease, and life expectancy persist.<sup>1</sup> Unsurprisingly, access to pharmaceuticals also varies tremendously around the world. Despite years of WHO’s essential drug

---

1. WORLD HEALTH ORGANIZATION, THE WORLD HEALTH REPORT 1999: MAKING A DIFFERENCE 13-20 (1999) (describing the significant disparities in health status that exist between rich and poor countries).

programs and the adoption of essential drug lists by many countries,<sup>2</sup> availability of drugs remains highly uneven.<sup>3</sup> The World Health Assembly has noted that “one third of the world’s population has no guaranteed access to essential drugs.”<sup>4</sup> In many developing countries, individuals and their families are expected to purchase drugs and medicines to treat their illnesses.<sup>5</sup> Weak government regulation and improper prescriptions from doctors may result in unsafe and ineffective drug use.<sup>6</sup> The danger of misuse is especially strong with antibiotics.<sup>7</sup> For many serious diseases, treatments are either unavailable or unaffordable.<sup>8</sup> In rural areas the situation is particularly difficult, as the only supplier of drugs is typically either a local hospital or health clinic which often lacks even the most basic drugs to treat common illnesses such as respiratory infections and diarrhea and very rarely has access to new drugs used to treat tuberculosis or HIV/AIDS.<sup>9</sup> Only a wealthy few in most countries can even think of obtaining HIV/AIDS drugs independently.<sup>10</sup>

Disparities in access to pharmaceuticals exact an unmistakable impact on health. Three million people died of AIDS in 2001. In 2000, 1.7 million died of tuberculosis and more than one million from malaria.<sup>11</sup> With the use of combination therapy in the United States and in other developed countries since 1996, AIDS cases and deaths have dropped substantially for

---

2. WORLD HEALTH ORGANIZATION, ESSENTIAL DRUG AND MEDICINES POLICY: HIGHLIGHTS-WHO MEDICINES STRATEGY: 2000-2003, at <http://www.who.int/medicines/strategy/whozip16e/ch03.htm> (last visited Apr. 29, 2002).

3. Access to essential drugs requires: (1) rational selection and use of medicine; (2) sustainable, adequate financing; (3) affordable prices; and (4) reliable health and supply systems. WHO Medicines Strategy, *Expanding Access to Essential Drugs*, available at [http://www.who.int/gb/EB\\_WHA/PDF/EB109/eeb1097.pdf](http://www.who.int/gb/EB_WHA/PDF/EB109/eeb1097.pdf) (last visited Oct. 16, 2002); but see DIANNA MELROSE, BITTER PILLS: MEDICINES AND THE THIRD WORLD POOR 148 (1982) (describing shortcomings of essential drug lists).

4. Revised Drug Strategy, World Health Assembly, 52nd Sess., Agenda Item 13, at 1, U.N. Doc. WHA/52.19 (May 24, 1999), available at [http://www.who.int/wha-1998/WHA99/PDF99/e\\_reso.pdf](http://www.who.int/wha-1998/WHA99/PDF99/e_reso.pdf) (last visited Feb. 21, 2002).

5. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, REPORT OF THE MEETING ON THE EVALUATION OF THE UNAIDS HIV DRUG ACCESS INITIATIVE 5 (2000) [hereinafter REPORT ON UNAIDS INITIATIVE]. Although extended families can provide significant support for many persons with HIV/AIDS, care remains unaffordable for those lacking family or those whose families’ resources are already depleted.

6. WORLD HEALTH ORGANIZATION, *supra* note 2.

7. *Id.*

8. See generally David P. Fidler, *Neither Science Nor Shamans: Globalization of Markets and Health in the Developing World*, 7 IND. J. GLOB. LEG. STUD. 191 (1999).

9. See generally PAUL FARMER, INFECTIONS AND INEQUALITIES: THE MODERN PLAGUES, preface, (1999) (describing disparities in access to TB and HIV drugs in Haiti and Peru and duty of physicians not to accept lack of resources as a justification for second class care).

10. Alex Duval Smith, *AIDS Summit: HIV Judge Attacks Mbeki for Grievous Ineptitude*, THE INDEPENDENT (London), July 11, 2000, at 14 (quoting Judge Edwin Cameron’s speech at the 13th World AIDS conference, in which he focused on the high cost of anti-HIV drugs as a barrier to care in S. Africa and noted, “I exist as a living embodiment of the iniquity of drug availability in Africa. Amidst the poverty of Africa, I stand before you because I am able to purchase health and vigour.”).

11. The Global Fund to Fight AIDS, Tuberculosis, and Malaria, at <http://www.globalfunddatm.org> (last visited Apr. 24, 2002)

the first time since the beginning of the epidemic.<sup>12</sup> Ninety-five percent of those infected with HIV worldwide live in developing countries,<sup>13</sup> and fewer than five percent have access to effective treatment.<sup>14</sup> Unlike in wealthy countries, AIDS cases and deaths in developing countries have continued to climb.<sup>15</sup> The United Nations Joint Programme on AIDS (UNAIDS) has identified unequal access to affordable treatment as one of the principal reasons for the drastically lower survival rates in developing countries.<sup>16</sup>

Disparities in access to treatments raise worrisome issues of equity. Although public health officials have emphasized solidarity among all people,<sup>17</sup> those living with HIV/AIDS perceive quite the opposite situation: a dissonant, two-tiered system. Since 1996, in the developed world, HIV/AIDS has become akin to other treatable chronic illnesses. In the developing and undeveloped world, it remains a deadly plague. Differential investment in AIDS prevention mirrors these disparities. In the mid-1990s, even though more than eighty five percent of infections occurred in the developing world, only about ten percent of the estimated \$2 billion spent annually on prevention went to slow the spread of HIV and AIDS in developing countries.<sup>18</sup> Today, with ninety-five percent of infections occurring in the developing world, the total funding for treatment and prevention in the poorest countries hovers around \$2

---

12. *HIV and AIDS—United States, 1981-2000*, MORBIDITY AND MORTALITY WKLY. REP. (Centers for Disease Control and Prevention, Atlanta, GA), June 1, 2001, at 430-34, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5021a2.htm>.

13. The United States Agency for International Development, *Global Health*, Frequently Asked Questions, available at [http://www.usaid.gov/pop\\_health/aids/News/aidsfaq.html](http://www.usaid.gov/pop_health/aids/News/aidsfaq.html) (last visited Sept. 23, 2002).

14. Joint United Nations Programme on HIV/AIDS, Press Release, Geneva, 10 September 2002, available at [http://www.unaids.org/whatsnew/press/eng/pressarc02/humanrights\\_100902.html](http://www.unaids.org/whatsnew/press/eng/pressarc02/humanrights_100902.html) (last visited Oct. 16, 2002).

15. "In the 45 most affected countries, it is projected that, between 2000 and 2020, 68 million people will die prematurely as a result of AIDS. The projected toll is greatest in sub-Saharan Africa where 55 million additional deaths can be expected." Joint United Nations Programme on HIV/AIDS, *The Impact of HIV/AIDS*, Fact Sheet 2002, available at [http://www.unaids.org/barcelona/presskit/factsheets/FSimpact\\_en.pdf](http://www.unaids.org/barcelona/presskit/factsheets/FSimpact_en.pdf) (last visited Oct. 16, 2002).

16. Joint United Nations Programme on HIV/AIDS, *The Report on the HIV/AIDS Epidemic 142-43* available at <http://www.unaids.org/barcelona/presskit/embargo.htm> (last visited Nov. 21, 2002).

17. The slogans of the three most recent International AIDS conferences illustrate the rhetoric—Vancouver, 1996, "One World, One Hope"; Geneva 1998, "Bridging the Gap"; and Durban 2000, "Break the Silence." International AIDS Conferences and IAS Conference on HIV Pathogenesis and Treatment, *Previous International AIDS Conferences*, available at [http://www.ias.se/page\\_1.asp?pageId=40](http://www.ias.se/page_1.asp?pageId=40) (last visited Oct. 16, 2002). The unfortunate gap between rhetoric and reality can be seen in the climbing HIV rates around the world and the falling death rates in the US and Western Europe. See generally JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, *AIDS EPIDEMIC UPDATE: DEC. 2001*, available at [http://www.unaids.org/worldaidsday/2001/Epiupdate2001/Epiupdate2001\\_en.pdf](http://www.unaids.org/worldaidsday/2001/Epiupdate2001/Epiupdate2001_en.pdf) (last visited Oct. 16, 2002).

18. Feminist.com Women's Feature Service, *Women of the World—Statistics* (compiled from U.N. sources), available at <http://www.feminist.com/resources/artsspeech/inter/womworldstats.html> (last visited Apr. 8, 2002).

billion.<sup>19</sup> While this looks like a substantial increase in spending in the developing world, spending still falls far below official estimates of \$10 billion needed annually to effectively treat HIV/AIDS and prevent its spread.<sup>20</sup>

### III. INTELLECTUAL PROPERTY – PREREQUISITE OR BARRIER TO HIV/AIDS TREATMENT IN THE DEVELOPING WORLD

Because of the great disparities in access to pharmaceuticals, active debate surrounds the international legal framework protecting intellectual property rights. On the one hand, some have argued that patents play little or no role in limiting access to essential AIDS drugs in Africa.<sup>21</sup> On the other hand, it has been widely reported that some countries have been reluctant to take any steps that could be interpreted as violating patent and intellectual property rules. Their uncertainty and fear over possible trade-related retaliation may deter them (as well as private industry) from exploiting opportunities for local manufacture or importation of pharmaceuticals.<sup>22</sup> In this way, the intellectual property system creates barriers, both perceived and real.<sup>23</sup>

---

19. The Global Fund to Fight AIDS, Tuberculosis, and Malaria, a cooperative international effort to mobilize both public and private support for efforts to reduce morbidity and mortality caused by some of the leading deadly diseases, has provided \$1.7 billion of this \$2 billion. UN Secretary General Kofi Anan has taken on a major role in trying to secure donations from governments, corporations, foundations and individuals to meet the projected requirements of the fund. *Efforts to Combat Overseas HIV/AIDS: Hearings Before Senate Foreign Relations Committee*, 107th Cong. (Feb. 13, 2002) (statement of Peter Piot, Executive Director, UNAIDS). “[The Global Fund] supports interventions for the prevention, treatment, care and support of people with these three diseases.” JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, GLOBAL FUND FACT SHEET, available at [http://www.unaids.org/fact\\_sheets/files/fsglobalfund\\_en.doc](http://www.unaids.org/fact_sheets/files/fsglobalfund_en.doc) (last visited Oct. 16, 2002).

20. The Secretary-General of the United Nations has called for annual funding of the Global Fund to reach \$10.5 Billion by 2005. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, PRESS RELEASE, GENEVA, 10 OCTOBER 2002, available at [http://www.unaids.org/whatsnew/press/eng/pressarc02/globalfund101002\\_en.html](http://www.unaids.org/whatsnew/press/eng/pressarc02/globalfund101002_en.html) (last visited Oct. 16, 2002). This figure represents an annual estimate of total funds necessary from all sources, including the Global Fund, to address HIV/AIDS. A similar estimate to address TB and Malaria is \$2 Billion. Global Fund to Fight AIDS, Tuberculosis and Malaria, Initial Questions on the Global Fund, February 2002, available at [http://www.globalfundatm.org/faq\\_gfund.html#9](http://www.globalfundatm.org/faq_gfund.html#9) (last visited Nov. 23, 2002).

21. Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 J. Amer. Med. Assoc. 1886, 1886 (2001).

22. Tido von Shoen-Angerer, *For Third World Doctors, Lack of Medicine Is a Crying Shame*, S.F. CHRON., June 25, 2000, at 4 (describing Thailand’s attempt to allow generic production of HIV medications, thwarted initially by U.S. pressure and then by fear of estranging foreign investors); Mukdawan Sakboon, *Use Compulsory Licensing*, THE NATION (Singapore), Mar. 26, 2000 (describing the threat of compulsory licensing as a factor in Brazil’s negotiating discounts on HIV medications and quoting the WHO’s representative in Thailand saying “No poor nation has ever used compulsory licensing, which is common in America and other industrialised countries.”), at <http://www.nationmultimedia.com/page.arcview.php3?clid=3&id=57572&usrss=1>.

23. Fidler, *supra* note 8, at 209-14 (arguing that the emerging regime to protect intellectual property is raising prices and constricting efforts by developing countries to provide medicines to the poor); Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives*

The relationship between patent protection and price is another source of controversy. Studies demonstrate that the presence of generic drugs results in lower pharmaceutical prices overall.<sup>24</sup> In some developing countries where patent protections are rare, however, and where local production capacity is nonexistent, HIV drugs cost more than in western countries.<sup>25</sup>

The scope and details of intellectual property protection, especially the current WTO system, are important for identifying provisions that can both support and deter access to treatments for residents of poor countries.

#### A. Patent Protections Pre- and Post-TRIPS

The current World Trade Organization (WTO) system is a very new phenomenon. It focuses on achieving worldwide uniformity of patent protections through restrictive patent laws modeled on those of the United States. Before 1994, both developed and undeveloped countries used a wide variety of approaches to intellectual property protection,<sup>26</sup> including: U.S.-style restrictive patents of relatively long duration;<sup>27</sup> shorter-term patents;<sup>28</sup> patents on processes but not products;<sup>29</sup> compulsory licensing of important drugs;<sup>30</sup> requirements that patent holders produce and sell the drug in the country granting the patent or lose the protection;<sup>31</sup> no patent protection for pharmaceuticals at all (as was the case in Argentina and Brazil until recently).<sup>32</sup>

The range of widely varying national laws that existed prior to 1995 results in difficulties:

National patent laws can vary to such an extent that a given invention may be patentable in one country but not another, be

---

*Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069 (1996).

24. Frederick T. Schut & Peter A.G. Van Bergeijk, *International Price Discrimination: The Pharmaceutical Industry*, 14 WORLD DEV. 1141, 1147 (1986) (finding that pharmaceutical prices drop when countries impose direct price controls, promote use of generics, or abolish patents; but noting also that the "real" cost of drugs (relative to purchasing power) in many developing countries is many times higher than in United States).

25. *Id.*

26. Weissman, *supra* note 23, at 1071-76 (describing patent policy options used pre-1994).

27. *Id.* at 1075-77 (1996).

28. MICHAEL J. TREBILCOCK & ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL TRADE* 310 (2d ed. 2000).

29. Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507, 520 (1996) (describing India's recognition of patents for pharmaceutical processes only, not for pharmaceutical products).

30. Janet Hamilton, *What's Going on in Intellectual Property Law?*, 84 AM. SOC'Y INT'L L. PROC. 256, 258 (1990) (discussing Canada's use of compulsory licensing).

31. Carl Moy, *The History of the Patent Harmonization Treaty: Economic Self-Interest as an Influence*, 26 JOHN MARSHALL L. REV. 457, 475-76 (1993).

32. Bruce Rubenstein, *Latin America Slow To Protect Patents Under NAFTA*, 6 CORP. LEGAL TIMES 17, (1996) (describing Brazil's reluctance to adopt patent protections); *Argentina: No Patents for Drugs Till 2005*, MARKETLETTER, Nov. 7, 1994, at 11 (describing delay in protection of patents in Argentina).

broadly protected in one country but only narrowly protected in another, or even be patentable to different persons in different countries...“Disharmony” [in patent laws across borders] creates trade barriers and friction at both the private and diplomatic level.<sup>33</sup>

Concerted and sustained lobbying by the pharmaceutical companies<sup>34</sup> succeeded in putting intellectual property issues on the trade agenda beginning in the 1980s and later established the U.S. model as the preferred version of patent protection. This version was officially enacted during the international forum that established the World Trade Organization and issued the Trade-Related Aspects of Intellectual Property Agreement (TRIPS).<sup>35</sup>

The stated purpose of TRIPS includes: “[reducing] distortions and impediments to international trade...and [ensuring] that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.”<sup>36</sup> While TRIPS emphasizes the private right characteristic of intellectual property and the need for a multi-lateral, multinational framework to protect these rights, it also recognizes the “special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.”<sup>37</sup> Countries that are party to the treaty have bound themselves to protect all products and processes against use, sale, import, or manufacture without the permission of the patent holder, except under very specific circumstances.<sup>38</sup> TRIPS demands that countries enforce patents for twenty years from the date of filing.<sup>39</sup> When a patent holder suspects a manufacturer of using a patented process to manufacture a product which appears identical to one made by the patent holder, TRIPS assigns the burden of proof for showing that the product did not infringe the patent on its manufacturer rather than on the holder of the patent.<sup>40</sup>

---

33. Donald S. Chisum, *Introduction*, 26 JOHN MARSHALL L. REV. 437, 438 (1993).

34. See Weissman, *supra* note 23, at 1075-77.

35. See Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 21, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round Vol. 1c. 31, 33 I.L.M. 81 (1994)[hereinafter TRIPS].

36. *Id.*, pmb1.

37. *Id.*, pmb1.

38. Article 28, paragraph 1 of TRIPS describes the rights of a patent holder as follows:

A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of the a patent is a product, to prevent third parties not having his consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having his consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

*Id.* art. 28 (internal citations omitted).

39. *Id.* art. 33.

40. *Id.* art. 34.

B. Will Strong Universal Patent Protection Decrease or Increase Access to Pharmaceuticals?

One of the chief arguments for patent protections in general is the need to encourage innovation and risk-taking, which are necessary for the successful development of new drugs.<sup>41</sup> In fact, some scholars assert that the establishment of property rights (including intellectual property) and economic development in western countries have a clear, consistent, and even causative relationship.<sup>42</sup>

Rapp and Rozek, for example, refer to data relating degrees of patent protection to levels of development and find a close correlation between strong patent protections and high economic growth and levels of development.<sup>43</sup> They argue that the overall costs to the economy of failing to protect patents (low levels of development and growth) outweigh the benefits (temporarily easier access to pharmaceuticals). They also assert that by failing to protect patents in pharmaceuticals, countries risk having "fewer new pharmaceutical products, reduced future growth of the domestic industry and, most importantly, poorer health for the country's residents."<sup>44</sup>

Supporters of strong patent protection often overlook the potential harms that higher prices will have on countries' citizens and public health. Singham addresses this concern directly, arguing that increased patent protection will neither raise prices nor be harmful to consumers because the numbers of drugs going off patent will be matched by the number of new patented (more expensive drugs). The problem with this argument is that it assumes that older drugs will meet the needs of "consumers" just as well as new ones.<sup>45</sup> This is clearly not the case with HIV medications. The very reason people with HIV are so anxious to gain access to the newest

---

41. See, e.g., T.W. Roberts, Letter to the Editor, *Cost of Drugs to the Third World*, THE TIMES (London), Dec. 10, 1999 (arguing that drug company patents and high prices are necessary to support drug development and to allow companies to recoup investment.); *The Poor Need Medicines, but the Drug Industry Is Not a Global Charity*, THE INDEPENDENT (London), Mar. 6, 2001, at 3 (arguing that the international system should be able to design and enforce a workable system of tiered pricing or to streamline the approval process of new drugs to reduce development costs and speed them to market albeit with greater risks); Deborah Hope, *Drug Patents Cause World Legal Fevers*, THE WEEKEND AUSTRALIAN, Mar. 2, 2002, at 30 (quoting GlaxoSmithKline spokesman Phil Thomson's statement that "patents do not block medicines. They stimulate research").

42. See, e.g., Richard T. Rapp & Richard P. Rozek, *Benefits and Costs of Intellectual Property Protection in Developing Countries*, J. WORLD TRADE 75 (Oct. 1990); Shanker A. Singham, *Symposium: Third Annual Latin American Competition and Trade Round Table: Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOK. J. INT'L L. 363, 372-79 (2000) (asserting an important relationship between strong patent protection laws in a country and high levels of investment in research and development and between strong patent protection and economic growth).

43. Rapp & Rozek, *supra* note 42, at 77-81.

44. *Id.* at 86.

45. Singham, *supra* note 42, at 386-87.



drugs is often that the new drug is a necessary part of combination therapy, because they need the new drug as an alternative to regimens that have been exhausted or to avoid serious side-effects.

Not all commentators agree that universal, strong patent protections are necessarily related to economic benefits. Some suggest that strong property protections can actually deter innovation by discouraging researchers from pursuing new products or processes that entail using one or more patent-protected materials.<sup>46</sup> Others argue that while countries with advantages in innovation, strong research infrastructure, and a tendency to “export information”—that is technical discoveries and innovations—will benefit from patent protections, those without those characteristics (mostly poorer countries) will be harmed by stronger protections.<sup>47</sup>

The degree to which patent protection and high prices are necessary to support research and development has been questioned.<sup>48</sup> Not only is the pharmaceutical industry consistently one of the most profitable industries,<sup>49</sup> but also those pharmaceutical firms that ranked among the Fortune 500 companies also devoted less of their total revenue to research and development of new drugs (R&D) (12.5 percent) than to profits (18.5 percent) or marketing and administration (30.4 percent).<sup>50</sup>

Even if high prices encourage R&D, they are not the only means of

---

46. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698 (1998); Steve Bunk, *Researchers Feel Threatened by Disease Gene Patents*, *THE SCIENTIST* 7 (Oct. 11, 1999).

47. Trebilcock and Howse argue that strengthened intellectual property protection might increase the economic welfare of certain information exporting countries, stronger protections in countries that lack a strong manufacturing sector or rely on imitation in manufacturing information importing countries might reduce economic welfare. They also relate the argument of Allan Deardorff that “global aggregate welfare may well be maximized if certain countries are *exempted completely* from requirements for intellectual property protection. The reason is that with respect to these poorer countries, the marginal increased rents to the patent holder are unlikely to be substantial enough to constitute significant incentives to further innovation. However, the losses to developing countries from being forced out of imitation or buying imitations from elsewhere would probably be more substantial.” TREBILCOCK & HOWSE, *supra* note 28, at 310-12 (quoting Allan Deardorff, *Should Patent Protection Be Extended to All Developing Countries?*, 13 *WORLD ECONOMY* 497-508 (1990)).

48. J. Love & J. Davids, *Property, Production, and Politics: Identifying the True Cost of Drug Development and Production and Clarifying TRIPS*, XIII Int'l Conf. on AIDS, July 9-14, 2000 Abstract no. TuPpE1210; D. Palmer et al., *Challenging International Trade Policy—Democratizing Access to Medicines Globally*, XIII Intl. Conf. on AIDS, July 9-14, 2000 Abstract no. TuOrE457.

49. PUBLIC CITIZEN, PHARMACEUTICALS RANK AS MOST PROFITABLE INDUSTRY AGAIN: “DRUGGERNAUT” TOPS ALL THREE MEASURES OF PROFITS IN NEW FORTUNE 500 REPORT (Apr. 17, 2002) (noting that the pharmaceutical industry ranked first in all three measures of profitability due to higher pill prices, high levels of advertising, and less spending on R&D), available at [http://www.citizen.org/congress/reform/drug\\_industry/profits/articles.cfm?ID=7416](http://www.citizen.org/congress/reform/drug_industry/profits/articles.cfm?ID=7416).

50. *Id.* at graphs 4-5 (illustrating the proportion of revenues of Fortune 500 Drug Companies going into R&D, profits, marketing and administration, and the comparison between profits and R&D investment for the ten most profitable Fortune 500 Drug Companies in 2001); PUBLIC CITIZEN, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S R&D “SCARE CARD” (July 2001), available at <http://www.citizen.org/publications/release.cfm?ID=7065>.

increasing R&D.<sup>51</sup> Governments could provide additional funding for R&D or, through international agreements, mandate public and corporate contributions to multi-national R&D funds. They could use general tax revenues or tax profits on drugs aimed primarily at developed world consumers to support R&D in “tropical” diseases, which primarily affect residents of developing countries.<sup>52</sup> A variation on this option—voluntary partnerships between governments, international organizations, private companies and researchers—exists in a limited form to address the need for more sustained research on tropical diseases.<sup>53</sup>

### C. TRIPS: Constraints and Flexibility

As stated above, TRIPS was drafted following extensive lobbying by international pharmaceutical manufacturers and reflects many values favorable to large multi-national corporations. By establishing a set of rules that requires all countries to provide uniform patent protections to all intellectual property products and processes, it tightens the screws on those countries, including many developing countries, that try to avoid adopting U.S.-style patent protections.

TRIPS does offer some flexibility to developing countries moving from weaker to stronger intellectual property regimes, however, by delaying the entry into force of the requirements for TRIPS-compliant provisions in developing countries and by providing specific and general exceptions that could be used by developing countries to increase access<sup>54</sup> and to protect public health or the environment.

The terms of TRIPS allow at least four exceptions that would permit developing countries to increase access while remaining compliant; it allows a country to (1) exclude products from patent protection where necessary to protect public health and the environment;<sup>55</sup> (2) create limited exceptions to patents, provided the country can show that the interests of the patent owner are not unreasonably infringed upon;<sup>56</sup> (3) issue compulsory licenses subject to certain restrictions;<sup>57</sup> and (4) impose price controls and taxes that do not discriminate between domestic and imported goods, which can be waived if the patent holder will license its product or process non-exclusively.<sup>58</sup> The efficacy of these exceptions will depend on how courts interpret them and balance the interests of patent

---

51. JAMES LOVE, PAYING FOR HEALTH CARE R&D: CARROTS AND STICKS (Oct. 19, 2001) (describing mechanisms available to governments to enhance R&D efforts), available at <http://www.cptech.org/ip/health/rnd/carrotsnsticks.html> (last visited Apr. 21, 2002).

52. Weissman, *supra* note 23, at 1072-75.

53. Richard J. O'Brien & Paul P. Nunn, *The Need for New Drugs Against Tuberculosis: Obstacles, Opportunities, and Next Steps*, 163 AM. J. OF RESPIRATORY AND CRITICAL CARE MEDICINE 1055-58 (2001), available at <http://ajrcm.atsjournals.org/cgi/reprint/163/5/1055.pdf>.

54. TRIPS, *supra* note 35, art. 27, ¶¶ 2, 34.

55. *Id.*, art. 27.

56. *Id.*, art. 30.

57. *Id.*, art. 34.

58. Weissman, *supra* note 23, at 1098.

holders, developing countries, and third parties.<sup>59</sup>

#### D. Indigenous Rights and Intellectual Property

The emerging area of indigenous peoples' rights also provides opportunities to re-define how and when intellectual property will be protected and how access to benefits will be guaranteed.<sup>60</sup> Modern intellectual property protections have often disfavored the types of knowledge most commonly held and valued by indigenous peoples. The requirements for novelty of invention and description of the patentable item by an identifiable creator have made much indigenous knowledge difficult to patent and therefore vulnerable to use or exploitation by others.<sup>61</sup> In fact, some writers claim that intellectual property, as it is currently conceptualized, promotes "biocolonialism" —the appropriation and conversion of biologically or genetically unique information from indigenous cultures to private intellectual property, largely for the benefit of western pharmaceutical and seed companies.<sup>62</sup> Indigenous peoples themselves have reportedly expressed widespread dissatisfaction with western intellectual property schemes because of their failure to recognize and protect much of what is important to their cultures.<sup>63</sup>

Others, however, see new developments in intellectual property and science as assets to indigenous peoples' rights movements and as opportunities for these peoples to protect their heritage while accruing economic benefit. A working group on indigenous peoples' rights enunciated this claim as follows:

Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property.

They have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts.<sup>64</sup>

---

59. *Id.* at 1100-15.

60. Rosemary J. Coombe, *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity*, 6 *IND. J. GLOBAL LEGAL STUD.*, 59, 77-82 (1998).

61. Audrey R. Chapman, *Approaching Intellectual Property as a Human Right: Obligations Related to Article 15 (1) (c)*, U.N. ESCOR, Comm. on Econ. Soc. and Cultural Rts., 24th Sess., at ¶¶ 25, 33, 44, U.N. Doc. E/C. 12/2000/12 (2000); Fidler, *supra* note 8, at 212-13.

62. Laurie Anne Whitt, *Part One: Interdisciplinary Perspective: Indigenous Peoples, Intellectual Property & the New Imperial Science*, 23 *OKLA. CITY U.L. REV.* 211, 214-15 (1998).

63. David J. Stephenson, *Symposium: Sixth Annual Tribal Sovereignty Symposium: The Nexus Between Intellectual Property Piracy, International Law, the Internet, and Cultural Values*, 14 *ST. THOMAS L. REV.* 315, 318-19 (2001).

64. *Draft Declaration on the Rights of Indigenous Peoples*, U.N. ESCOR, Comm. on Hum. Rts., Working Grp. on Indigenous Populations, 11th Sess., art. 29, U.N. Doc. E/CN.4/Sub.2/1993/29 (1993).

Whitt asserts that one solution is for indigenous communities to develop alternatives to western-style intellectual property standards. Possibilities include: "community intellectual property," which would allow communities, instead of individuals, to identify and protect from expropriation knowledge and resources that had existed for generations; an "inalienability of cultural property," which would protect the heritage for future generations of the community; and extensions of conventional copyright allowing protection of intangible expressions (including genetic resources).<sup>65</sup> Others argue that indigenous peoples and nations with large indigenous populations ought to use the mechanisms available through TRIPS to extend protection to valuable national and local resources.<sup>66</sup> Another approach sees international human rights provisions as tools to modify intellectual property rights claims, ensuring that the rights and interests of indigenous peoples are protected, even though their interests differ from the dominant culture.<sup>67</sup>

The use of human rights principles to reconstruct copyright laws that protect indigenous peoples' heritage is one example of how human rights can work as a framework for resolving intellectual property issues. The campaign of indigenous peoples for more flexibility in intellectual property doctrine resonates with the claims of public health advocates and persons with HIV/AIDS in the developing world.

#### E. Other Barriers to Access to Pharmaceuticals

High prices or protectionist laws are not the only barriers to providing high quality HIV care in the developing world. Both advocates and opponents of treatment access agree that there are other obstacles to high quality care in the developing world.<sup>68</sup> Persistent barriers include the lack of public health infrastructure to provide testing, counseling, disease surveillance, and partner notification programs. Most developing countries also have a shortage of clinicians and facilities experienced in providing anti-retroviral treatment and monitoring patients for adherence and side effects. They also lack other social services including drug treatment, mental health care, and prevention education.<sup>69</sup>

---

65. Whitt, *supra* note 62, at 255-57.

66. TREBILCOCK & HOWSE, *supra* note 28, at 334 (claiming that TRIPS offers nations the potential to protect genetic resources of biodiversity via patent or other national restrictive laws).

67. Stephenson, *supra* note 63, at 331-32.

68. See Zackie Achmet, *Commentary: Most South Africans Cannot Afford Anti-HIV Drugs*, 324 BRIT. MED. J., 214-18 (2002) (arguing that patent laws prohibiting the production of generic antiretroviral drugs keep prices out of the reach of most South Africans); Donald Berwick, "We All Have AIDS": *Case for Reducing the Cost of HIV Drugs to Zero*, 324 BRIT. MED. J. 214-18 (2002) (recounting the story of how an editorial demanding that the price of HIV drugs be reduced received no response from pharmaceutical companies); Richard Sykes, *Commentary: The Reality of Treating HIV and AIDS in Poor Countries*, 324 BRIT. MED. J. 214-18 (2002) (discussing the need to develop infrastructure to distribute price-reduced drugs).

69. REPORT ON UNAIDS INITIATIVE, *supra* note 5, at 2 (listing barriers to obtaining HIV-

Structural barriers also influence the quality and nature of HIV prevention and care services.<sup>70</sup> Structural factors negatively influencing HIV care and prevention include low levels of economic development, frequent population migrations, political instability, gender inequality, drug policies that promote risky behavior or further marginalize drug users, and laws and policies that maintain any of these conditions.<sup>71</sup> The largest barrier, however, may be the political inertia among governments with limited resources to make public health, equity, and specifically, treatment of HIV/AIDS, priority issues.<sup>72</sup>

Although these barriers seem substantial, they should not dissuade countries from taking steps toward providing more widespread access to pharmaceuticals. Providing HIV/AIDS treatment may have important collateral benefits, such as spurring development of a public health infrastructure, preserving the working abilities of many affected professionals, and providing hope to individuals and families affected by HIV/AIDS.<sup>73</sup>

#### IV. ACCESS TO PHARMACEUTICALS AS A HUMAN RIGHT

The HIV/AIDS epidemic has shaped how advocates think of health and human rights and how they approach their work. Early in the epidemic, public health officials and advocates acknowledged the potential role of human rights and included recognition of that role in international and national strategies.<sup>74</sup> Officially, human rights language has been integrated into most international and national HIV/AIDS strategies developed in the last decade.<sup>75</sup> Unfortunately, realization of human

---

related drugs); Barbara Crossette, *Poor African Countries Lack Ways to Monitor Use of New AIDS Drugs, Experts Warn*, N.Y. TIMES, Apr. 1, 2001 (describing challenges to providing HIV treatment safely in countries with poor health infrastructure); *GALEN to Assist Safe Introduction of ARV Drugs*, U.S. NEWSWIRE, Apr. 9, 2001 (reporting that the International Association of Physicians in AIDS Care (IAPAC) argue successful HIV treatment faces many other obstacles besides the high price of drug treatment).

70. Kim M. Blankenship et al., *Structural Interventions in Public Health*, 14 AIDS S11 (suppl. 1) (2000).

71. Richard G. Parker et al., *Structural Barriers and Facilitators in HIV Prevention: A Review of International Research*, 14 AIDS S22 (Suppl. 1) (2000).

72. All governments can claim to have limited resources—either because the country is poor in an absolute sense, or because government policies prioritize tax reduction over public spending.

73. Piot, *supra* note 19.

74. *World Summit of Ministers of Health, London Declaration on AIDS Prevention*, WHO Doc. WHO/GPA/INF/88.6 (Jan. 28, 1987); *Global Strategy for the Prevention and Control of AIDS*, World Health Assembly Res. WHA 40.26 (May 5, 1987), available at <http://www.aidslaw.ca/Maincontent/otherdocs/Newsletter/vol6nos1-22001/discrimination.htm> (last visited Oct. 16, 2002); *Avoidance of Discrimination in Relation to HIV-infected People and People with AIDS*, World Health Assembly Res. WHA 41.24 (May 13, 1988).

75. *Guidelines on HIV/AIDS and Human Rights as Adopted by the Second International Consultation on HIV/AIDS and Human Rights, Report of the Secretary General*, Second International Consultation on HIV/AIDS and Human Rights (Geneva, Sept. 23-25, 1996), at 11, U.N. Doc. E/CN.4/1997/37 (1997).

rights—meaning both countries’ success in guaranteeing fundamental human rights and their embrace of a human rights perspective on HIV/AIDS—often lags far behind the rhetoric of the official strategies.

An innovative yet elusive assertion that has emerged from the early years of the health and human rights movement is the argument that realization of human rights is a necessary pre-condition to good health.<sup>76</sup> Social epidemiologists have observed that fundamental determinants of health, which are often distinct from traditional “health indicators,” shape the health of populations and thus impact the health of individuals within that population.<sup>77</sup> These fundamental determinants of health include income, socio-economic status, social capital, social cohesion, and race/racism.<sup>78</sup> Jonathan Mann and others applied similar analysis using indicators of human rights. Their argument was most persuasive when considering the particular vulnerability of women and other groups to HIV.<sup>79</sup> In societies in which women have secondary social and legal status to men, where they are usually dependent on men for economic security, and where it is culturally prohibited for women to question men’s sexual activity or to control when and how they have sex, even comprehensive public health education and provision of condoms will not reduce women’s risk of infection with HIV (or STDs, or many other diseases). Women will not be able to use health information fully to protect themselves and their children until they have equal realization of their human rights, both legal and actual.<sup>80</sup>

Activists throughout the world make similar arguments for the necessity of realization of human rights in relation to access to pharmaceuticals. They argue that without governments’ commitment to promote and ensure sharing medical technology at least as vigorously as they have pledged to protect intellectual property rights under TRIPS, the poor in many nations will never achieve good health.

#### A. Foundation in International Human Rights Instruments

---

76. Jonathan Mann et al., *Health and Human Rights*, 1 HEALTH AND HUMAN RIGHTS 6, 19-22 (1994).

77. See Lisa F. Berkman & Ichiro Kawachi, *A Historical Framework for Social Epidemiology*, in SOCIAL EPIDEMIOLOGY 3-12 (Lisa F. Berkman & Ichiro Kawachi, eds., 2000) [hereinafter SOCIAL EPIDEMIOLOGY]; Michael Marmot, *Multilevel Approaches to Understanding Social Determinants*, in SOCIAL EPIDEMIOLOGY, *supra*, 349, 353; Geoffrey Rose, *Sick Individuals and Sick Populations*, 14 INT’L J. OF EPIDEMIOLOGY, 32-38 (1985); GEOFFREY ROSE, *THE STRATEGY OF PREVENTIVE MEDICINE* (1992).

78. John Lynch & George Kaplan, *Socioeconomic Position*, in SOCIAL EPIDEMIOLOGY, *supra* note 77, at 13-35; Nancy Krieger, *Discrimination and Health*, in SOCIAL EPIDEMIOLOGY, at 36-75; Ichiro Kawachi, *Income Inequality and Health*, in SOCIAL EPIDEMIOLOGY, at 76-94; Lisa F. Berkman & Thomas Glass, *Social Integration, Social Networks, Social Support, and Health*, in SOCIAL EPIDEMIOLOGY, at 137-73; Ichiro Kawachi & Lisa Berkman, *Social Cohesion, Social Capital and Health*, in SOCIAL EPIDEMIOLOGY, at 174-90.

79. Jonathan Mann & Sofia Gruskin, *Women’s Health and Human Rights: The Health and Human Rights Movement*, 1 HEALTH AND HUMAN RIGHTS 309, 309-66 (1995); LAWRENCE O. GOSTIN & ZITA LAZZARINI, *HUMAN RIGHTS AND PUBLIC HEALTH IN THE AIDS PANDEMIC* (1997).

80. GOSTIN & LAZZARINI, *id.* at 46.

A careful reader will find no “right to access to pharmaceuticals” in the International Bill of Human Rights or in any subsequent modern human rights instruments. However, such an obligation—although not a defined human right itself—is firmly grounded in the implications of existing substantive provisions and in the special needs created by the current circumstances.

International human rights instruments provide legal support for a right to access to treatment as part of existing human rights law and suggest possible ways to reconcile apparently conflicting interests of commerce and public health. These instruments include several provisions that are highly relevant to access to pharmaceuticals. Both the Universal Declaration of Human Rights (UDHR) and the International Covenant on Economic, Social, and Cultural Rights (ICESCR) incorporate provisions guaranteeing the right to health. Specifically, the UDHR states, “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including...medical care and necessary social services, and the right to security in the event of...sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”<sup>81</sup> The ICESCR makes the right more explicit: “the right to...the highest attainable standard of physical and mental health.”<sup>82</sup> The ICESCR also obligates states to take steps necessary to achieve “prevention, treatment and control of epidemic, endemic, occupational and other diseases...”<sup>83</sup> and “creation of conditions which would assure to all medical service and medical attention in the event of sickness.”<sup>84</sup>

The same documents guarantee the right to share in the benefits of science and technology. The UDHR states, “Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits...”<sup>85</sup> and “the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is author.”<sup>86</sup> The ICESCR provides: “the right to take part in cultural life”<sup>87</sup>; “the right to enjoy the benefits of scientific progress and its applications”<sup>88</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>89</sup> Notably, both the UDHR and ICESCR combine within the same article the right to protection of “authors’” rights in the property interests from their creations *and* the right to share in the benefits of scientific

---

81. Universal Declaration of Human Rights, art. 25.1, G.A. Res. 217A(III), U.N. GAOR, 3d Sess., at 71, U.N. Doc. A/810 (1948) [hereinafter UDHR].

82. International Covenant on Economic, Social, and Cultural Rights, art. 12.1, G.A. Res. 2200A(XXI) U.N. GAOR, Supp. No. 16, at 49, U.N. Doc. A/6316 (1966), reprinted in 6 I.L.M. 360 [hereinafter ICESCR].

83. *Id.*, art. 12.2.c.

84. ICESCR, *supra* note 82, art. 12 § 1, ¶ d.

85. UDHR, *supra* note 81, art. 27 § 1.

86. *Id.*, art. 27 § 2.

87. ICESCR, *supra* note 82, art. 15 § 1, ¶ a.

88. *Id.*, art. 15 § 1, ¶ b.

89. *Id.*, art. 15 § 1, ¶ c.

advancement.<sup>90</sup>

Finally, the UDHR also protects the right to life: “Everyone has the right to life, liberty and security of person.”<sup>91</sup> The International Covenant on Civil and Political Rights (ICCPR) incorporates the right to life by stating: “Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.”<sup>92</sup>

Importantly, pursuant to the ICESCR, each nation agreed to “take steps individually and through international assistance and cooperation, 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 by all appropriate means, including particularly the adoption of legislative measures.”<sup>93</sup>

Tensions between sharing and protecting substantive information about scientific advances and between national responsibility for human rights and international obligations of rich countries to poorer ones are built into the fiber of the UDHR and the ICESCR. Resolving these tensions requires balancing the conflicting goals and carefully navigating international rules regarding trade and intellectual property. It also requires recognition of the fact that, in the era of modern public health and medicine, access to the benefits of scientific advances, including the best means of prevention and treatment, is inextricably bound up with individuals’ ability to realize their rights to health and life.<sup>94</sup>

Even if we were not able to find specific legal means of addressing questions of access to pharmaceuticals within the human rights legal framework, the current status of public health needs around the world suggests that access is clearly a human rights issue in the broadest sense. The United Nations Charter and the Universal Declaration of Human Rights express broad notions of social justice and equality of dignity and rights that go beyond the individual rights enumerated in the specific human rights instruments. Along with the ICESCR and the ICCPR, they form the foundations of international human rights law.<sup>95</sup> Significantly, the

---

90. See also *id.* art. 15 § 2 (“The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.”); art. 15 § 3 (“The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.”); art. 15 § 4 (“[T]he States Parties to the present covenant recognize the benefits to be derived from the encouragement and development of international contacts and cooperation in the scientific and cultural fields.”).

91. UDHR, *supra* note 81, art. 3.

92. International Covenant on Civil and Political Rights, adopted Dec. 19, 1966, S. Exec. Doc. E, 95-2, art. 6, ¶ 1, 999 U.N.T.S. 171 [hereinafter ICCPR].

93. *Id.*, art. 2, ¶ 1.

94. Paul Farmer et al, *Community-Based Approaches to HIV Treatment in Resource-Poor Settings*, 358 LANCET 404 (2001).

95. The United Nations Charter applies to all member states, including the United States, but is concerned mostly with the founding of the United Nations and less with articulating specific human rights norms or obligations. The UDHR is non-binding on its signatories because it is a declaration rather than a convention or treaty. The degree of international acceptance of the UDHR has been so great, however, that it has achieved the status of “customary international law” with its terms applicable to all member states. INTERNATIONAL



U.N. Charter and the UDHR also illustrate the use of human rights as a “mode of moral reasoning rooted in or articulating a vision of the good in social relations.”<sup>96</sup> In this context, the current gross disparities in access to medicines, health outcomes, and investment of resources seem fundamentally unfair.

#### B. Support in Other Sources of Law

A wide range of other international and domestic provisions relate to access issues. First, and perhaps foremost in legal advocacy efforts, are those domestic laws and constitutions that have incorporated human rights into the substantive rights guaranteed to their people.<sup>97</sup> Such legal provisions can form the theoretical and procedural basis for local efforts to enforce individual human rights using advocacy and the court system. Actual realization of human rights through domestic provisions depends, of course, on a relatively strong and independent judiciary and government resources to back any finding of obligation.

International and national codes of research ethics that mandate consideration of distributive justice issues support requiring access to new pharmaceuticals at least to those subjects or *groups* who have participated in the research.<sup>98</sup> While codes of research ethics do not make any claims to

---

HUMAN RIGHTS 617 (Frank Newman & David Weissbrodt eds., 1990) (noting that the UDHR is “widely acknowledged as reflecting binding norms of customary international law....”). Although the United States played an important role in drafting the ICESCR and the ICCPR, it has ratified only the ICCPR. Thus, while the legal obligations stemming expressly from the ICESCR do not apply to the United States, the broad obligations to respect, protect, and fulfill the whole range of human rights contained in the UDHR and alluded to in the U.N. Charter do apply.

96. Scott Burris, *Introduction: Merging Law, Human Rights and Social Epidemiology*, 30 J. OF L., MEDICINE & ETHICS 498, 502 (2002).

97. See Janet Koven Levit, *The Constitutionalization of Human Rights in Argentina: Problem or Promise?*, 37 COLUM. J. TRANSNAT'L L. 281, 292-302 tbl. 1 (1999) (describing incorporation of human rights substantive norms into constitutions across Latin America and the exclusions and limitations of such internalization); THE RIGHT TO HEALTH IN THE AMERICAS: A COMPARATIVE CONSTITUTIONAL STUDY (Hernán L. Fuenzalida-Puelma & Susan Scholle Connor eds., 1989) (describing efforts to incorporate the “right to health” into Latin American Constitutions); Hector Fix-Fierro & Sergio Lopez-Ayllon, *The Impact of Globalization on the Reform of the State and Law in Latin America*, 19 HOUS. J. INT'L L. 785, 797-99 (describing acceptance of jurisdiction of the regional Inter-American Court of Human Rights by 14 countries and the incorporation of human rights norms into constitutions in a number of countries, including El Salvador, Argentina and Paraguay).

98. NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, Part B, § 3 (U.S. Department of Health Education and Welfare, 1979) (“[W]henver research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.”), available at <http://ohrp.osphs.dhhs.gov/humansubjects/guidance/belmont.htm> (last visited Apr. 26, 2002) [hereinafter BELMONT REPORT]; WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS ¶¶ 19, 30 (1964) (“Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried

act as tools to resolve larger human rights issues, their basic premise that the benefits and burdens of research should be fairly distributed<sup>99</sup> strongly supports the idea that individuals and groups who bear the burdens of research should be provided an opportunity to benefit from the results of that research. Thus, study sponsors have an obligation to those individuals and groups who willingly undertake the risks of research—unanticipated harms, unpleasant or dangerous side effects, or failure of study regimens or devices—to ensure that the subjects receive new treatments or interventions discovered in the course of the study. This obligation has implications both for short-term individual studies and the long-term obligations of governments, institutions, and private entities pursuing health research in the developing world.

Parties to the General Agreement on Tariffs and Trade (GATT) have agreed on principles of sustainable development that foster protection of the environment, growth of domestic industries for essential goods and services, and the creation of domestic infrastructure.<sup>100</sup> These goals arguably include bolstering a country's ability to manufacture medicines needed to treat significant public health problems. Moreover, international agreements regarding the interpretation of treaties and trade agreements indicate that states' obligations under human rights should take precedence over other international agreements.<sup>101</sup> Finally, trade agreements themselves allow states to act to protect the public health<sup>102</sup> and to promote sectors vital to their development, as well as to prevent "abuse of patents" that unreasonably restrain trade and the transfer of intellectual property.<sup>103</sup>

#### V. RECONCILING CONFLICTS, FINDING POSSIBLE SOLUTIONS

This section considers possible ways to reconcile the potentially conflicting demands of two bodies of international law—human rights and intellectual property provisions—that are crucial to the debate over access to pharmaceuticals in poor countries. International human rights law emphasizes the primary values of respecting human dignity, enhancing

---

out stand to benefit from the results of the research... At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study."), available at <http://www.med.umich.edu/irbmed/FederalDocuments/hhs/HHS45CFR46.html#46.401> [hereinafter DECLARATION OF HELSINKI]; COUNCIL OF INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS guidelines 5, 10, 12, 21 (Jan. 2002), available at [http://www.cioms.ch/guidelines\\_january\\_2002.htm](http://www.cioms.ch/guidelines_january_2002.htm) (last visited Apr. 26, 2002) [hereinafter CIOMS GUIDELINES].

99. BELMONT REPORT, *supra* note 98, ¶¶ 19, 30; CIOMS GUIDELINES, *supra* note 98, at guideline 12.

100. Marrakesh Agreement, *supra* note 35, pmb. (referring to member countries' commitment to sustainable development).

101. Vienna Convention on the Law of Treaties, May 22, 1969, 1155 U.N.T.S. 331, 8 I.L.M. 679.

102. TRIPS, *supra* note 35, art. 27, ¶ 2.

103. *Id.*, art. 8, ¶ 2.

health, and promoting the right to life, while infringing on other rights as little as possible. From intellectual property provisions we may draw on the full range of exceptions to patent protection allowed under TRIPS, as well as the power of states to tax, use price controls, and adopt tiered pricing. Additionally, potential solutions ought to include other strategies, such as governments negotiating agreements with pharmaceutical companies for donations or discounts, undertaking brokered deals for purchase of generics, and seeking debt cancellation under specific new programs. Finally, some would suggest that more radical solutions ought to be considered, even if they are not ultimately necessary.

#### A. Human Rights as a Framing Mechanism

Article 15 of the ICESCR establishes a framework for intellectual property rights in three related paragraphs. At the same time, however, the article poses the difficult challenge of how to interpret, prioritize, and reconcile the seemingly conflicting rights contained within it. Article 15 asserts that “[t]he States Parties to the present Covenant recognize the right of everyone...To take part in cultural life...to enjoy the benefits of scientific progress and its applications...[and] 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>104</sup>

These rights have a meaning and context within the Covenant itself, as well as in the larger realm of international legal provisions relating to the same subjects. Both the UDHR and the ICESCR address these rights in the same article, which suggests that the drafters intended them to be linked and reconciled—or at least balanced.<sup>105</sup> A balanced interpretation would neither abolish intellectual property protections nor unduly infringe on the right of people to benefit from scientific innovations. Rather, such an interpretation would recognize both the importance of protecting intellectual property for the promotion of new marketable drugs and of allowing states to take reasonable steps to protect and preserve public health by making important drugs affordable and available.<sup>106</sup> A middle ground that preserves and maximizes both interests would represent an appropriate and balanced interpretation of the drafters’ goals.

Human rights instruments, such as the ICESCR<sup>107</sup>, recognize that many

---

104. ICESCR, *supra* note 82, art. 15, § 1, ¶¶ a-c.

105. Chapman, *supra* note 61, ¶¶ 19-24 (examining record of the drafting of Article 27 of the UDHR and Article 15 of the ICESCR and the adoption of the ICESCR to show that delegates intended all three provisions to be seen as interrelated and that recognition of each was essential to full enjoyment of all).

106. World Health Organization, *Statement by the World Health Organization on the Outcome of the World Trade Organization’s Doha Ministerial Conference*, Nov. 15, 2001 (expressing pleasure with WTO ministers’ clear conclusion that the TRIPS agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ rights to protect public health and, in particular, promote access to medicines for all.”), at <http://www.who.int/inf-pr-2001/en/state2001-18.html> (last visited Apr. 21, 2002); WHO Medicines Strategy, *supra* note 3.

107. The ICESCR provides,

of the rights contained in them are not absolute and must necessarily be limited under certain circumstances in order to protect other rights or to preserve the overall intention of the documents.<sup>108</sup> For example, although the right to protection of property is important for full realization of the rights protected by the Covenant, Article 4 of the ICESCR clearly recognizes that it could be limited, when done so by law and “for the purpose of promoting the general welfare.”<sup>109</sup>

Reconciling the tension between sharing scientific advances and protecting intellectual property will require balancing not only these obligations, but also the underlying interests of the parties, including promoting commerce and protecting public health. In addressing these competing interests Audrey Chapman explains,

A human rights approach takes what is often an implicit balance between the rights of inventors and creators and the interests of the wider society within intellectual property paradigms and makes it far more explicit and exacting. A human rights approach is predicated on the centrality of protecting and nurturing human dignity and the common good. From a human rights perspective, therefore, the rights of the creator are not absolute but conditional on contributing to the common good and welfare of the society.<sup>110</sup>

Without trying to create a hierarchy of human rights, it is nonetheless possible to recognize the fundamental importance of the right to life. Without it, no realization of other rights is possible. The HIV epidemic threatens the right to life of millions of people. Rights to private property, while important, should not take precedence over the right to life. Since sharing scientific information and medical advances in this case directly supports the right to life, it ought to be ensured through means that

---

The State Parties to the present Covenant recognize that, in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.  
ICESCR, *supra* note 82, art. 4.

108. See also UDHR, *supra* note 81, art. 29, ¶ 2; ICCPR, *supra* note 90, art. 4 (“In time of public emergency which threatens the life of the nation and the existence of which is officially proclaimed, the States Parties to the present Covenant may take measures derogating from their obligations under the present Covenant to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with their other obligations under international law and do not involve discrimination solely on the ground of race, colour, sex, language, religious or social origin...”)

109. Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights, Maastricht, June 2-6, 1986, ¶¶ 46-56, (providing an interpretation of Article 4 of the ICESCR on permissible limitations of ESC rights and the necessary criteria and procedures for such limitation), at [http://www.unhchr.ch/tbs/doc.nsf/\(Symbol\)/E.C.12.2000.13.En?Opendocument](http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/E.C.12.2000.13.En?Opendocument) (last visited Apr. 26, 2002) [hereinafter Limburg Principles].

110. Chapman, *supra* note 61, ¶ 27.

respect, protect, and fulfill other human rights. If reasonable limitations on the property rights of authors can bring about greater protection of the right to life—for instance, by restricting the geographic scope of patent protection, changing the time of exclusive enjoyment, or permitting uses under licensing provisions that protect the right to some return on investment—and these limitations fit within the provisions of existing international trade and intellectual property regimes, then these limitations should be considered to be well within what was intended by the drafters and interpreters of the UDHR and the ICESCR.<sup>111</sup>

Another approach to reconciliation would understand “authors’ rights” as being intended to protect the creative efforts of individuals or groups of researchers, but not the monopoly interests of multi-national corporations or nations. To the degree that protection exceeds individual needs, it could be limited to ensure other rights.

More generally, human rights considerations in Article 15 of the ICESCR impose conditions on “authors’” rights protected and by extension on the international and domestic intellectual property regimes developed to protect those rights. Intellectual property rights should be limited when necessary to protect the public health and to the degree necessary to guarantee the general welfare. As Chapman puts it,

To be consistent with the full provisions of Article 15, the type and level of protection afforded under any intellectual property regime must facilitate and promote cultural participation and scientific progress and do so in a manner that will broadly benefit members of society both on an individual and collective level. These considerations go well beyond a simple economic calculus often governing intellectual property law.<sup>112</sup>

The basic terms of TRIPS, which grant patent protection to all suitable processes and products for twenty years with limited exceptions, may satisfy neither the letter nor the spirit of this human rights mandate if they deter developing countries from utilizing the measures acceptable under international law to provide drugs at affordable prices.<sup>113</sup> If the exceptions to TRIPS are liberally interpreted and respected by both economically powerful countries and multinational corporations, however, the TRIPS regime could allow compliance with human rights standards.<sup>114</sup>

Recognizing some limitations on the right to intellectual property so as to respect, protect and fulfill human rights is also wholly consistent with the Vienna Convention on the Law of Treaties, other trade provisions, and principles of sustainable development.<sup>115</sup> The United Nations Committee

---

111. Limburg Principles, *supra* note 109.

112. Chapman, *supra* note 61, ¶ 29.

113. *Id.* ¶ 62.

114. Weissman, *supra* note 23, at 1096-1117; *see generally*, Chapman, *supra* note 61 (discussing intellectual property as a human right).

115. TRIPS, *supra* note 35, pmb1.

on Economic Social and Cultural Rights stated in 1999,

Human rights norms must shape the process of international economic policy formulation so that the benefits for human development of the evolving international trading regime will be shared equitably by all, in particular the most vulnerable sectors ... Trade liberalization must be understood as a means, not an end. The end which trade liberalization would serve is the objective of human well being to which international human rights instruments give legal expression.<sup>116</sup>

Utilizing human rights as a framing mechanism offers the advantage of providing a system of values that can modify economic behavior and norms, and even the negative aspects of the trend towards globalization.<sup>117</sup> In the words of the U.N.'s High Commissioner for Human Rights:<sup>118</sup>

Globalization as an economic process must be subject to the moral and ethical imperative to which the international human rights instruments give legal expression....Human rights provide a rigorous framework to empower people from around the world to harness the energies of the global movement and shape a new globalization that benefits all people.<sup>119</sup>

Although the human rights movement has been criticized, rightly or wrongly, for calling every good a "right," that criticism is inapt in this case. One need not conceptualize a human right, *per se*, for access to pharmaceuticals. Rather, access to pharmaceuticals and other important advances of science derives from solid obligations under existing, long-established rights. "Human rights" is important to the access problem more as a system of law and form of moral persuasion than as a substantively expanding definitional system. It is one of the few mechanisms that can be used logically and persuasively to bridge the gap between the tragic effects and dimension of the HIV/AIDS epidemic and

---

116. U.N. ESCOR, 21st Sess., 47th mtg. at ¶ 5, U.N. Doc. E/C.12/1999/9 (1999).

117. Chapman, *supra* note 61, ¶ 6.

The establishment of the World Trade Organization in 1994 and the coming into force of the international [TRIPS Agreement]...have strengthened the global character of intellectual property regimes....Unless human rights advocates provide an effective intellectual and organizational counter weight to economic interests, the intellectual property landscape will be reshaped in the years ahead without adequate consideration of the impact on human rights.

118. As an official international spokesperson for the United Nations and an advocate of human rights, the High Commissioner has been recognized for her important work in the field, especially her contribution to increasing international awareness and recognition of economic, social, and cultural rights. *See, e.g.*, Press Release, Amnesty International, United Nations: Mary Robinson's Departure a Loss for Human Rights, Mar. 19, 2002 (AI-index: IOR 40/005/2002).

119. Mary Robinson, *Tell Leaders that Human Rights Aren't Optional*, INT'L HERALD TRIB., Feb. 7, 2002, at 6.

the unavailability of existing treatments. Guaranteeing access to pharmaceuticals will also require commitments from the fields of development and international cooperation and security.

#### B. Options Under TRIPS

Existing trade provisions permit countries to take certain actions designed to increase access to pharmaceuticals in order to address pressing public health problems.<sup>120</sup> These emergency mechanisms include: exceptions from patentability; limits on patents where patent holder's rights are not unreasonably burdened; parallel importing; compulsory licensing; and generic substitution.<sup>121</sup> Countries can also use taxes on pharmaceuticals, royalties, and price controls that are not discriminatory.<sup>122</sup> The rules allow countries to grant tax breaks and price control variances to companies that agree to grant non-exclusive licenses for production.

Other innovative strategies are also worth considering. Pharmaceutical companies could accept the widespread use of tiered pricing (or price discrimination) that would allow companies to offer drugs for very low fees in some settings, while maintaining high prices in others (although companies suspect, perhaps correctly, that this strategy will create pressure from consumers in more affluent countries to lower all prices).<sup>123</sup>

Compulsory licensing has received much attention recently for a few reasons. It offers a potentially powerful tool for countries with pressing public health needs requiring resort to both new drugs and drugs still under patent in other countries, particularly high-cost drugs.<sup>124</sup> Major patent holders have staunchly resisted any efforts by developing countries to use compulsory licensing for fear of establishing a precedent for developing countries to avoid honoring patents.<sup>125</sup> However, compulsory licensing is explicitly allowed under the TRIPS agreement<sup>126</sup> and ought to be available to developing countries facing crises such as HIV/AIDS or other deadly epidemics.<sup>127</sup> According to one proposed model, governments seeking to utilize compulsory licensing and comply with TRIPS should: (1) be simple, avoid overly legalistic provisions or expensive mechanisms (e.g., use administrative not judicial mechanisms); (2) include strong government-use provisions, at least as strong as those adopted by western countries, such as the U.S., U.K., and Germany; (3) provide a simple system for setting the level of compensation to patent holders; (4) allow production for export under specific circumstances; and (5) allow

---

120. Weissman, *supra* note 23, at 1098.

121. See *supra* Subsection III.A for discussion of substance of TRIPS and its exceptions.

122. Weissman, *supra* note 23, at 1072.

123. *European Report*, "European Pharmaceutical Industry Defends Third World Actions," European Information Services, Mar. 17, 2001, No. 2577.

124. Chapman, *supra* note 61, ¶ 63.

125. Tom Abate, *Drug Makers Yield to Pressure; Multinational Firms Offer Tiered Pricing for Life-Saving Medications*, S.F. CHRON., Mar. 25, 2001, at A15.

126. TRIPS, *supra* note 35, art. 31.

127. Sakboon, *supra* note 22.

emergency authorizations to address public health crises.<sup>128</sup>

The international community could also address some of the competing burdens faced by developing countries by canceling all or most of their debt.<sup>129</sup> In 1996, the International Monetary Fund and the World Bank began a program aimed at systematically reducing the debt burden of many of the world's poorest countries. This project, the Heavily Indebted Poor Countries (HIPC) Initiative, provides direct assistance for eligible countries to reduce sharply their foreign debt. An additional initiative, commenced in 1999, will allow countries to reduce their foreign debt to 150% of the value of their exports or 250% of their annual government revenues. These mechanisms are expected to relieve about two-thirds of most countries' debts.<sup>130</sup> The World Bank's early evaluation of this program suggests that it will more than double the funds available in many countries for social expenditures and that an average of 25% of all debt relief is going to health care (not including other priority programs addressing HIV/AIDS).<sup>131</sup> While debt relief will not transform poor countries overnight or make them able to afford high-priced drugs, it could allow these countries to assume some or all of the costs of imported generics or to begin building capacity for local manufacture.

Other options involve no challenge to international or national trade and patent regimes. For example, some suggest that donations and negotiated discounts are the answer to supplying HIV treatments to the poorest countries.<sup>132</sup> In fact, a number of drug companies have promised

---

128. James Love, *Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord* (Jan. 21, 2001), available at <http://www.cptech.org/ip/health/cl/recommendedstatepractice.html> (last visited Apr. 21, 2002).

129. Marc Borbely, *Activists: IMF, World Bank AIDS Recommendations 'Morally Sickening'*, UNITED PRESS INT'L, Apr. 18, 2000 (Activists argue that, instead of giving money, the World Bank, the IMF and the international community ought to cancel the debt of developing countries in order to allow them to invest in their own infrastructures). On the tenth anniversary of the Convention of the Rights of the Child, Theo-Ben Gurirab, President of the UN General Assembly, noted that the heavy debt of the world's poorest nations makes it difficult for them to invest in child welfare. He stated that, among countries in Sub-Saharan Africa, the amount spent on servicing foreign debt each year outweighs their entire expenditures on health and education, *UN Assembly President Calls for "Generous Funds—Unwavering Commitment" To Realize Culture of Peace*, M2 PRESSWIRE, Nov. 12, 1999.

130. Press Release, The World Bank, World Bank and IMF Support US\$3 Billion In Debt Service Relief For Tanzania Under Enhanced HIPC Initiative, Nov. 27, 2001, (No: 2002/133NB), available at <http://www.worldbank.org/news/pressrelease.nsf> (last visited May 7, 2002).

131. As a result of this reduction, countries have increased their spending on social programs from US \$4.4 billion in 1999 to US \$6.9 billion in 2002. Estimates are that two-thirds of total debt relief will be used for education and health care (forty percent for education, twenty-five percent for health care), while other priority programs include HIV/AIDS programs. THE WORLD BANK, FINANCIAL IMPACT OF THE HIPC INITIATIVE: FIRST 25 COUNTRY CASES tables 1, 3, Mar. 2002, available at [http://www.worldbank.org/hipc/Financial\\_Impact\\_March0602.pdf](http://www.worldbank.org/hipc/Financial_Impact_March0602.pdf).

132. *Boehringer Ingelheim Joins Largest-Ever Global Program with United Nations Agencies to Accelerate Access to HIV/AIDS Care and Treatment in Developing World*, UNIV. NEWS SERV., May 11, 2000 (announcing B-I's decision to join the groups offering discounts, and describing other significant barriers to good treatment and care); James Ciment, *U.S. Drug Companies Announce Vaccine Initiative*, 320 BRIT. MED. J. 736, Mar. 18, 2000 (reporting on a plan by four vaccine



steep discounts across Africa and in other crisis situations.<sup>133</sup> Donations and discounts, however, do not create reliable sources of supply over the long term and do not help develop domestic capacity. Both strategies allow pharmaceutical companies to maintain control of the cost, supply, profits, and manufacturing capacity of essential medicines.

In 1997 the Joint United Nations Programme on HIV/AIDS (UNAIDS) began the HIV Drug Access Initiative (DAI), which is intended to develop and implement new ways to improve access to HIV drugs and build treatment capacity in poor countries. Funded by UNAIDS, cosponsors, and donors, the DAI is a public-private partnership that includes several of the largest pharmaceutical manufacturers of anti-retrovirals and associated drugs to treat opportunistic infections. In its first phase, from 1997 through early 2000, the DAI showed promise in mobilizing a combination of donors, increasing the capacity of health care workers in the poorest countries to administer anti-retrovirals, and expanding the program to other countries. During that time, however, the program brought treatment to relatively few people with AIDS.<sup>134</sup> Moreover, although DAI was originally able to secure significant discounts through negotiations with its pharmaceutical manufacturing partners, by 1999 DAI found it necessary to utilize the exceptions to patent and trade rules. In 1999 DAI resorted to negotiating separately with producers of generic versions of several HIV drugs, beginning discussions with Brazilian manufacturers for generic versions of anti-retrovirals in March of 2000.<sup>135</sup> Unfortunately, HIV infection rates continue to increase in many developing countries. Some activists and clinicians, frustrated with moderate approaches to providing access to pharmaceuticals, desire more aggressive action.<sup>136</sup> Radical

---

manufacturers to donate \$150 million worth of "state of the art" vaccines to the developing world); *AIDS Drugs for Poor Nations*, Editorial, N.Y. TIMES, Mar. 12, 2001, at A14 (reporting that Merck was lowering the price of two important HIV drugs to one tenth of what they sold for in western countries).

133. Maggie Farley, *Six Companies Agree to Discounts as U.N. Prepares Massive Campaign Against the Epidemic*, L.A. TIMES, Apr. 6, 2001, at A1-14 (Kofi Annan successfully negotiates discounts from six companies at the same time the U.N. campaign against AIDS announced); Abate, *supra* note 123 (noting that drug company offers of discounts were being made as an attempt to head off international action that could lead to the undermining of patents); Gavin Yamey, *Drug Companies Cut HIV Drug Prices in the Developing World*, 320 BRIT. MED. J. 1357, May 20, 2000 (discussing the decision of five multinational firms to cut the price of HIV drugs in the developing world).

134. From 1997 to 1999, pilot programs were set up in Uganda, Côte d'Ivoire, Chile and Vietnam. In addition to setting up national advisory boards and training doctors and other health care workers to use anti-retrovirals and to treat opportunistic infections, the DAI managed to get modest numbers of people with HIV/AIDS on anti-retroviral therapy (ARV). The initial meeting evaluation reported that in Uganda, out of an estimated one million people with HIV/AIDS, 900 were on ARV; in Côte d'Ivoire, out of an estimated 800,000 infected, 650 were on ARV; in Chile, out of 16,000 infected, 2500 were on ARV; and in Vietnam, out of an estimated 88,000 infected, seventy were on ARV. REPORT ON UNAIDS INITIATIVE, *supra* note 5, at 6-7.

135. *Id.* at 4 (reporting that, after initial negotiations with companies brought no more discounts, DAI began working with generic manufacturers).

136. Donald Berwick, "We All Have AIDS": Case For Reducing the Cost of HIV Drugs to Zero, 324 BRIT. MED. J. 214, 214-16, Jan. 26, 2002; Achmet, *supra* note 68, at 214-18.

solutions include changing or abolishing TRIPS, removing medicine and health-related products entirely from the current system of intellectual property protections, and returning to an earlier type of intellectual property system that extended patent protection only to processes and not to products. This last approach has allowed countries such as India to develop a thriving domestic pharmaceutical industry.<sup>137</sup> India has benefited from its own internal manufacturing of cheap generics and produces the least expensive anti-retrovirals in the world.<sup>138</sup> Latin American countries in particular have adopted other legal means to improve access to pharmaceuticals.

## VI. CASE STUDY: BRAZIL AND ACCESS TO ANTI-RETROVIRAL MEDICATIONS

### A. Medications

In several countries in Latin America, including Brazil, Costa Rica, Argentina, Colombia, Chile and Venezuela, advocates have used legal measures including legislation and the courts to establish a “right to treatment” with HIV medications.<sup>139</sup> These efforts were made possible by the widespread incorporation into Latin American law of the rights to health, health care, and the benefits from scientific advances.<sup>140</sup> Brazil’s government has made treatment of all those infected with HIV its goal and has taken important steps through its legal, public health, pharmaceutical sectors to make this a reality. How Brazil addressed this issue, its relative successes and challenges it continues to face can provide instruction for other countries.

### B. Brazil’s HIV Epidemic

In the early 1990s, Brazil faced a rapidly increasing epidemic of HIV/AIDS. In 1994, the World Bank projected that Brazil would have 1.2 million people living with HIV by the year 2000.<sup>141</sup> The Brazilian government, its industries, and its people mobilized to defy that grim prediction. By adopting a policy that guaranteed all persons with HIV the right to free anti-retroviral medication, focusing its prevention efforts, and reinforcing its public health infrastructure to facilitate both effective prevention and treatment efforts, Brazil reached the year 2000 with only

---

137. Judy Rein, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines*, 21 NW. J. INT’L L. & BUS. 379, 386 (2001).

138. Ellen ‘t Hoen & Suerie Moon, *Pills and Pocketbooks: Equity Pricing of Essential Medicines in Developing Countries* (July 11, 2001), available at <http://www.accessmed-msf.org/upload/ReportsandPublications/20920021811218/4-5.pdf>.

139. Enrique Gonzalez Mac Dowell, *Juridical Action for the Protection of Collective Rights and Its Legal Impact: a Study Case 2* (Aug. 2000) (on file with author); see also *infra* note 173 (noting Brazilian legislative strategies).

140. MacDowell, *supra* note 139.

141. Piot, *supra* note 19.

540,000 people infected with HIV.<sup>142</sup> AIDS deaths during this period decreased by sixty percent.<sup>143</sup> Part of this success was due to greatly increased access to anti-retroviral therapy for persons living with HIV. In 1997 approximately 25,000 persons in Brazil received combination therapy; by 2002 at least 100,000 were on therapy.<sup>144</sup> Brazil's Minister of Health identifies three principles responsible for the country's success in delivering free universal HIV care: (1) committed leadership at the top; (2) involvement of community and civil society groups in efforts to reach poor and deliver treatment; and (3) affordable medicines.<sup>145</sup>

Increased access was attributable largely to government commitment, the reduced costs of pharmaceuticals made possible by domestic manufacture of generic drugs, and negotiated price discounts for other drugs.<sup>146</sup> The actual costs of HIV therapy in Brazil have fallen from an estimated annual cost of \$7,858 per person in 1997 to \$4,137 per person in 2001.<sup>147</sup> In the United States, the same regimens cost between \$10,000 and \$15,000 annually. Additionally, although the Brazilian government spent between \$300 million and \$320 million per year in the late 1990s to provide HIV care, it saved an estimated \$420 million on hospital costs over the same period, because fewer patients with HIV were getting sick and dying.<sup>148</sup>

### C. Brazil's Intellectual Property and Patent Laws

Like many developing countries, Brazil did not recognize or enforce patents on pharmaceuticals before 1994. After joining the WTO, Brazil began the process of adopting legislation that would fulfill the TRIPS requirements. In 1996, it enacted the Industrial Property Law,<sup>149</sup> which provided patent protection for drugs (and other industrial products) developed after that time as long as the manufacturer conducts some part of the drug's manufacture in Brazil.<sup>150</sup> This "local working" requirement, in addition to the TRIPS clause that exempts from patent protection drugs in existence prior to 1994, has enabled the Brazilian government to license generic local production of eight of the twelve current AIDS medications.<sup>151</sup>

---

142. *Id.*

143. *Id.*

144. *Id.*

145. Trudy Rubin, *Africa Must Learn from Brazil's AIDS Fight*, *BALT. SUN*, July 5, 2001, at 11A (Brazilian Health Minister Jose Serra's description of success of program).

146. *Id.*

147. *Interests that Kill: US Pressures Brazil To Abandon Successful AIDS Program*, ACTION ALERT (Int'l Gay & Lesbian Human Rights Comm., San Francisco, CA), Feb. 6, 2001 at <http://www.iglhrc.org/world/southamerica/Brazil2001Jan.html> (last visited Apr. 4, 2002).

148. Miriam Jordan, *Merck Vows AIDS Help for Brazilians*, *WALL ST. J.*, Mar. 29, 2001, at A10.

149. Lei No. 9.279, de 14 de maio de 1996, D.O.U. de 15.05.1996, at <http://www.cptech.org/ip/health/cl/brazil1.html> (last visited Apr. 28, 2002) [hereinafter Law No. 9.279].

150. *Id.* art. 68 (requiring patent holders to manufacture their patented products in Brazil or be subject to compulsory licensing).

151. Naomi A. Bass, Note, *Implications of the TRIPS Agreement for Developing Countries Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 *GEO. WASH. INT'L L.*

In 1999, the President of Brazil issued a decree establishing rules for compulsory licensing using another provision of the 1996 patent law that permits compulsory licensing in cases of national emergency, including situations in which there is an impending public health crisis.<sup>152</sup> This would allow licensing of post-1994 drugs. Thus far, Brazil has not issued compulsory licenses under this provision, but it has used the threat of licensing to encourage companies to negotiate price discounts.<sup>153</sup>

#### D. Brazil's Economy and Health Statistics

The World Bank classifies Brazil as an upper-middle-income country.<sup>154</sup> Its per capita GDP of \$6,500<sup>155</sup> lies well above levels in many of the world's poorest nations,<sup>156</sup> but far below the \$36,000 mark of the United States.<sup>157</sup> Life expectancy in 1999 was sixty-seven years and infant mortality was thirty-two per 1000 live births. Eighty-seven percent of its population has access to safe water and 77% to improved sanitation.<sup>158</sup> These average figures mask substantial inequalities in income and health status. The "Gini index," a well-known indicator of national income inequality, rates Brazil as 148th out of 150 countries, showing that income disparities in Brazil are among the starkest in the world.<sup>159</sup> Extreme disparities in income are associated with disparities in health status, meaning that the poorest Brazilians remain highly vulnerable to ill health.<sup>160</sup> Despite Brazil's middle-

---

REV. 191, 207 (2002).

152. Presidential Decree No. 3.201 of Oct. 6, 1999 (establishing rules concerning the granting, ex officio, of compulsory licenses in cases of national emergency and public interest provided for in article 71 of Law No. 9.279), at <http://www.cptech.org/ip/health/c/brazil/PresDecree.html> (last visited Apr. 28, 2002).

153. Bass, *supra* note 151, at 209; Sakboon, *supra* note 22.

154. WORLD BANK GROUP. DATA AND STATISTICS: COUNTRY CLASSIFICATION, at <http://www.worldbank.org/data/countryclass/classgroups.htm> (last visited May 9, 2002). Brazil is classified as upper-middle-income. This group includes thirty-eight countries with gross national income (GNI) per capita between \$2,996 and \$9,265 per year. For comparison, low income countries have GNIs per capita of less than \$756 per year (there are sixty-three countries in this bracket, including at least thirty-five in Africa). *Id.*

155. CIA, THE WORLD FACTBOOK (2001) (giving information on geography, economy, government and other aspects for each country), at <http://www.cia.gov/cia/publications/factbook/> (last visited Apr. 29, 2002). Other middle-income countries with significant HIV/AIDS epidemics include South Africa, per capita GDP of \$8,500; Botswana, per capita GDP of \$6,600; Namibia, per capita GDP of \$4,300. Lower-middle income countries include India, per capita GDP of \$2,200 and Zimbabwe, per capita GDP of \$2,500.

156. *Id.* Angola has a GDP per capita of \$1,000; the Congo has a GDP per capita of \$600; Guinea-Bissau has a GDP per capita of \$850 and Malawi has a GDP per capita of \$900.

157. *Id.* (describing same sectors for the United States).

158. *Brazil: Social Services, World of Information Country Report*, QUEST ECONOMICS DATABASE, JANET MATTHEWS INFO. SERVS., Mar. 18, 2002, at 16. Worldwide, eighty-eight percent of people have safe water, while only sixty percent have adequate sanitation. WHO, *Water and Sanitation*, at [http://www.who.int/m/topics/water\\_sanitation/en/index.html](http://www.who.int/m/topics/water_sanitation/en/index.html) (last visited Feb. 11 2002).

159. Rodolfo Espinoza, *Too Rich, Too Poor*, BRAZIL, May-June 2000, at <http://www.brazzil.com/cvrmay00.htm> (last visited Apr. 4, 2002).

160. Hooman Momen, *Emerging Infectious Diseases—Brazil*, 4 EMERGING INFECTIOUS DISEASES, Jan.-Mar. 1998, (describing major emerging infectious diseases in Brazil including malaria, American Trypanosimiasis, Leishmaniasis, dengue fever, measles, AIDS and other

income status, Brazilians experience relatively high rates of malaria, measles, cholera, hepatitis and a range of other parasitic and viral infections, including HIV/AIDS.<sup>161</sup>

Brazil's strategy—to guarantee access to pharmaceuticals, strengthen its public health infrastructure, and use a combination of generic manufacture and direct and indirect negotiation with drug companies to drive down costs—may have other health benefits. These benefits may include strengthening the network of public health and primary care providers and, more generally, educating the population about health issues. Critics of efforts to provide universal access to HIV therapies, however, argue that providing treatment will have opportunity costs. They argue that funds needed to provide primary care or fight other diseases will be diverted to AIDS, to the detriment of overall health. Brazil's experience suggests otherwise. Brazil hopes to save on future medical care costs through current spending on AIDS therapies. It is projected that Brazil's investment of \$444 million on AIDS drugs in 2000 will allow it to realize substantial savings through prevented future hospitalizations.<sup>162</sup> In 2001, Brazil passed on the \$35 million savings achieved through this strategy to fund other public health initiatives directed at low-income families.<sup>163</sup> Although opportunity costs should factor into designing optimal public health interventions,<sup>164</sup> HIV treatment is a worthy priority that must not be neglected.

#### E. Brazil as a Model

Director of UNAIDS Peter Piot,<sup>165</sup> the UN,<sup>166</sup> the Inter-American Bank<sup>167</sup> and numerous activists, including South African labor unions,<sup>168</sup> have hailed Brazil's achievements in providing HIV/AIDS therapy as a resounding success and potential model for other developing countries. Brazil's achievements in these areas have drawn substantial criticism, however, from TRIPS supporters,<sup>169</sup> the pharmaceutical industry, and

---

viral diseases such as hepatitis A and D, cholera and various fungal infections), at <http://www.cdc.gov/ncidod/EID/vol4no1/momen.htm>.

161. *Id.*

162. "The only study of the program's benefits so far shows that the decline in hospitalizations from opportunistic infections from 1997 to 1999 saved the Health Ministry \$422 million." Tina Rosenberg, *Look at Brazil*, N.Y. TIMES, Jan. 28, 2001, § 6 (Magazine) at 26.

163. Discounts Here to Stay, Kevin Gopal, 21 *Pharmaceutical Executive* 24 (No. 10, Oct. 1, 2001) ("the ministry threatened to invoke a compulsory license to manufacture Viracept (nelfinavir), forcing Roche to cut its price by 40 percent").

164. GOSTIN & LAZZARINI, *supra* note 79, at 61-63.

165. Piot, *supra* note 19.

166. Peter Capella & James Meikle, *U.N. Backs Use of Cheap Generic Anti-AIDS Drugs*, THE GUARDIAN (London), Feb. 21, 2001, at 3.

167. Elena Moreno, *Latin America-HIV/AIDS IDB Urges Countries to Adopt Brazil's HIV/AIDS Prevention Model*. EFE NEWS SERV., Mar. 8, 2002.

168. Congress of South African Trade Unions, *South Africa; Defeating HIV: Now is the Time!*, AFR. NEWS, Feb. 14, 2002.

169. TREBILCOCK & HOWSE, *supra* note 28, at 310-12 (noting that the recording industry and various manufacturers of frequently copied goods—such as "Rolex" watches—also strongly

powerful countries such as the United States. The U.S. brought a complaint to the WTO seeking review of Brazil's Industrial Property Law for possible violations of TRIPS.<sup>170</sup> The U.S. dropped its suit after Brazil agreed not to export its generic drugs.<sup>171</sup> News that Medecins Sans Frontieres (Doctors Without Borders) entered into an agreement with Brazilian companies to purchase combination therapy in Brazil for trials in South Africa<sup>172</sup> suggests that the potential for controversy still exists and that Brazil might again find itself the subject of U.S. or pharmaceutical industry complaints.

#### F. Challenges Still Facing Brazil

Brazil's achievements may also be eroded by other developments, chiefly the passage of time. Brazil can argue legitimately that it should be able to manufacture generic versions of the anti-AIDS drugs that existed

---

supported the mandate for all countries to adopt stronger patent provisions under TRIPS).

170. Sarah Boseley, *Brazil Faces Sanctions Over Cheap AIDS Treatment*, Editorial, SYDNEY MORNING HERALD, Apr. 21, 2001, at 18; *No Patent on Compassion*, ST. LOUIS POST-DISPATCH, Feb. 20, 2001, at B14 (In January 2001, the U.S. asked the WTO to form a trade court to hear patent dispute with Brazil). For the U.S. Trade Representative's perspective on the conflict with Brazil over threats to use compulsory licensing, see SPECIAL REPORT OF THE U.S. TRADE REPRESENTATIVE 10, Apr. 30, 2001, available at <http://www.cptech.org/ip/health/c/brazil> (last visited Apr. 28, 2002.)

171. The United States has a history of objecting to Brazil's intellectual property regimes. In 1987 the U.S. imposed a 100 percent tariff on selected Brazilian imports to the U.S. to signal its disapproval of the existing Brazilian law. Michael Manoochehri, *Unethical Patent Law: How the United States and the WTO Impact the Health of Brazilian Citizens*, FREE INFORMATION PROPERTY EXCHANGE, Apr. 26, 2001, available at <http://www.freeipx.org/display.php?id=46>. The U.S. calculated its penalties to match the estimated \$39 million it claims were lost to American pharmaceutical companies. Weissman, *supra* note 23, at 1078-79. Brazil's enactment of the 1996 law represented an attempt to avoid another costly round of sanctions. However, the willingness of the Brazilian government to encourage local manufacture of generic (unpatented) drugs in Brazil, and to threaten to issue compulsory licenses for newer drugs has drawn the continued ire of both the U.S. government and pharmaceutical companies. The U.S. brought one complaint to the WTO and, although it dropped the suit, it may initiate complaints in the future. In a joint communication, the U.S. and Brazil agreed to a resolution of the dispute about the compatibility of Article 68 of Brazil's Industrial Property Law (Law No. 9.279, art. 96) with the TRIPS Agreement as follows:

Without prejudice of the U.S. and Brazil's different interpretations of the consistency of Article 68 with the TRIPS Agreement, the U.S. Government will withdraw the WTO panel against Brazil concerning the issue, and the Brazilian Government will agree, in the event it deems necessary to apply Article 68 to grant compulsory license on patents held by U.S. companies, to hold prior talks on the matter with the U.S. These talks would be held within the scope of the U.S.-Brazil Consultative Mechanism, in a special session scheduled to discuss the subject.

Joint Communication Brazil-United States, June 25, 2001, available at <http://www.cptech.org/ip/health/c/brazil/statement06252001.html>; Press Release, Office of the U.S. Trade Representative, United States and Brazil Agree to Use Newly Created Consultative Mechanism To Promote Cooperation on HIV/AIDS and Address WTO Patent Dispute, June 25, 2001, available at <http://www.ustr.gov>; Laurie Garrett, *U.N. Session Faces Hurdle; Muslim Nations Balk at Language on Gays*, NEWSDAY, June 26, 2001, at A07 (noting that the U.S. dropped its claim against Brazil in the WTO trade court when Brazil agreed not to export generic drugs manufactured in Brazil).

172. *Medecins Sans Frontieres Imports Generic Drug in Challenge to Patent Laws*, VIRUS WEEKLY, 13 (Feb. 19, 2002) (announcing that MSF will import combination therapy manufactured in Brazil to South Africa for use in clinical trials).

before 1994, because TRIPS applies only to drugs patented and placed on the market after that date. The evolving nature of anti-HIV therapies means that new drugs are being developed all the time and are necessary to treat a rapidly mutating virus. Pre-1994 drugs will soon be obsolete for many patients. TRIPS does not extend such lenient terms to post-1994 drugs, the drugs that will provide the most effective treatment.

Brazil will have to face several difficult alternatives. The government could pay market prices for new drugs (impossible at current prices), seek compulsory licensing of drugs patented since 1994,<sup>173</sup> or continue to try to negotiate directly with pharmaceutical companies for steep discounts on future drugs. So far, the government has successfully used the threat of issuing compulsory licenses to persuade drug companies to negotiate price discounts on new HIV drugs.<sup>174</sup>

Other challenges concern the long-term impact of TRIPS and the Industrial Products Law on investment in Brazil's domestic pharmaceutical industry. Domestic manufacture of generic drugs under threat of compulsory licensing could deter developers of new pharmaceuticals from operating in Brazil if they felt that their patents would not be enforced by the government. On the other hand, a robust manufacturing sector—even one based on imitation of existing drugs—could benefit the economy and the pharmaceutical industry. First, building capacity to manufacture generic drugs could help meet more general public health needs by preventing or curing other illnesses with drugs that have been off-patent for years. Second, providing universal access to HIV medications for persons with HIV will reduce the numbers of productive workers lost to HIV/AIDS over future years, provide an ongoing market for domestically produced generic HIV drugs, and reduce national costs for hospitalization and related care. Savings in these areas could be devoted to other public health objectives or to funding government-sponsored research and development of new drugs.

#### G. Future of Brazil's Program

As in other countries, the future of Brazil's efforts to offer HIV therapies depends on many factors. One key determinant will be the willingness of developed countries to respect the flexibility provided in the TRIPS agreement for developing countries to respond to local conditions, including public health needs, economic crises, and claims of indigenous groups.<sup>175</sup> If developed countries do not respect these aspects of TRIPS, it is unlikely that developing countries will be able to meet the dual obligations facing them: to provide intellectual property protection within the

---

173. Compulsory licensing is permitted under art. 31 of TRIPS. Brazil has potential routes available under its national law to utilize this exception. See Law No. 9.279, *supra* note 149, art. 68 (permitting generic manufacture of drugs that are not locally produced), and art. 71 (permitting compulsory licensing to address a national health emergency).

174. Bass, *supra* note 151, at 209.

175. *Id.* At 220-22.

---

---

international framework while promoting access to pharmaceuticals desperately needed to fight AIDS, malaria, TB, and other pandemics of deadly disease.

#### H. Brazil's Success May Be Key to Options for Poorer Countries

The future of Brazil's efforts, and those of other middle-income countries, may be interconnected with the potential options for poorer countries. While Brazil, South Africa, Thailand, India and other middle-income countries with industrial bases have the potential to manufacture drugs domestically, other countries lack a functional industrial base, transportation, banking institutions, or other assets necessary to build domestic industry. Such countries are among the poorest in the world—including many in Africa, the Caribbean and Asia—as well as those whose infrastructure or economies have been destroyed by war or civil conflict. For all these reasons the poorest countries may have few options for acting alone under TRIPS. One option for these countries—parallel importing—would be facilitated by development of regional capacity to manufacture generic drugs in countries like Brazil or India. Generic pharmaceuticals in excess of the domestic needs could be exported to the poorest countries, helping to meet their needs while also benefiting the middle-income producers of generics. For example, the Asociacion Agua Buena, a human rights organization based in Costa Rica, has gone public with an offer to buy combination therapy manufactured generically in Brazil for patients in other countries in the region.<sup>176</sup> The pharmaceutical industry fears this type of export of generically manufactured drugs as the beginning of “arbitrage”—the development of a parallel international market in generics that could decrease companies' profits from sales of patented drugs.<sup>177</sup> Both pharmaceutical manufacturers and the U.S. may oppose this request.

The benefits to generic manufacturers such as Brazil depend as well on both the level of demand—which can be increased if a legal right to treatment is established—and the ability of poorer countries to pay for imports. Organizations like Asociacion Agua Buena have sought to force government agencies to provide HIV treatment by bringing cases on behalf of individuals in hopes of establishing legal precedents that articulate a right to HIV treatment, including combination therapy.<sup>178</sup> Such legal obligations might put more countries on the market for low-cost, generic pharmaceuticals from Brazil or other countries. In 1997, several persons

---

176. In an open letter to the Health Minister, the Association offered to pay the full annual costs of the treatment and shipping for a patient named Ibel Martinez in Honduras. Letter from Richard Stern, Executive Director, Association Agua Buena, to Dr. Paulo Teixeira, Brazil Ministry of Health (Apr. 7, 2002) (on file with author).

177. *European Report*, *supra* note 123.

178. Asociacion Agua Buena petitioned the Interamerican Human Rights Commission on behalf of an individual living with HIV/AIDS in El Salvador. Enrique Gonzalez Mac Dowell, *Juridical Action for the Protection of Collective Rights and Its Legal Impact: A Study Case* (Sept. 29-Oct. 1, 2001) (paper presented at the American Society of Law, Medicine, and Ethics Annual Meeting Honoring Jonathan M. Mann.)



with HIV/AIDS successfully petitioned the Costa Rican Supreme Court to order the national social security system to provide them triple anti-retroviral therapy.<sup>179</sup> The government began to comply with the order and provide patients with triple therapy in late 1997.<sup>180</sup> The groundwork for this decision was laid, in part, by Costa Rica's adoption of a law prohibiting discrimination against persons with HIV/AIDS.<sup>181</sup>

#### I. Beyond Brazil: Continuing Challenges Achieving Universal Access

Even if parallel importing were allowed, however, and prices dropped to \$1 a day or less,<sup>182</sup> many countries, including those hardest hit by HIV/AIDS in Africa, might not be able to afford treatment for all those who need it. In some countries treatment costs are greater than the yearly income of most residents and far exceed the annual per capita health budget. Moreover, many countries simply lack an adequate public health infrastructure, skilled personnel, and laboratories to deliver such care.

The situation in lower- and lowest-income countries illustrates a separate, but related, failing of the current international system. Although international agreements, including the WTO and the international human rights instruments, obligate richer nations to assist poorer nations in realizing the benefits of the treaties,<sup>183</sup> national commitments often fall far

---

179. Press Release, Association Triangulo Rosa, Costa Rican Supreme Court Rules Government Must Provide New AIDS Meds (Sept. 30, 1997) (on file with author). In two court rulings issued on Sept. 23 and 25, 1997, the Supreme Court of Costa Rica ordered the national social security agency, Caja Costarricense de Seguro Social or CCSS, to pay for triple combination therapy with HIV anti-retrovirals for William Garcia three other plaintiffs living with AIDS. Local advocates expected the decisions to open the door for many other Costa Ricans with HIV/AIDS to apply directly to CCSS to receive treatment.

180. Richard Stern, *The Psychologist as Advocate: Access to Medication for People with AIDS in Costa Rica*, at ¶¶ 39-41 (2000) (unpublished article e-mailed from Stern, on file with author) (describing history of advocacy since 1996 in Costa Rica, culminating with Supreme Court cases, and describing early implementation of the court order). Stern reports, "By agreement with the Judges, People with AIDS will receive the medications when their T-4 Cell Counts are below 350 or when they have become ill with 'opportunistic infections.'" *Id.* ¶ 41. As of March 2000, 440 Costa Ricans were reportedly receiving combination therapy pursuant to this order. Mortality from AIDS reportedly dropped from 102 in 1997 to forty-four in 1998. *Id.* ¶ 42.

181. Letter from Richard Stern to Jorge Taiana, Secretary, Interamerican Human Rights Commission (Sept. 25, 1999) (on file with author) (petitioning for an immediate order directing the government of El Salvador to provide HIV/AIDS medicines for Odir Miranda, a citizen of El Salvador living with AIDS, includes mention of Costa Rican law).

182. Kumar Sanjay, *Indian Company Offers Low Cost AIDS drugs*, 357 THE LANCET 616 (Feb. 24, 2001) (Cipla offers to sell combination therapy for \$1200 per year wholesale; \$600 per year to governments; \$350 per year to Medecins Sans Frontieres).

183. Marrakesh Agreement Establishing the World Trade Organization, *in* Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125 (1994) ("Recognizing further that there is need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development."); ICESCR, *supra* note 82, art. 2 ("Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-

short of what is needed. Take for example the new Global Fund to Fight AIDS, Tuberculosis, and Malaria. UNAIDS has estimated that successfully combating the AIDS epidemic will require \$10 billion/year. To date, the Fund has only received pledges of \$2.1 billion and actual funds of \$1.2 billion. The U.S. government has contributed about \$500 million.<sup>184</sup> Compare this to the U.S. defense budget (FY99, before the “war on terrorism” began) of \$276.7 billion, and our national spending priorities become painfully apparent. While international commitment exists on paper to support poor countries’ fight against AIDS, this commitment is dwarfed by the measures taken to prepare for war and provide for national defense. This is so, even though the U.S. State Department, Kofi Annan, and Peter Piot note that AIDS represents the one of greatest threats to security in the world, by harming economies, destabilizing societies, and leaving large numbers of children without parents, education, homes, or socialization.<sup>185</sup>

Creating real opportunities to increase access to drugs will require meeting a number of challenges. First, a key problem remains concerning how to guarantee government commitment and resources to provide access to pharmaceuticals, especially during difficult economic times. Second, although the current intellectual property system may be interpreted or modified, if necessary, to permit access to drugs at affordable prices, the international community must still fulfill the long-term need for sustainable domestic development and public health capacity. Such development will in turn make each country more independent and more able to support its own comprehensive public health infrastructure. A robust public health infrastructure will reduce morbidity and mortality from all causes and perhaps prevent the next pandemic. Using a human rights framework to establish a “right to access to pharmaceuticals” and modifying international law to respect and fulfill that right may be a necessary first step, but it will be insufficient by itself to create meaningful, long-term capacity and commitment to address public health needs and health emergencies.<sup>186</sup>

---

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 by all appropriate means, including particularly the adoption of legislative measures.”); art. 15 (“The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture. 3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity. 4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.”)

184. The Global Fund to Fight AIDS, Tuberculosis & Malaria, Pledges, *available at* [http://www.globalfundatm.org/files/Financial\\_contributions\\_011002.htm](http://www.globalfundatm.org/files/Financial_contributions_011002.htm) (last visited Nov. 21, 2002).

185. Piot, *supra* note 19.

186. Robinson, *supra* note 119, at 6 (In a globalized civil society, corporations must share responsibility for humanizing globalization, including respecting human rights and integrating them into corporate decision-making standards.)

## J. Other National Examples

Recent developments in South Africa illustrate both the potential for legal solutions supported by strong international pressure<sup>187</sup> and the inability of legal solutions (so far) to overcome a lack of government commitment to the specific goal of providing HIV/AIDS therapy. Although South African law permits domestic manufacture of generic drugs and Indian companies have offered generic combination therapy to the government of South Africa, NGOs, and individuals at relatively low prices,<sup>188</sup> the government has begun no widespread program to promote HIV treatment. Nor has the government or local pharmaceutical firms initiated generic production.<sup>189</sup>

India faces another dilemma entirely, with a domestic industry capable of producing medicine at affordable prices but a web of local laws keeping domestic prices relatively high, an overall lack of resources in the health budget to cover anti-HIV drugs—even at affordable prices—and the need to conform its laws to TRIPS in the near future.<sup>190</sup> One proposal to reconcile TRIPS demands with the needs of Indian citizens is to reduce corporate taxes on research and development for pharmaceuticals.<sup>191</sup> The hope is that this would allow India's pharmaceutical companies to compete in the international pharmaceutical market with its own patented drugs.<sup>192</sup>

## VII. CONCLUSION

Viewed in the context of international law and ethics, it is possible to understand access to affordable pharmaceuticals for deadly diseases as no less a human rights issue than the protection of "authors'" rights to the benefits of their creations. Human rights instruments provide a potential structure for balancing these seemingly conflicting interests that is supported by language in trade agreements, official statements of trade bodies, rules of interpretation of treaties, and other international norms. Human rights provisions were intended, among other goals, to influence the application and implementation of trade provisions. These provisions should be interpreted to complement and promote fulfillment of substantive human rights norms. Intellectual property protections adopted to protect the fundamental rights of authors and other creators are not

---

187. Editorial, *South Africa's AIDS Victory*, N.Y. TIMES, Apr. 20, 2001, at A18.

188. Sanjay Kumar, *Indian Company Offers Low Cost AIDS Drugs*, THE LANCET, Feb. 24, 2001 (describing Cipla's plans to offer combination therapy at \$350 per year to Medecins Sans Frontieres, \$600 per year to governments, and \$1200 per year to individuals and noting that the cost of similar therapy in Western markets is \$10,000 to \$15,000 per year).

189. See *South Africa's AIDS Victory*, supra note 178; Jon Jeter, *Trial Opens in South Africa AIDS Drug Suit: Firms Seek to Block Law Allowing Generic Substitutes for Patented Medicines*, WASH. POST, Mar. 6, 2001, at A1 (describing efforts by the pharmaceutical industry to block a 1997 law allowing the South African government to override patents on AIDS medicines).

190. Suresh Koshy, *The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective*, 1 B.U. J. SCI. & TECH. L. 4, 55 (1995).

191. *Id.*

192. *Id.*

---

---

absolute. Property rights must be limited to the degree necessary to protect the public health and general welfare in democratic societies. Numerous mechanisms already exist that can modify intellectual property rights without abrogating a right to property, removing incentives to innovation, or threatening research and development of new drugs. These mechanisms include: tiered pricing, promoting manufacture of generics that are off patent, seeking compulsory licensing for crucial drugs, parallel importing and developing an international framework to prevent resale of inexpensive drugs in Western markets. These devices should be applied first, but other innovative strategies should also be considered. Such strategies might include higher levels of debt relief for the poorest countries, taxing pharmaceutical company profits to support treatment or R&D in developing countries, shortening the term of patent protection or eliminating patents entirely for some countries.

International human rights provide a legal structure for advocacy for access to treatment and a range of advocacy strategies, both within the legal system and based on moral persuasion. Advocates and activists have begun to use these tools to establish a "right to treatment" in various countries and to persuade governments to make access to pharmaceuticals a priority. Multinationals and developed countries have not evidenced a willingness to respect the flexibility remaining in the new intellectual property system. This may significantly undermine the confidence of developing countries in the value of this system. Governmental and business endorsement of a more flexible approach may be dependent on the recognition by both developed and developing countries that AIDS represents an actual emergency.

On a larger scale, challenges include how to promote sustained development of the poorest nations and to secure the international resource commitment that will be necessary if medicines are to be made widely available at affordable prices. The international community has thus far not stepped up to share resources, provide sustained commitment, or help build infrastructure. Advocacy on these issues is at least as important as legal battles to establish a "right to treatment."

After two decades of focusing on tracking and trying to prevent spread of HIV/AIDS, the world community now has a real opportunity to reduce the tragic gulf between treatments available to those in the developed and developing worlds. In the process we could help obtain life-extending treatments for millions of those infected around the world. Increasing treatment should not decrease efforts to prevent new infections, nor should any of those at risk feel complacent about the burden of HIV infection. However, if we fail to decrease the disparity between those worlds now we will miss a real opportunity to bolster both public health and human rights.