

**PATENT NECESSITY: INTELLECTUAL  
PROPERTY DILEMMAS IN THE BIOTECH  
DOMAIN & TREATMENT EQUITY FOR  
DEVELOPING COUNTRIES**

*J.M. Spectar\**

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\* Dr. J.M. Spectar, Director of Studies, Rockefeller College, Princeton University. Ph.D., 1999, Claremont Graduate University; M.A.P., 1997, Claremont Graduate University; J.D., 1992, University of Maryland School of Law; M.A., 1992, George Washington University; M.B.A., 1989, Frostburg State University; B.A., 1989, University of La Verne.

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## I. INTRODUCTION

The dearth of access to affordable AIDS therapies in developing countries is increasingly blamed on the intellectual property norms of the North and their operationalization in global free trade regimes. This article examines key issues, interests, orientations and preferences in the North-South debate on intellectual property rights (IPRs) and the prospects for treatment equity for HIV/AIDS patients in developing countries. The article argues that the North-South logjam over the nature, purpose and extent of IPRs, as illustrated by the polemics over the patentability of plant genetic resources and their ensuing pharmaceutical products, constitutes a significant stumbling block to achieving treatment equity for developing countries. The article further argues that to achieve much

needed treatment equity for HIV/AIDS, the international community must examine and adopt new approaches that transcend the strictures of the North-South conflict over intellectual property. The article concludes with recommendations designed to improve the prospects for treatment equity for developing countries within the context of a global pandemic without undermining the basic framework of intellectual property protection.

First, the article reviews the differences between North and South on intellectual property rights, especially with regard to the patentability of plants that often provide the compounds for commercial pharmaceutical products. Then, focusing on the illustrative case of plant genetic resources, the article discusses the differing North-South postures, preferences and priorities that have often colluded to create an impasse in negotiations on IPR protection. In the main, the article argues that the inability of the North and South to satisfactorily resolve key questions about the nature, purpose and extent of intellectual property protection in the previous negotiations sowed the seeds of future conflicts over issues such as compulsory licensing and sovereign rights. In Part II, the article examines the HIV/AIDS treatment gap between North and South and the efforts to close this chasm by achieving treatment equity. Here, the article will examine the perceived impact of the interaction between intellectual property norms and international trade rules, particularly TRIPS, on the affordability of AIDS therapies. Specifically, the article will focus on how the simmering unresolved issues in the North-South schism on the matter of intellectual property rights culminated in conflict over compulsory licensing for HIV/AIDS therapies. Against the backdrop of the North-South treatment gap, the article examines the illustrative conflict between the United States and South Africa over IPR protections, specifically over the matter of compulsory licensing for AIDS therapies and the application of trade policy. In Part III, the article argues that to achieve much needed treatment equity for HIV/AIDS, the international community must examine and adopt new approaches that break the North-South logjam over protection of intellectual property. The article makes several recommendations designed to increase the prospects for achieving treatment equity in the context of the AIDS pandemic

without undermining global intellectual property and trade regimes.

## II. NORTH-SOUTH DEBATE OVER INTELLECTUAL PROPERTY RIGHTS

Below, the article examines North-South perspectives on intellectual property rights, focusing on the divergence in views on the nature, purpose and extent of IPRs in the biotech domain. The failure of both North and South to satisfactorily resolve key differences about intellectual property protection continues to fan the flames in the fracas over access and affordability.

### A. *Introduction to Biotechnology*

The growth of biotechnology has been spurred by advances in biodiversity prospecting,<sup>1</sup> a practice that many believe will someday lead to a cure for several ailments, including HIV/AIDS.<sup>2</sup> The practice of “biodiversity prospecting” or “natural products drug discovery” involves the quest for “bioactive compounds contained in natural sources such as plants, fungi, insects, microbes, and marine organisms.”<sup>3</sup> These complex bioactive molecules cannot be produced in labs.<sup>4</sup> Because the major “centers of genetic diversity,” or the “centers of origin of the world’s economically important crops,”<sup>5</sup> are located mostly in the tropics or subtropics,<sup>6</sup> biodiversity prospectors must venture into the tropical forests or other natural habitat in order to locate them.<sup>7</sup> These

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1. See John R. Adair, Comment, *The Bioprospecting Question: Should the United States Charge Biotechnology Companies for the Commercial Use of Public Wild Genetic Resources?*, 24 *ECOLOGY L.Q.* 131, 135 (1997).

2. Edgar J. Asebey & Jill D. Kempenaar, *Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention*, 28 *VAND. J. TRANSNAT’L L.* 703, 706 (1995).

3. *Id.*

4. *Id.*

5. Shayana Kadidal, *Plants, Poverty, and Pharmaceutical Patents*, 103 *YALE L.J.* 223, 224 n.8. The phrase “centers of genetic diversity” was coined by N. I. Vavilov, the famed Soviet botanist, in the 1920s. *Id.*

6. Klaus Bosselmann, *Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity*, 7 *COLO. J. INT’L ENVTL. L. & POL’Y.* 111, 113 (1996).

7. See Christopher Hunter, Comment, *Sustainable Bioprospecting: Using*

regions are endowed with rich, biodiverse resources largely because tropical areas were able to preserve their genetic diversity during the Ice Age while the vegetative assets of the temperate zones were interred in a deep freeze.<sup>8</sup> It is estimated that about fifty percent of all species are in the tropical forests, including nearly half of the 250,000 species of the higher plants found on earth.<sup>9</sup>

Although most of the “lucrative” “centers of genetic diversity” are in the tropical areas of the Third World,<sup>10</sup> the plant breeders, patent holders, and marketers of engineered plant genetic resource (PGR) products are located in the North,<sup>11</sup> particularly the United States.<sup>12</sup> The Northern biotechnology firms use the germplasm from the tropical forests of the South and elsewhere to create new varieties of plants, animals, and microorganisms, as well as pharmaceuticals.<sup>13</sup> To determine potential “usefulness and commercial viability,”<sup>14</sup> scientists screen plant material gathered from a source country.<sup>15</sup> Thus, after a Northern company “discovers” a compound with “therapeutic value in traditional medical practices,” it refines its chemistry, and obtains a patent for the refined product “giving it the opportunity to reap

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*Private Contracts and International Legal Principles to Conserve Raw Medicinal Materials*, 25 B.C. ENVTL. AFF. L. REV. 129, 131, 136 (1998).

8. *See id.*

9. *Id.* (noting only one percent of tropical rain forest species have been surveyed to determine any future beneficial uses).

10. Kadidal, *supra* note 5, at 224.

11. *See generally* Asebey & Kempenaar, *supra* note 2, at 704-716 (noting that all bioprospecting screening facilities are located in the developed world).

12. *See id.* at 732.

13. *See* Hunter, *supra* note 7, at 135-41. Biotechnology engineering includes the creation of new varieties of plants, animals, and microorganisms. Bosselmann, *supra* note 6, at 114. The Biodiversity Convention defines biotechnology as “any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use.” Convention on Biological Diversity, Jun. 5, 1992, 31 I.L.M. 818, art. 2. Genetic material from plants and animals is the basic source for biotechnology. Bosselmann, *supra* note 6, at 116. The chemical chromosomal information in the alleles of living plant cells provides raw material for plant breeders and biotechnologists. *Id.*

14. Asebey & Kempenaar, *supra* note 2, at 706.

15. *Id.*

monopoly profits.”<sup>16</sup> It is estimated that about twenty-five percent of all pharmaceuticals sold in the United States are derived from or originated from plants,<sup>17</sup> and sales of biotechnological pharmaceutical products are expected to exceed billions of dollars annually.<sup>18</sup>

*B. Intellectual Property & Multilateral Trade Regimes*

The developed countries (DCs) of the North are generally very protective of intellectual property rights, going to great lengths to assure that international agreements do not derogate from vested patent rights.<sup>19</sup> At the end of the nineteenth century, biological inventions, including new plant varieties, were generally considered unsuitable for patent protection.<sup>20</sup> By the early part of the twentieth century, the difficulties associated with obtaining patents for the cultivation of plants and the increasing realization that new plant varieties had tremendous commercial potential led many DCs to pass laws for the protection of new plant varieties.<sup>21</sup> While DCs do not generally allow the patenting of naturally occurring substances, when material that was “previously unknown in its purified and isolated form” is refined into a distinguishable product which demonstrates “unexpected properties,” it may be patented.<sup>22</sup>

The United States has extended significant intellectual property rights to plant breeders.<sup>23</sup> For example, the U.S. Plant

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16. David P. Fidler, *Symposium on Globalization at the Margins: Perspectives on Globalization from Developing States: Neither Science Nor Shamans: Globalization of Markets and Health in the Developing World*, 7 IND. J. GLOBAL LEG. STUD. 191, 212-213 (1999).

17. Asebey & Kempenaar, *supra* note 2, at 705-706.

18. See Phillip Yip, Comment, *Product and Process Patent Protection in Biotechnology: Too Much or Too Little?*, 17 J. CORP. L. 659, 661 (1993); See also Michael P. Vandenberg, Note *The Rutabaga That Ate Pittsburgh: Federal Regulation of Free Release Biotechnology*, 72 Va. L. Rev. 1529, 1531 (1986).

19. See *id.* at 127.

20. *Id.* at 122.

21. *Id.* at 123.

22. Asebey & Kempenaar, *supra* note 2, at 711.

23. *Id.*

Patent Act of 1930<sup>24</sup> created exceptions in patent laws to provide patent protection for some plants—giving breeders who created new cultivars the right to exclusively propagate the patented plant by asexual reproduction for seventeen years.<sup>25</sup> In addition, the 1970 Plant Variety Protection Act<sup>26</sup> widens the scope of protection to include cultivars that are reproduced sexually.<sup>27</sup>

The 1961 International Convention for the Protection of New Varieties of Plants (UPOV Convention)<sup>28</sup> established a new global type of intellectual property protection for new plant varieties, thereby creating the so-called “plant breeder’s rights.”<sup>29</sup> To qualify for patent protection, the new plant variety was required to be clearly distinguishable by at least one important characteristic from all the others.<sup>30</sup> Under the UPOV convention, breeder’s rights are protected regardless of the origin—“artificial or natural”—of the initial variation from which the new plant variety was developed.<sup>31</sup>

In the view of the Northern defenders of the patent system and the opponents of compulsory licensing, IPRs reward industry, innovation and ingenuity.<sup>32</sup> The North also maintains that the disclosure requirements of the patent system foster research

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24. 35 U.S.C. § 161 (1994).

25. Mark A. Urbanski, *Chemical Prospecting, Biodiversity Conservation, and the Importance of International Protection of Intellectual Property Rights in Biological Materials*, 2 BUFF. J. INT’L L. 131, 153 (1995).

26. 7 U.S.C. §§ 2321-2583 (2000).

27. Urbanski, *supra* note 25, at 153.

28. International Convention for the Protection of New Varieties of Plants, *opened for signature* Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 109 [hereinafter UPOV Convention]. The parties to the UPOV Convention are known as the UPOV (*Union por la Protection des Obtentions Végétales* or International Union for the Protection of New Varieties of Plants). *About the UPOV*, at <http://www.upov.int/eng/about/upov.htm#union> (last visited Mar. 13, 2002). The UPOV consisted of nineteen DCs in 1961. Urbanski, *supra* note 25, at 159-160. It currently has forty-nine members. *States Party to the International Convention for the Protection of New Varieties of Plants*, at <http://www.upov.int/eng/ratif> (last visited Mar. 13, 2002).

29. Bosselmann, *supra* note 6, at 123.

30. *Id.*

31. UPOV Convention, *supra* note 28, art. 6.

32. See Asebey & Kempenaar, *supra* note 2, at 710.

because they provide security to sponsors.<sup>33</sup> In addition, the North claims that by increasing the commercial value of plant genetic resources, biotechnology patents help spread the technological gains obtained from biodiversity.<sup>34</sup>

It is also argued that the least developed countries (LDCs) have the most to gain from strengthening their IP systems, particularly because they lack the technological ability to engage in successful piracy.<sup>35</sup> For example, while piracy may provide a developing country with cheaper copies of some drugs, it is difficult to replicate new drugs since advanced innovative technology is often required.<sup>36</sup> In addition, the LDCs require large capital investments to develop a technological base.<sup>37</sup> Furthermore, a country's refusal to comply with the prevailing IP regime may also endanger its citizens to the extent that drug makers (who spend as much as \$359 million developing a single drug) may refuse to sell their products in countries lacking an effective patent system.<sup>38</sup> Finally (and ironically), prohibitions on compulsory licensing help promote scientific research and development of industries in developing nations.<sup>39</sup> These arguments suggest that by modifying their IP systems and transforming their economies into market-based economies with free trade systems the LDCs will encourage foreign capital necessary for development.<sup>40</sup>

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33. Bosselmann, *supra* note 6, at 127.

34. Asebey & Kempenaar, *supra* note 2, at 710.

35. Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 65 (1998).

36. See David Benjamin Snyder, Comment, *South Africa's Medicines and Related Substances Control Amendment Act: A Spoonful of Sugar or a Bitter Pill to Swallow?*, 18 DICK. J. INT'L L. 175, 190 (1999).

37. McCabe, *supra* note 35, at 65.

38. Snyder, *supra* note 36, at 2. The U.S. Office of Technology Assessment (OTA) estimates that it costs \$359 million to develop a drug. *Id.* at 38 n.119. Yet some skeptics contend the figure is based on "heroic estimates of the costs of pre-clinical research, much of which is paid for by the government, and conducted in government and university laboratories." *Id.*

39. See Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 954 (2000).

40. McCabe, *supra* note 35, at 65.

Several judicial decisions, treaties and multilateral agreements have accelerated the pace of biotechnology patents.<sup>41</sup> As a result of the favorable climate towards patenting biotechnology in the United States, many European companies have considered relocating their biotechnology firms to the United States.<sup>42</sup> In addition, the North used the Uruguay Round of the GATT as a forum for the protection of IPR.<sup>43</sup> Protection of biotechnological inventions was raised in the GATT negotiations in the context of the “trade-related aspects of intellectual property rights” accord.<sup>44</sup>

The North consistently places the protection of intellectual property rights at the apex of its global trading agenda.<sup>45</sup> Within the GATT/WTO system, the North has successfully tied enjoyment of WTO membership—and its attendant benefit of nondiscriminatory trade in goods and services—with Member States’ agreement to abide by global intellectual property regimes.<sup>46</sup> In particular, states are expected to grant intellectual property rights greater protection through compliance with the mandatory Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>47</sup> TRIPS was designed to strengthen

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41. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (holding that genetically engineered living organisms can be patented). Later, in *Ex Parte Hibbard*, 227 USPQ 443 (Bd. Pat. App. & Inter. 1985), the court held that plants, seeds, and tissue cultures can be protected by general patent law as well as plant protection legislation.

42. See Bosselmann, *supra* note 6, at 128.

43. See Urbanski, *supra* note 25, at 159.

44. See Bosselmann, *supra* note 6, at 121. See also Asebey & Kempenaar, *supra* note 2, at 710-711.

45. Fidler, *supra* note 16, at 209.

46. See *id.*; Duane Nash, *Berkeley Law Journal Annual Review of Law and Technology; VI. Foreign & International Law, South Africa's Medicines and Related Substances Control Amendment Act of 1997*, 15 BERKELEY TECH. L. J. 485, 487-88 (2000).

47. Fidler, *supra* note 16, at 209. See *General Agreement on Tariffs and Trade—Multilateral Trade Negotiations (The Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Counterfeit Goods*, (1994) 33 I.L.M. 81 (1994). [hereinafter TRIPS]. In addition to liberalization of trade in goods, the WTO's Multilateral Trade Agreements (MTAs) include a General Agreement on Trade in Services (GATS) and Trade-Related Investment Measures (TRIMS). Eleanor M. Fox, *Toward World Antitrust and Market Access*, 91 A.J.I.L. 1, 14 (1997).

and harmonize global IPRs with the avowed purpose of the agreement being “to reduce distortions and impediments to international trade . . . taking into account the need to promote effective and adequate protection of intellectual property rights.”<sup>48</sup>

C. *The View from the South: One Person’s Biotech, Another’s Biopiracy*

Many developing countries have protested what they consider the North’s inequitable appropriation and profiteering from germplasm acquired in the South.<sup>49</sup> The South is concerned by the “historical practice of Western pharmaceutical companies exploiting for global profit therapeutic remedies developed by traditional healers in developing societies.”<sup>50</sup> The South argues that Northern companies are making considerable profits from investments based on the exploitation of the South’s germplasm, without any obligation to return anything to the guardians of knowledge in the locus of discovery.<sup>51</sup>

Critics call this practice “biopiracy” and “biocolonialism,” with many developing countries charging that their natural resources are being stolen by the North.<sup>52</sup> Biological and cultural resources of the South are obtained gratis, as ‘raw materials,’ transformed by the laboratories of the North, and then become protected intellectual property under the prevailing global trade regimes.<sup>53</sup> The pharmaceutical products developed from the natural resources of the “periphery” are exported back to developing countries, “where they largely benefit the rich and powerful because of their intended medical purpose or cost.”<sup>54</sup> As a result, developing countries are reluctant to extend patent

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48. TRIPS, *supra* note 47, at 84.

49. *See* Fidler, *supra* note 16, at 213.

50. *Id.* at 212.

51. *See id.* at 212-13.

52. *Id.* at 213.

53. Keith Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not So Brave) New World Order of International Intellectual Property Protection*, 6 *IND. J. GLOBAL LEGAL STUD.* 11, 49 (1998).

54. Fidler, *supra* note 16, at 213.

protection to drugs<sup>55</sup> and other Northern products.<sup>56</sup>

Writers are increasingly “questioning whether the flow of benefits of international intellectual property protection, which are part of the whole ‘free trade’ package may be skewed to the advantage of the economies, cultures, and nations of the North.”<sup>57</sup> Fidler concludes that the biopiracy controversy reveals Northern pharmaceutical companies have viewed traditional medicine through utilitarian lenses, treating it as a “commodity, or a natural resource of the periphery, to be exploited for the benefit of health in the core.”<sup>58</sup>

The commodification of traditional medicinal knowledge appears driven by narrow profit concerns to the detriment of the developing countries.<sup>59</sup> For example, the Eli Lilly Corporation used Madagascar’s wild rosy periwinkle to develop “wonder drugs” like vinblastine and vincristine for the treatment of Hodgkin’s disease and pediatric lymphatic leukemia.<sup>60</sup> These drugs yield millions of dollars in revenues annually for Eli Lilly;<sup>61</sup> Madagascar reportedly earns nothing from them.<sup>62</sup> At the same time, the South imported and engineered germplasm in the form of expensive pharmaceuticals.<sup>63</sup> The South resented the fact that the commercially bred lines from the North were protected by patents, whereas the germplasm of the South was generally acquired gratis.<sup>64</sup>

The Third World states are often hostile towards the North’s IPRs, because they believe their purpose is to “reinforce the

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55. Nash, *supra* note 46, at 486.

56. See McCabe, *supra* note 35, at 52-53.

57. Aoki, *supra* note 53, at 16-17. The “copyright industries” of the North are not “economically marginal;” 25 billion dollars in 1985 in Britain (2.9% of GNP); 5.8% of U.S. GNP, employing 5% of U.S. workforce. Urvashi Butalia, *The Issues at Stake: An Indian Perspective on Copyright*, in COPYRIGHT AND DEVELOPMENT: INEQUALITY IN THE INFORMATION AGE 49, 52 (Philip G. Altbach ed., 1995).

58. Fidler, *supra* note 16, at 213.

59. See *id.* at 212-13.

60. Kadidal, *supra* note 5, at 223-24.

61. *Id.* at 224.

62. *Id.*

63. Bosselmann, *supra* note 6, at 132.

64. *Id.*

economic power” of the North, and to “transfer wealth from the poorer countries to the richer ones.”<sup>65</sup> According to the South, the northern patent system helps preserve the North’s technological superiority and, concomitantly, deprives the South of much-needed technology transfers.<sup>66</sup> Developing countries, not major producers of intellectual property, “have little incentive to vigorously protect it. Weak protection is justified on grounds that the developing world needs maximum access to Western intellectual goods for its development and that stringent standards of protection are debilitating.”<sup>67</sup> Thus, many believe that “the value of a patent system to developing countries remains controversial, and that single developing countries could suffer hardship because of growing dependence on foreign patents with few countervailing benefits.”<sup>68</sup>

Some developing countries have also taken issue with the enormous costs associated with developing and maintaining an elaborate intellectual property system.<sup>69</sup> Plagued by scarce resources, most governments in developing countries claim they cannot afford the costs of intellectual property protection, including procurement drafting and the loss of low cost alternatives to legitimate products.<sup>70</sup> At a minimum, the immediate short-term effect of a robust intellectual property system will be higher royalty payments from developing countries to developed countries.<sup>71</sup> The relative cost of South-North royalty payments is likely to be exacerbated by fluctuations in the foreign currency exchange rates.<sup>72</sup>

Although the North believes that pirating provides no real

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65. *Id.* at 127.

66. *Id.*

67. Tara Kalagher Giunta & Lily H. Shang, *Ownership of Information in a Global Economy*, 27 GEO. WASH. J. INT’L L. & ECON. 327, 330 (1994) (noted in Nash, *supra* note 46, at 485 n.5).

68. J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT’L LAW. 345, 354.

69. McCabe, *supra* note 35, at 54-55.

70. Amy R. Edge, *Preventing Software Piracy Through Regional Trade Agreements: The Mexican Example*, 20 N.C. J. INT’L L. & COM. REG. 175, 190 (1994).

71. McCabe, *supra* note 35, at 55.

72. *Id.*

economic benefit,<sup>73</sup> “the developing countries tend to believe that pirating intellectual property fuels economic development.”<sup>74</sup> In some cases, piracy can benefit a country by providing patented technology without the additional cost of royalty payments to acquire it.<sup>75</sup> The country’s economy obtains a windfall from the cost savings as well as from exporting the counterfeit goods to other countries that have weak or nonexistent IPR protection systems.<sup>76</sup>

The emerging international legal regime protecting intellectual property affects health in developing countries, particularly to the extent that it limits access to healthcare.<sup>77</sup> The impact of TRIPS on access to life-saving medicines is especially serious when considering that about one-third of the world’s population does not have access to essential drugs.<sup>78</sup> Global public health experts are concerned about the TRIPS-heightened protection of pharmaceutical patents and related property rights.<sup>79</sup> In particular, they are worried that the agreements that seek to “harmonize protection of intellectual property rights among WTO members using norms developed in industrialized countries” will adversely affect access to patented medicines (such as AIDS drugs) in developing countries by raising prices.<sup>80</sup>

Whereas many developing countries did not recognize pharmaceutical patents prior to TRIPS (and thus were able to make drugs affordable and accessible to their peoples) members of the WTO must comply with the Agreement’s patent provisions or face the possibility of claims and even trade sanctions.<sup>81</sup>

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73. *Id.* at 56.

74. Mark Ritchie et al., *Intellectual Property Rights and Biodiversity: The Industrialization of Natural Resources and Traditional Knowledge*, 11 St. John’s J. Legal Comment 431, 437 (1996).

75. Snyder, *supra* note 36, at 189.

76. *Id.*

77. Fidler, *supra* note 16, at 209-10.

78. *Id.* at 210.

79. David P. Fidler, *International Law and Global Public Health*, 48 KAN. L. REV. 1, 29 (1999).

80. *Id.*

81. *Id.* at 29-30.

Prior to the policy shift wrought by TRIPS and Northern efforts to enforce them, many developing countries refused to recognize patents on pharmaceutical products.<sup>82</sup> For example, Brazil and Thailand did not extend patent protection to pharmaceuticals until pressured by the United States to do so.<sup>83</sup> Many developing countries are concerned that TRIPS requirements for intellectual property rights could result in “a higher cost burden for newer, patent-protected essential drugs, further reducing access to health care.”<sup>84</sup> In addition, while enactment of TRIPS is sought to avoid piracy of Northern intellectual property in the South, many contend that

the ideological content of these piracy claims becomes evident when considering that the fears seem to mask the amount of piracy occurring in the opposite direction—invaluable biological and cultural resources flowing out of the countries of the South as ‘raw materials’ into the developed nations of the North where they are magically transformed in the laboratories of pharmaceutical and agricultural corporations into protected intellectual properties whose value is underwritten by provisions of multilateral agreements such as TRIPS.<sup>85</sup>

Fidler maintains that this nexus between trade benefits and participation in the Northern-driven intellectual property regime has compelled many in the South to change their policies on intellectual property protections.<sup>86</sup> Keith Aoki contends the

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82. Bernard Pecoul et al., *Access to Essential Drugs in Poor Countries: A Lost Battle?*, 281 JAMA 361, 365 (1999).

83. Nash, *supra* note 46, at 486 n.8.

84. Fidler, *supra* note 16, at 29 n.99; Press Release, World Health Organization, WHO to Address Trade and Pharmaceuticals (May 22, 1999), available at <http://www.who.int/inf-pr-1999/en/pr99-wha13.html>.

85. Aoki, *supra* note 53, at 49. Thus, while royalties lost by United States as a result of Third World piracy and ineffective IPR protection were estimated at \$202 million per year for agricultural chemicals and \$2.5 billion annually for pharmaceuticals, “if the contributions of the Third World peasants and tribespeople are taken into account, the roles are dramatically reversed: the United States would owe Third World countries \$302 million in agriculture royalties and \$5.1 billion for pharmaceuticals.” VANDANA SHIVA, *BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE* 56 (1996).

86. Fidler, *supra* note 16, at 209-10.

TRIPS Agreement accomplishes “through the potential threat of economic ostracism what could not be accomplished through negotiations independent of the international economic framework.”<sup>87</sup> Under the “ideological banner” of free trade, “rules that purportedly were meant to encourage and protect creative expression and scientific innovation were now put in place, giving owners the legal means to reach extraterritorially into Third World countries to prevent unauthorized use.”<sup>88</sup> This expanded reach of the intellectual property regimes of the developed nations occurred at the detriment of the South, particularly African countries at the periphery of the international market.<sup>89</sup> As Vandana Shiva writes,

Eurocentric notions of property and piracy are the bases on which the IPR laws of the GATT and the [WTO] have been framed . . . . At the heart of the GATT treaty and its patent laws is the treatment of biopiracy as a natural right of Western corporations, necessary for the “development” of Third World communities.<sup>90</sup>

The developing countries are often reluctant to cede jurisdiction of IP protection to the GATT/WTO that they viewed as pro-North, preferring instead the regime of the World Intellectual Property Organization (WIPO).<sup>91</sup> Meanwhile, the

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87. Aoki, *supra* note 53, at 21.

88. *Id.* at 20.

89. Ruth L. Gana, *The Myth of Development, The Progress of Rights: Human Rights to Intellectual Property and Development*, 18 *Law & Pol’y* 315 (1996).

90. *See* Shiva, *supra* note 85, at 3, 5 (cited in Aoki, *supra* note 53, at 47-48).

When Europeans first colonized the non-European world, they felt it was their duty to “discover and conquer,” to “subdue, occupy, and possess,” . . . [e]verything, every society, every culture. The colonies have now been extended to the interior spaces, the “genetic codes” of life-forms from microbes and plants to animals, including humans. The assumption of empty lands, *terra nullius*, is now being expanded to ‘empty life,’ seeds and medicinal plants . . . [and this] same logic is being used to appropriate biodiversity from the original owners and innovators by defining their seeds, medicinal plants, and medical knowledge as nature, as non-science, and treating tools of genetic engineering as the yardstick of “improvement.”

*Id.*

91. Nash, *supra* note 46, at 485 n. 3.

North believes WIPO is hostile to its interests and has insisted that the GATT/WTO are the legitimate fora.<sup>92</sup>

*D. The Case of Plant Genetic Resources*

The issues of plant genetic resources and the biodiversity regime illustrate the differing North–South postures, preferences and priorities that have often colluded to create an impasse in negotiations on IPR protection and expanded access to affordable resources for developing countries. Major attempts at improved cooperation, including the common heritage of mankind framework and the Biodiversity Convention, became entangled in North–South issues such as sovereign rights and compulsory licensing. The inability of both sides to satisfactorily resolve central questions about the nature, purpose, extent and impact of intellectual property protection bedeviled these negotiations, sowing the seeds for future confrontations about access and affordability.

In the 1980s, the debate over patentability of pharmaceutical products developed from biodiverse resources gained center stage in international negotiations with significant implications for intellectual property rights.<sup>93</sup> To redress the perceived inequities, the Third World states began lobbying in the UN for a more equitable arrangement with regard to germplasm acquired from its forests and other natural habitat.<sup>94</sup> In addition, many developing countries began to take steps to ensure that pharmaceutical firms in the North did not acquire “indigenous knowledge without fair return for the investment of the indigenous society.”<sup>95</sup>

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92. *Id.*

93. See Neil D. Hamilton, *Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources*, 28 TULSA L.J. 587, 600 (1993). This division over patents and property rights is likely to resurface with renewed intensity if as it is likely, some push for inclusion of strong common heritage language in a prospective international convention on the human genome. For a discussion of international legal issues of the human genome and prospective convention, see generally, J.M. Spectar, *The Fruit of the Human Genome, Cautionary Tales About Technology, Investment and the Heritage of Humankind*, 23 LOY. L.A. INT'L & COMP. L. REV. (Fall 2000).

94. See Hamilton, *supra* note 93, at 600.

95. Fidler, *supra* note 16, at 213; Ehsan Masood, *Old Scores Surface as African*

In 1983, the Food and Agriculture Organization (FAO) Commission on Plant Genetic Resources was designated as the world forum for discussing the “use, control, and conservation” of germplasm.<sup>96</sup> The Commission formulated and adopted the International Undertaking on Plant Genetic Resources.<sup>97</sup> The Undertaking sought to resolve the purported inequity in PGR exchanges.<sup>98</sup> In the Undertaking, the South endeavored to create a system of free access for all plant genetic resources including the elite commercially bred lines or “special genetic stocks” of the North.<sup>99</sup> Article 1 of the Undertaking stated the goal of the agreement is to “ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes.”<sup>100</sup> To achieve these objectives, the Undertaking declared that “plant genetic resources are a heritage of mankind to be preserved, and to be freely available for use, for the benefit of present and future generations.”<sup>101</sup> Thus, the traditional lines and germplasm from the South and the commercially bred lines of the North were to be freely available to all,<sup>102</sup> with the latter no longer being protected by plant breeders’ rights.<sup>103</sup>

The North was generally receptive to the view that the unrefined germplasm of the South constituted the common heritage of mankind (CHM) and should be subject to a free access

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*States Face New Opportunities*, 392 NATURE 540 (1998); Ricardo Bonalume Neto, *Brazil’s Scientists Warn Against ‘Nationalistic’ Restrictions*, 392 NATURE 538 (1998).

96. See Hamilton, *supra* note 93, at 600.

97. FAO Res. 8/83, *International Undertaking on Plant Genetic Resources*, UN Food and Agriculture Organization, 22nd Sess., Annex 1, Agenda Item 16, U.N. Doc. C/83/REP (1983) [hereinafter *Undertaking*]. Over 100 countries, excluding the United States, signed the Undertaking. Hamilton, *supra* note 93, at 602.

98. See *Undertaking*, *supra* note 97, art. 1.

99. See *id.* art. 2; Bosselman, *supra* note 6, at 132.

100. *Id.* art. 1.

101. *Undertaking*, *supra* note 97. In the South, only Ethiopia voted against the Undertaking. See Kadidal *supra* note 5, at 230 n.41.

102. Bosselmann, *supra* note 6, at 132-33.

103. See *id.* at 132.

regime.<sup>104</sup> Northern commercial interests were able to use the open access CHM approach to their benefit, while allegedly ignoring or paying lip service to the reciprocity required by the Undertaking.<sup>105</sup> For example, CHM style open access to germplasm resources of the South provided a “basis for access” for Eli Lilly in its acquisition and use of Madagascar’s rosy periwinkle to develop very lucrative drugs.<sup>106</sup>

But there was great concern in the North about the implications of the common heritage approach on plant breeders’ rights, particularly because many believed the common heritage principle would undermine the patent protection of new plant varieties.<sup>107</sup> As a result, the United States expressed its reservations to the Undertaking,<sup>108</sup> claiming it violated U.S. treaty obligations and threatened fundamental conceptions of private property rights.<sup>109</sup> The concerns over the economic consequences of the Undertaking on the intellectual property rights of the biotechnology industry caused some in the North to refuse to sign it.<sup>110</sup>

The Third World states subsequently argued they got little in exchange for opening access to their germplasm and traditional lines.<sup>111</sup> They argued that they had given up their enormous treasure trove of genetic material for the genetically limited lines of the North.<sup>112</sup> Although the latter were technologically complex, they were of questionable usefulness to the South.<sup>113</sup> For example, Third World farmers, for the most part, lacked the capital to take

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104. James O. Odek, *Bio-Piracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. INTELL. PROP. L. 141, 153-57. In addition, Odek points out that UPOV’s position that breeders’ rights accrue, whether the origin of the initial variation is artificial or natural, endorses the CHM concept. *Id.* at 148.

105. See Hamilton, *supra* note 93, at 600.

106. Asebey & Kampenaar, *supra* note 2, at 708.

107. See Hamilton, *supra* note 93, at 601.

108. See *id.* at 602.

109. Bosselmann, *supra* note 6, at 133 (noting eight industrial nations protested that the Undertaking violated the existing UPOV treaty).

110. Hamilton, *supra* note 93, at 602.

111. Kadidal, *supra* note 5, at 229.

112. *Id.*

113. *Id.*

advantage of the commercial lines that were intended for intensive, large-scale industrial agriculture, in conjunction with advanced pesticides and herbicides.<sup>114</sup> In addition, it was posited that the Undertaking mostly served the United States' commercial interest in preserving diversity, while doing nothing to address the South's urgent need for the capital necessary to acquire agricultural technology.<sup>115</sup> Meanwhile, the South was still importing the engineered germplasm in the form of seeds.<sup>116</sup> As Aoki has observed, common heritage/public trust approaches may advantage the North to the detriment of the South:

We need to be careful about constructing the public domain to avoid conceiving of the biological and cultural resources of the Third World as belonging to the "common heritage of humanity", thereby effectively putting them up for grabs by entrepreneurs from the developed countries eager to turn such public domain items into private intellectual property.<sup>117</sup>

The Third World states opposed to the Undertaking proposed a system of national sovereignty in genetic resources.<sup>118</sup> In effect, the respective governments, on behalf of the breeders of the traditional lines and raw germplasm, would hold IPRs.<sup>119</sup> Such a system, they contended, would permit protection of hybrid strains—something that was disallowed in the Undertaking—unless a special exemption was first obtained.<sup>120</sup> Meanwhile, others in the South decided to retaliate against the North by demanding, *inter alia*, intellectual property rights (IPRs) for their farmers' preservation efforts.<sup>121</sup>

As a result of the mounting opposition (from both the United

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114. Bosselmann, *supra* note 6, at 133.

115. Kadidal *supra* note 5, at 229. Western crops are generally very homogenous. Genetic diversity is required to ensure "collective resistance" to epidemics such as the Irish potato famine of the mid nineteenth-century. *Id.* at 229, 229 n.38.

116. CALESTOUS JUMA, *The Gene Hunters: Biotechnology and the Scramble for Seeds* 169-70 (1989).

117. Aoki, *supra* note 53, at 46.

118. Kadidal, *supra* note 5, at 230.

119. *Id.*

120. *Id.*

121. *Id.* at 224-25.

States and the South), the Undertaking was modified in several annexes.<sup>122</sup> The first two annexes in 1989 recognized the concepts of farmers' rights and plant breeders' rights.<sup>123</sup> In the 1989 annex, the FAO stated that breeders' rights are not incompatible with the Undertaking and it interpreted the document to read that legal protection for patented new plant varieties was permissible.<sup>124</sup> Similarly, the acceptance of the concept of farmers' rights signified recognition of the work done by Third World farmers in developing and preserving the biodiverse resources.<sup>125</sup> To deal with the South's concerns regarding compensation for the farmers, who preserve the biodiverse resources, the FAO established the International Fund for Plant Genetic Resources (IFPGR).<sup>126</sup> However, a lack of funding has severely undermined the efficacy of the IFPGR.<sup>127</sup>

Finally, the third annex adopted in 1991 at the 26th FAO Conference stipulated that "nations have sovereign rights over their plant genetic materials."<sup>128</sup> In particular, it amended the CHM provision of the Undertaking: "the concept of mankind's heritage, as applied in the International Undertaking on Plant Genetic Resources, is subject to the sovereignty of the states over their plant genetic resources."<sup>129</sup> The Undertaking and its three

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122. Hamilton, *supra* note 93, at 601-02.

123. F.A.O. Res. 4/89, *International Undertaking on Plant Genetic Resources, amended 1989, 1991*, U.N. Food and Agriculture Organization, 25<sup>th</sup> Sess., Annex I: Agreed Interpretation of the International Undertaking (1989), available at <http://www.mtnforum.org/resources/library/iupgr91a.htm> (last visited Mar. 13, 2002 [hereinafter *Undertaking Annex I*]; F.A.O. Res. 5/89, *International Undertaking on Plant Genetic Resources, amended 1989, 1991*, U.N. Food and Agriculture Organization, 25<sup>th</sup> Sess., Annex II: *Farmers' Rights*, available at <http://www.mtnforum.org/resources/library/iupgr91a.htm> (last visited Mar. 13, 2002) [hereinafter *Undertaking Annex II*].

124. *Undertaking Annex I, supra* note 123; *Undertaking Annex II, supra* note 123.

125. *See Undertaking Annex I, supra* note 123.

126. *See Undertaking Annex II, supra* note 123.

127. Hamilton, *supra* note 93, at 603.

128. F.A.O. Res. 3/91, *International Undertaking on Plant Genetic Resources, amended 1989, 1991*, U.N. Food and Agriculture Organization, 26<sup>th</sup> Sess., Annex III, available at <http://www.mtnforum.org/resources/library/iupgr91a.htm> (last visited Mar. 13, 2002).

129. *Id.*

annexes provided the backdrop for the Earth Summit's deliberations on biodiversity, patents, compulsory licensing and North-South equity.<sup>130</sup>

*E. The Biodiversity Convention*

At the United Nations Conference on Environment and Development (UNCED) or the Earth Summit in Rio in 1992,<sup>131</sup> the differences between the United States and the South over plant genetic resources resurfaced.<sup>132</sup> In particular, the matter of 'sovereign rights' over PGR was at the fore during negotiations for the Biodiversity Convention.<sup>133</sup>

At Rio, there were tensions between the concept of sovereign "property" rights over "national" resources and the interests of the international community.<sup>134</sup> In particular, Principle 21 of the Stockholm Declaration on the international environment,<sup>135</sup> which recognizes the sovereign rights of states over their own resources, was the subject of heated North-South polemics during the negotiations for a Biodiversity Convention.<sup>136</sup> At the June 1991 Beijing Ministerial Conference on Environment and Development,<sup>137</sup> the ministers from 41 developing countries declared they had "the sovereign right to use their own natural resources in keeping with their developmental and environmental objectives."<sup>138</sup> The Group of 77, composed of governments of developing countries, reiterated this position in 1991 at a

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130. See Hamilton, *supra* note 93, at 604-05.

131. Convention on Biological Diversity, *supra* note 13.

132. See Bosselman, *supra* note 6, at 136.

133. See *id.* at 136.

134. See *id.*

135. *Report of the United Nations Conference on the Human Environment*, [1972] 26 U.N.Y.B. 320, U.N. Doc. A/Conf. 48/14/Rev. 1. Principle 21 of the Stockholm Declaration recognizes the sovereign rights of states over their own resources. *Id.* But it also imposes an obligation on each state to ensure that its activities do not cause damage to the environment of other states or areas beyond national jurisdiction. *Id.*

136. See Bosselman, *supra* note 6, at 135-36.

137. *Letter dated 1 July 1991 from the Charge d'affairs a.i. of the Permanent Mission of China to the United Nations addressed to the Secretary-General*, U.N. GAOR, 46<sup>th</sup> Sess., U.N. Doc. A/46/293 (1991).

138. Bosselman, *supra* note 6, at 135.

preparatory conference for the UNCED.<sup>139</sup>

The Biodiversity Convention, which has as its broad themes the conservation of biodiversity, sustainable use, and equitable sharing of plant genetic resources<sup>140</sup> has been described as vague and “impressively opaque.”<sup>141</sup> The document does not refer to plant genetic resources as the Common Heritage of Mankind.<sup>142</sup> The North’s attempt to include language with CHM implications for plant genetic resources in the Convention “arguably failed.”<sup>143</sup> Instead, the Preamble merely states that the conservation of biodiversity is a “common concern of humankind.”<sup>144</sup>

Articles 3 and 15 echo the annex to the FAO Undertaking by recognizing the “sovereign rights” of nations in their natural resources,<sup>145</sup> leading to the conclusion that a country can block access to its genetic resources unless it can negotiate acceptable terms.<sup>146</sup> The Convention also requires research results be shared in a “fair and equitable way.”<sup>147</sup> Article 16 requires that the technology for exploiting plant resources be made available to the South, where necessary, on fair terms as well as on a mutually agreed basis.<sup>148</sup> Article 16(4) requires each party to take appropriate legislative, administrative or policy measures to ensure that the private sector “facilitates access to[] joint development and transfer of technology.”<sup>149</sup> Article 19 requires contracting parties to “promote and advance priority access” to the

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139. *Id.* at 136.

140. Convention on Biological Diversity, *supra* note 13, at art. 1.

141. *The Earth Conference; Biodivisive*, ECONOMIST, Jun. 13, 1992, at 93.

142. See Bosselman, *supra* note 6, at 137.

143. Asebey & Kempenar, *supra* note 2, at 717. The Third World realized the CHM principle was, in this case, inimical to their interests. See David R. Downes, *New Diplomacy for the Biodiversity Trade: Biodiversity, Biotechnology, and Intellectual Property in the Convention on Biological Diversity*, 4 *TOURO J. TRANSNAT'L L.* 1, 6 (1993). Some commentators saw the Convention as the onset of “a move away from the ‘common heritage position’” by the South. Bosselman, *supra* note 6, at 137.

144. Convention on Biological Diversity, *supra* note 13, pmbl.

145. *Id.* at arts. 3, 15.

146. Bosselman, *supra* note 6, at 138.

147. Convention on Biological Diversity, *supra* note 13, art. 15(7).

148. *Id.* art. 13(1)-(2).

149. *Id.* art. 16(4).

results and benefits of biotechnology research on fair and mutually agreed terms.<sup>150</sup> The North shall provide primary financing for the agreement and this is apparently a condition precedent for the South's performance of its obligations (particularly the granting of access to biodiverse resources).<sup>151</sup>

The Bush administration objected to articles 16 and 19, claiming these provisions, particularly the latter, undermined the prevailing system of IPRs.<sup>152</sup> In addition, many U.S. biotechnology firms objected to article 16(4), which they considered a compulsory licensing provision.<sup>153</sup> As a result, the United States refused to sign the convention.<sup>154</sup> Nevertheless, the Clinton administration subsequently signed the agreement in June 1993, albeit reserving the right to develop an Interpretive Statement on the issue of compulsory licensing.<sup>155</sup> The U.S. Senate has not ratified the Biodiversity Convention.<sup>156</sup>

### III. NARROWING THE GAP: TREATMENT EQUITY, COMPULSORY LICENSING & THE UNITED STATES-SOUTH AFRICA CASE

The debate over treatment equity is inextricably linked with North-South divisions over intellectual property protection.<sup>157</sup> Recent controversies about the unavailability of AIDS drugs to millions of poor infected persons have placed the matter of pharmaceutical patents at the forefront of the global agenda,<sup>158</sup> particularly within the context of North-South differences over the issue of compulsory licensing.<sup>159</sup> Yet, certain efforts to achieve treatment equity, particularly through "compulsory

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150. *Id.* art. 19(2).

151. *Id.* art. 20(4)-(4).

152. *See* Bosselman, *supra* note 6, at 139-40.

153. *Id.* at 139; Asebey & Kempenaar, *supra* note 2, at 717-18.

154. *Id.* at 713-14.

155. *See* Asebey & Kempenaar, *supra* note 2, at 713, 718.

156. *Id.* at 718.

157. *See id.* at 712, 713.

158. *See* BUREAU OF OCEANS AND INT'L LAND AND SCIENTIFIC AFFAIRS, U.S. DEP'T OF STATE, 1999 U.S. INTERNATIONAL RESPONSE TO HIV/AIDS, at [http://www.state.gov/www/global/oes/health/1999\\_hiv\\_aids\\_rpt/issues.html](http://www.state.gov/www/global/oes/health/1999_hiv_aids_rpt/issues.html) (March 16, 1999) [hereinafter INTERNATIONAL RESPONSE].

159. *See* Ford, *supra* note 39, at 942-43, 946.

licensing,” appear to violate the intellectual property rights of the pharmaceutical companies in the business of developing life-saving cures for illnesses such as AIDS.<sup>160</sup> Given the history of the North–South logjam over the nature, purpose and extent of IPRs, as illustrated by the polemics over the patentability of plant genetic resources,<sup>161</sup> it is hardly surprising that the issue has evoked such rancor and recriminations on both sides of the divide.

Below, this Article examines the North–South HIV treatment gap and the prospects for narrowing the gap through a strategy of compulsory licensing. Then, the Article suggests that for real results to be achieved, both sides must move beyond their scripted positions and forge unique solutions to a most unusual human tragedy—the global AIDS pandemic.

#### A. *The Treatment Gap*

UNAIDS<sup>162</sup> estimates that most of the people currently infected with HIV worldwide will die within ten years if they do not receive up-to-date medical treatment.<sup>163</sup> Yet, treatment “remains little more than a dream” for the 90% of victims in developing countries.<sup>164</sup> According to UN Secretary General Kofi Annan, “Millions of children and adults are becoming infected, falling ill and dying without the barest essentials in medical treatment, counseling or social support.”<sup>165</sup>

Treating a single HIV-infected person with the standard three–drug cocktail costs \$10,000 or more and making this treatment protocol available worldwide would cost an estimated \$36.5 billion, with Africa alone accounting for over \$24 billion in

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160. *See id.* at 952, 954, 966.

161. *See Asebey & Kempenaar, supra* note 2, at 710-12.

162. UNAIDS is the Joint United Nations Program on HIV/AIDS. *See generally* UNAIDS website at <http://www.unaids.org> (last visited Mar. 13, 2002).

163. *See AIDS Conference Sounds Alarm Over Rich-Poor Divide*, CNN Interactive, July 4, 1998 at <http://www.cnn.com/HEALTH/9807/04/aids/> [hereinafter *Rich-Poor Divide*].

164. *Id.*

165. *Id.*

costs.<sup>166</sup> Although the costs of antiretroviral therapy range from U.S. \$10,000 to U.S. \$15,000 per person per year,<sup>167</sup> many African countries spend just about \$5 a year per person on health care.<sup>168</sup> In addition, effective treatment requires an extensive public health infrastructure that can continuously monitor compliance with complex treatment protocols.<sup>169</sup> Less than 5% of African AIDS victims have access to basic care and many are expected to die without any treatment for opportunistic infections like tuberculosis and malaria.<sup>170</sup>

Many physicians in South Africa do not mention known effective remedies to their patients because they know the patients cannot afford the drugs.<sup>171</sup> Even South Africans who, among Africans, have some of the highest average incomes (about \$6,000) cannot afford antiretroviral therapy that costs about \$12,000 annually.<sup>172</sup> The burden on scarce resources is so high that the “cash-strapped” South African government refused to provide the drug AZT to rape victims when demanded by public health experts and AIDS activists.<sup>173</sup> In addition, in 1999,

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166. *Id.* The \$24 billion figure estimate for the entire continent seems relatively mild when compared to some others. For example, the Ugandan Minister of Health has stated that providing access to currently available treatments to AIDS afflicted Ugandans alone would cost \$24 billion—in a country with an annual budget of \$2 billion. See President William J. Clinton, Opening Remarks at the National Summit on Africa (Feb. 17, 2000), at [http://www.state.gov/www/regions/africa/000217\\_clinton\\_summit.html](http://www.state.gov/www/regions/africa/000217_clinton_summit.html).

167. INTERNATIONAL RESPONSE, *supra* note 158.

168. *World Bank Pledges \$500 Million for AIDS fight in Africa*, at <http://www.cnn.com/2000/HEALTH/AIDS/07/08/aids.advancer.02/index.html> [hereinafter *World Bank*].

169. See INTERNATIONAL RESPONSE, *supra* note 158.

170. See Vice President Al Gore, Statement in the Security Council on AIDS in Africa (Jan. 10, 2000), at [http://www.un.int/usa/00\\_002.htm](http://www.un.int/usa/00_002.htm) [hereinafter *Gore UN Remarks*].

171. Ford, *supra* note 39, at 951 (citing Debra Rosenberg & John Barry, *No Money, No Meds: South Africa Needs Access to Cheap AIDS Medicine, But Drug Companies Want a Say in What They Get and How They Get It*, NEWSWEEK, July 12, 1999, at 32).

172. Rosenberg & Barry, *supra* note 171, at 32.

173. Charlayne Hunter-Gault, *Cash-Strapped S. African Government Cuts AIDS Drug Programs*, CNN Interactive, at <http://www.cnn.com/HEALTH/9905/06/safrica.azt/> (May 6, 1999).

the government ended a pilot project that provided AZT to pregnant HIV-positive women.<sup>174</sup> The former South African Minister of Health, Ms. Nkosazana Zuma, said projects such as the AZT project eat up the resources the government has for all AIDS-related programs: "With the limited resources we have, we have to make choices in terms of what we prioritize—even about AIDS . . . . And at the moment, the priority is prevention."<sup>175</sup> As her successor Health Minister Manto Msimang stated, "It costs (\$10,100) a year to treat one AIDS patient and I don't have the budget."<sup>176</sup>

While AIDS experts currently estimate that it will cost at least \$3 billion to fight the African AIDS pandemic, that figure accounts only for prevention and basic health care—it does not include the cost of anti-AIDS drugs.<sup>177</sup>

### *B. The Emerging Principle of Treatment Equity*

Due to the lack of affordable AIDS therapies in South, many in the international community are calling for "treatment equity" between the North and the South.<sup>178</sup> Treatment equity is the umbrella phrase given to the view that "there needs to be greater equity in access to treatments between patients in developed and developing countries."<sup>179</sup>

The problem of "treatment equity" is sometimes conceptualized in stark North-South, gender, class and even racial dimensions.<sup>180</sup> For example, many of the participants at

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174. *Id.*

175. *Id.*

176. *See South Africa to Press for Cheaper AIDS Drugs*, at <http://www.unfoundation.org/unwire/archives/UNWIRE000608.asp> (last visited July 19, 2000).

177. *See* WORLD BANK, *supra* note 168.

178. *See* U.S. DEP'T OF STATE, 1999 U.S. INTERNATIONAL RESPONSES TO HIV/AIDS, ROLE OF THE PHARMACEUTICAL INDUSTRY, at [http://www.state.gov/www/global/oes/health/1999\\_hiv aids\\_rpt/pharm\\_role.html](http://www.state.gov/www/global/oes/health/1999_hiv aids_rpt/pharm_role.html) (last visited Nov. 15, 2001) [hereinafter *Role of the Pharmaceutical Industry*].

179. *Id.*

180. *See* U.S. DEP'T OF STATE, 1999 U.S. INTERNATIONAL RESPONSES TO HIV/AIDS, ASSESSMENT OF U.S. INTERESTS, at [http://www.state.gov/www/global/oes/health/1999\\_hiv aids\\_rpt/ assess\\_us.html](http://www.state.gov/www/global/oes/health/1999_hiv aids_rpt/ assess_us.html) (last visited Mar. 13, 2002) (addressing the impact of HIV/AIDS on the debates about both North-South issues and gender equity)

the Global Health Council's Conference (June 20-22 1990) expressed "concern for the racial and class issues" in Africa's AIDS crisis.<sup>181</sup> As one participant stated, "It's really painful that in this global village, some of us are living with HIV, and some of us are dying."<sup>182</sup> Former Congressman Ron Dellums, a participant at the conference, put forth an ambitious remedy for the problem of access to care and treatment as he called for "an AIDS Marshall Plan' to provide the medical, pharmaceutical, infrastructural, educational and other assistance needed to deal with the crisis."<sup>183</sup> The problem of treatment equity is also inextricably linked with the matter of women's international human rights and gender equity.<sup>184</sup> As a State Department Report noted, policy development and implementation with regard to the pandemic must look at the impact of AIDS on "gender equity, and its challenges to principles of human rights."<sup>185</sup>

Achieving treatment equity is consistent with national and international efforts to realize the right to health.<sup>186</sup> Over the

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[hereinafter ASSESSMENT OF U.S. INTERESTS]; International AIDS Economics Network, A Continent in Crisis: Africa and the AIDS Pandemic, at <http://www.worldbank.org/aids-econ/africa/global.htm> (last visited Nov. 15, 2001) (excerpting from the Global Health Council's 26th Annual Conference in which the concerns for the racial and class issues involved in Africa's HIV/AIDS crisis were addressed by the participants).

181. International AIDS Economics Network, A Continent in Crisis: Africa and the AIDS Pandemic, at <http://www.worldbank.org/aids-econ/africa/global.htm> (last visited Mar. 13, 2002).

182. *Id.* (quoting comments of Michael Angaga, Network of African People with HIV/AIDS).

183. *Id.* As former NAACP Chairman Julian Bond stated, "African-Americans, too, must no longer sit idly by as Africans die by the millions." Julian Bond, *US Leadership Needed on Aids in Africa*, BOSTON GLOBE, Aug. 1, 1999, at E7.

184. See INTERNATIONAL RESPONSE, *supra* note 158 (warning that women are becoming HIV-infected at faster rates than men, but the imbalance of power between men and women in most cultural settings limits women's ability to protect themselves in that they are often forced to accept unsafe sex).

185. See ASSESSMENT OF U.S. INTERESTS, *supra* note 180.

186. See generally J.M. Spectar, *The Hydra Hath But One Head: The Socio-Cultural Dimensions of the AIDS Epidemic & Women's Right to Health*, 21 B.C. THIRD WORLD L.J. 1, 13-16 (2001) (citing various international agreements and declarations indicating nations' commitments in realization of a human right to health in the context of gender equity).

last half-century, several international human rights documents, including several regional agreements, guarantee a right to health that embraces a right to receive treatment.<sup>187</sup> In addition, article 27 of the Universal Declaration of Human Rights grants all persons a “right . . . to share in scientific advancement and its benefits”<sup>188</sup> as well as “[t]o enjoy the benefits of scientific progress and its applications.”<sup>189</sup>

Achieving treatment equity typically involves calling for price reductions, achieved in part through compulsory licensing, as well as actively working through all available private and public networks to disseminate information and foster changes

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187. Article 25 of the Universal Declaration of Human Rights (UDHR) states, “[e]veryone has the right to the standard of living adequate for the health and well-being of himself and his family.” Universal Declaration of Human Rights, G.A. Res. 217, U.N. GAOR, 3rd Sess., pt. 1, at 76 (1948). This includes the right to “medical care and necessary social services” as well as “the right to security” in the event of sickness or “other lack of livelihood in circumstances beyond [her] control.” *Id.* In addition, Article 12 of the International Covenant on Economic, Social and Cultural Rights notes that everyone has the right to health, and to realize this right, states must take steps necessary for the “prevention, treatment and control of epidemic, endemic, occupational and other diseases.” International Covenant on Economic, Social and Cultural Rights, art. 12, G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No. 16, at 51, U.N. Doc. A/6316 (1966). With regard to regional instruments, article 16 of the African Charter on Human and Peoples’ Rights includes a right to health. The parties to the Charter pledge to take “the necessary measures to protect the health of their people.” Organization of African Unity: Banjul Charter on Human and Peoples’ Rights, Jan. 1982, 21 I.L.M. 58, 61. In addition, the European Social Charter also includes “the right to social and medical assistance.” European Social Charter, Oct. 18, 1961, 529 U.N.T.S. 89, art. 13. Meanwhile, the American Declaration of the Rights and Duties of Man includes a right to the preservation of health. AMERICAN DECLARATION OF THE RIGHTS AND DUTIES OF MAN 3 (Pan Am. Union 1957).

188. Universal Declaration of Human Rights, *supra* note 187, art. 27.

189. International Covenant on Economic, Social and Cultural Rights, art. 15, *supra* note 187, at 51. This position is also echoed in the Vienna Declaration and Programme of Action of the World Conference on Human Rights that states that “everyone has a right to enjoy the benefits of scientific progress and its applications.” United Nations World conference on Human Rights: Vienna Declaration and Programme of Action, U.N. GAOR, 48th Sess., 22nd mtg., pt. 1, at 24, U.N. Doc. A/Conf. 157/24 (1993), reprinted in 32 I.L.M. 1661, 1667 (1993). See also Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind, G.A. Res. 3384, U.N. GAOR, 30<sup>th</sup> Sess., Supp. No. 34, at 86, U.N. Doc. A/10034 (1975), available at <http://www1.umn.edu/humanrts/instreet/s2dustp.htm> (last visited Mar. 13, 2002).

in policy.<sup>190</sup> For others strengthening public health infrastructures to address the pandemic, is a key aspect of treatment equity.<sup>191</sup> A common example of a strategy to improve treatment equity is “the use of mechanisms such as private sector leveraging to help communities and governments tap into additional financial resources.”<sup>192</sup> In addition, achieving treatment equity also involves harnessing “the talent and power of the private sector” to direct more biomedical research efforts to “major killer diseases in the developing world.”<sup>193</sup> Furthermore, to attain treatment equity, health care systems for HIV/AIDS infected individuals should be designed and administered in an equitable manner.<sup>194</sup> Treatment equity may also include increased efforts to expand the recruitment of women and other underrepresented groups in clinical trials.<sup>195</sup> Other efforts to achieve treatment equity include commitments by pharmaceutical industries to make therapies accessible to patients and others connected to the trials even after the clinical studies are completed.<sup>196</sup>

Yet, while the prevailing view indicates that there should be greater equity in access to treatments between patients in developed and developing countries, many in the pharmaceutical industry are concerned that the issue goes beyond affordability.<sup>197</sup> Opponents of compulsory

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190. See U.S. DEPT OF STATE, 1999 U.S. INTERNATIONAL RESPONSE TO HIV/AIDS, ROLE OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS, at [http://www.state.gov/www/global/oes/health/1999\\_hiv aids\\_rpt/ngos\\_role.html](http://www.state.gov/www/global/oes/health/1999_hiv aids_rpt/ngos_role.html) (last visited Mar. 13, 2002) [hereinafter Role of NGOs].

191. U.S. DEPT OF STATE, 1999 U.S. INTERNATIONAL RESPONSE TO HIV/AIDS, CONCLUSION, at [http://www.state.gov/www/global/oes/health/1999\\_hiv aids\\_rpt/conclusion.html](http://www.state.gov/www/global/oes/health/1999_hiv aids_rpt/conclusion.html) (last visited Mar. 13, 2002).

192. See Role of NGOs, *supra* note 190.

193. See Gore UN Remarks, *supra* note 170.

194. See International Response, *supra* note 158.

195. See Allyn L. Taylor, *Women's Health at a Crossroad: Global Responses to HIV/AIDS*, 4 HEALTH MATRIX 297, 306-07 & n.32 (1994) (citing National Comm'n on Acquired Immune Deficiency Syndrome, *America Living With AIDS: Transforming Anger, Fear and Indifference into Action* 95, 101 (1991), which recommends the inclusion of women and minorities in clinical trials).

196. See Role of the Pharmaceutical Industry, *supra* note 178.

197. *Id.*

licensing are further concerned by the “potential misuse and abuse of antimicrobial drugs in developing countries.”

<sup>198</sup> The pharmaceutical industry claims that even if an unlimited amount of drugs were made available “access to HIV/AIDS therapies in the developing world may be thwarted by the lack of basic medical care, poor infrastructure, and the lack of national political will and commitment.”<sup>199</sup> In addition, the potential misuse is exacerbated by the fact that many developing countries have inadequate or non-existent regulatory controls over antimicrobial drugs.<sup>200</sup> The absence of proper medical or regulatory supervision over the prescription and distribution of antimicrobial drugs has contributed to the “irrational” and “undisciplined” use of such drugs, resulting in the development of antimicrobial resistance to diseases such as tuberculosis and malaria.<sup>201</sup>

Further, many developing countries are having great difficulty allocating “scarce resources to effectively implement prevention, education, and treatment programs and effectively cope with the complex social, cultural, and economic factors involved in improving health.”<sup>202</sup> Even at substantially lower prices, many LDCs still would be unable to obtain maximum clinical benefit from the new treatment drugs, like protease inhibitors or other antiretroviral therapy.<sup>203</sup> The lack of properly trained medical personnel supporting public health infrastructure, as well as inadequate distribution mechanisms, makes the use of protease inhibitors and other antiretroviral therapy “impractical,” potentially inefficacious and even “hazardous.”<sup>204</sup> These “combination therapies” require strict dosage schedules and well-trained medical support systems to

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198. See Fidler, *supra* note 16, at 212.

199. See Role of the Pharmaceutical Industry, *supra* note 178.

200. See Fidler, *supra* note 16, at 212.

201. *Id.* at 212.

202. See INTERNATIONAL RESPONSE, *supra* note 158.

203. *Id.*

204. *Id.*

ensure continuous use.<sup>205</sup> Improper use of therapy increases may lead to the emergence of a drug-resistant virus, which worsens the impact of HIV/AIDS in affected populations.<sup>206</sup>

In addition to reduced treatment costs and an improved health infrastructure, the pharmaceutical industry maintains that government commitment is “required to provide incentives for private individuals and firms to pursue responsible development of new drug therapies and to develop the necessary public health infrastructure.”<sup>207</sup> Such intervention will facilitate “the development of therapies that are consistent with internationally recognized rights and standards” as well as increase the availability of effective therapies and services.<sup>208</sup> As some strains of HIV appear to be developing resistance to therapies, many in the pharmaceutical industry argue that indiscriminate compulsory licensing further worsens the problem of resistant strains of HIV.<sup>209</sup> Below, this Article examines the attempt by developing countries such as South Africa to achieve treatment equity through compulsory licensing and the reaction of the North.

### C. *Compulsory Licensing, AIDS & the U.S.–South Africa Case*

The fracas over the lack of access to life-saving HIV/AIDS therapies in the South and the pharmaceutical industry’s dogged defense of the prevailing intellectual property regime has reached a boiling point in the issue of compulsory licensing of patents.<sup>210</sup> As governments in the South grapple with the pandemic, compulsory licensing has emerged as a solution to the problem of expensive AIDS therapies manufactured in the North.<sup>211</sup>

Under the practice of compulsory licensing, the government of a developing country issues licenses to local firms to

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205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.*

209. *See Fidler, supra* note 16, at 212.

210. *Id.* at 210.

211. *See id.* at 210-11.

manufacture lower-cost, generic versions of patented HIV/AIDS drugs.<sup>212</sup> Critics charge AIDS therapies are exorbitantly priced in part because of the “intellectual property rights that pharmaceutical companies hold over the drugs in question.”<sup>213</sup> It is feared that any future HIV vaccine would be similarly priced out of reach.<sup>214</sup> Prices tend to decrease sharply after governments issue compulsory licenses.<sup>215</sup> The AIDS drug AZT costs \$239 per month in the United States, while averaging about \$48 per month in India where the drug is unregulated.<sup>216</sup> Given that the issuance of a compulsory license has sometimes resulted in a seventy-five percent reduction in prices,<sup>217</sup> governments of developing countries argue for the right to issue such licenses for expensive Northern pharmaceuticals.<sup>218</sup> Additionally, several NGOs and international HIV/AIDS activists have requested that governments in the South rely on compulsory licensing as a means of achieving access to effective AIDS therapies such as AZT.<sup>219</sup>

Most developed countries, on the other hand, argued for strict restrictions on compulsory licensing.<sup>220</sup> While TRIPS arguably permits compulsory licensing of patents in limited situations,<sup>221</sup> many governments in the North and Northern pharmaceutical concerns have expressed opposition to indiscriminate compulsory licensing of pharmaceutical

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212. *Id.*

213. *Id.* at 210.

214. *Id.*

215. *See Ford, supra* note 39, at 946. Some sources estimate that compulsory licensing can lower prices of medicines by as much as seventy-five percent. *Id.* at 11 n.21.

216. Nathan Ford & Daniel Berman, *AIDS and Essential Medicines and Compulsory Licensing* 3, at <http://www.eptech.org/march99-cl/report1.html> (last visited Mar. 13, 2002). Discarding the ability to use compulsory licensing will reportedly drive up the costs of pharmaceuticals in Canada by an extra \$7 billion by the year 2010. *See* Wendy S. Vicente, *Questionable Victory for Coerced Argentine Pharmaceutical Patent Legislation*, 19 U. PA. J. INT'L ECON. L. 1101, 1132 (1999).

217. *See Ford, supra* note 39, at 11 n.21.

218. *See id.* at 946.

219. *See Fidler, supra* note 16, at 210.

220. *See Ford, supra* note 39, at 946.

221. *See, e.g., Fidler, supra* note 16, at 211.

patents.<sup>222</sup> Thus, efforts by South Africa to permit compulsory licensing for patented HIV/AIDS drugs were met with strong U.S. opposition, precipitating major diplomatic and legal squabbles.<sup>223</sup> Several Northern pharmaceutical companies challenged the compulsory licensing law in South African courts, with one pharmaceutical industry representative calling compulsory licensing “a form of patent piracy” and “stealing.”<sup>224</sup> As the Assistant U.S. Trade Representative for Intellectual Property Issues stated, the U.S. government is “negative toward compulsory licensing.”<sup>225</sup>

In 1997, South Africa enacted the Medicines and Related Substances Control Amendment Act<sup>226</sup> designed to increase access to affordable AIDS therapies by making drugs less expensive.<sup>227</sup> The Act sought to address the pandemic in South Africa and the problem of treatment equity by granting the South African Minister of Health the power to engage in compulsory licensing and parallel importation of pharmaceuticals.<sup>228</sup> Section 10 grants the Minister of Health the power to permit the compulsory licensing of pharmaceuticals, “so long as the product was initially marketed by the owner or with the owner’s consent, but without any other expressed limitation.”<sup>229</sup> The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances in order to protect the public health.<sup>230</sup> To that effect, notwithstanding anything to the contrary contained in the Patent Act, 1978 (Act No. 57 of 1978), the Minister may

(a) determine that the rights with regard to any

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222. *See id.*

223. *Id.* (stating that Thailand also attempted compulsory licensing and received a similar response from the United States).

224. *Id.* Merrill Goozner, *Third World Battles for AIDS Drugs*, CHI. TRIB., Apr. 28, 1999, at 1.

225. Goozner, *supra* note 224, at 1.

226. Medicines and Related Substances Control Amendment Act 90 of 1997 (S. Afr.) [hereinafter Medicines Amendment].

227. Nash, *supra* note 46, at 486.

228. *Id.* at 492.

229. *Id.*

230. Medicines Amendment, *supra* note 226, §15(C).

medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent; [and] (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported.<sup>231</sup>

The new law was apparently aimed at lowering pharmaceutical prices by changing or modifying existing patent laws.<sup>232</sup> Many in the North interpreted the Act to mean the Minister of Health could selectively end patent rights for pharmaceuticals.<sup>233</sup> In fact, the United States and some European countries stated that they interpreted section 15(c) to permit the Minister of Health to approve the use of more affordable medicines in contravention of any patent under the 1978 Patents Act of South Africa.<sup>234</sup>

The Act provoked strong criticism from Northern governments and pharmaceutical interests.<sup>235</sup> Even before the Act's passage in the South African parliament, the governments of the United States, France and Switzerland warned South Africa against its passage, arguing it violated TRIPS.<sup>236</sup> Merck, the German drug manufacturer of the antiretroviral Indinavir Sulphate (Crixivan) "warned the South African government that it was reconsidering a fifty million Rand investment in South Africa in light of the bill . . . and that it would review future

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231. *Id.*

232. *See Snyder, supra note 36, at 176.*

233. *See id.* at 182.

234. *Id.* at 183.

235. *See Nash, supra note 46, at 492.*

236. *Id.* at 492 n. 46.

investments upon the bill's passage."<sup>237</sup> A major U.S. drug manufacturer warned that if the law was not repealed or modified, it would terminate all operations in South Africa, thereby eliminating thousands of jobs.<sup>238</sup> The Act was also challenged by the Pharmaceutical Association of South Africa, composed "significantly" of local licensees of western pharmaceutical firms, who promptly challenged the Act's legality in Pretoria High Court.<sup>239</sup> In addition, the International Federation of Pharmaceutical Manufacturers warned that pharmaceutical companies may punish South Africa by refusing to introduce new drugs, including AIDS therapies, unless the Act was repealed.<sup>240</sup> The pharmaceutical companies claimed that there were alternative ways of achieving lower prices including reforming South Africa's inefficient distribution chain by eliminating extensive mark-up prices by middle-men, and by halting the pilfering of drugs from public hospitals.<sup>241</sup>

Meanwhile, the United States government maintained that the Act was invalid under the TRIPS and it responded by threatening economic sanctions against South Africa.<sup>242</sup> The United States pressured South Africa to suspend or repeal the Act,<sup>243</sup> invoking statutes such as section 301 of the Trade Act of 1974.<sup>244</sup> The 1988 Amendment to section 301<sup>245</sup> permits the U.S. President to seek the elimination of "unjustifiable" or

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237. *Id.* at 492 n. 47.

238. Snyder, *supra* note 36, at 177.

239. Nash, *supra* note 46, at 493.

240. Snyder, *supra* note 36, at 177.

241. *Id.* Mirryena Deeb of the Pharmaceutical Manufacturing Association of South Africa pointed out that the RSA government was already receiving the lowest prices on drugs, but public hospitals were losing about fifty percent of drugs to theft. *Id.* at 190. Drugs, beds, medical equipment and computers were allegedly being stolen and resold in the private sector, thus increasing the cost of medical services. *Id.* Additionally, the cartel of middlemen in South Africa mark up drug prices by as much as eighty-two percent, compared to the United States with a mark-up of twenty-five percent. *Id.*

242. Nash, *supra* note 46, at 486.

243. See Nash, *supra* note 46 at 495-96.

244. 19 U.S.C. § 2411 (1994).

245. Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, § 1301, 102 Stat. 1107, 1164.

“unreasonable” trade practices;<sup>246</sup> and the Trade and Tariff Act of 1984 makes intellectual property protection actionable under section 301 of the 1974 Trade Act.<sup>247</sup> The Omnibus Trade and Competitiveness Act of 1988 also requires an annual review by the U.S. Trade Representative of U.S. trading partners with regard to compliance with trade rules.<sup>248</sup> The U.S. Trade Representative is responsible for identifying countries that deny “adequate and effective protection” of IPRs or which “deny fair and equitable market access” to U.S. commercial interests.<sup>249</sup> These countries are placed on either a “watch list” or a “priority watch list,” and the latter could be followed in certain cases “by trade retaliation consisting of increased duties and/or import restrictions.”<sup>250</sup> The U.S. Trade Representative called on the South African Government to bring its IPR regime into “full compliance with TRIPS” before a January 1, 2000 deadline and “clarify that the powers granted in the Medicines Act are consistent with its international obligations and will not be used to weaken or abrogate patent protection.”<sup>251</sup>

In response to the Act, Charlene Barshefsky, the U.S. Trade Representative, placed South Africa on the watch list in 1998 and 1999, citing violations of the TRIPS.<sup>252</sup> The U.S. Trade Representative’s 1998 annual report identified the South African Act as the United States’ “largest patent rights concern.”<sup>253</sup> The U.S. Congress also expressed its disapproval,

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246. 19 U.S.C. § 2411.

247. Nash, *supra* note 46, at 494 (citing the Trade and Tariff Act of 1984, 15 U.S.C. § 2007.8 (1994)).

248. See 19 U.S.C. § 2213(b) (2000) (stating that USTR and the Secretary of the Treasury shall prepare an annual report for Congress detailing, *inter alia*, “the impact on United States of market barriers and other unfair practices, of countries that are trading partners of the United States. . .”).

249. 19 U.S.C. § 2242(a) (2000).

250. United States Trade Representative, *The President’s 2001 Annual Report on the Trade Agreements Program*, available at <http://www.ustr.gov/reports/ch6.pdf> (last visited Mar. 13, 2002).

251. Press Release, United States Trade Representative, USTR Announces Results of Special 301 Annual Review (Apr. 30, 1999), available at <http://www.ustr.gov/releases/1999/04/99-41.html> (last visited Mar. 13, 2002).

252. Nash, *supra* note 46, at 495, 497 n. 66.

253. United States Trade Representative, *The President’s 1997 Annual Report*

conditioning future aid to South Africa on the Secretary of State's issuance of a report summarizing efforts to work with South Africa to repeal the act.<sup>254</sup> On June 30, 1998, the White House announced it was withholding preferential treatment for four South African export items.<sup>255</sup> On February 5, 1999, the State Department reported to Congress that South Africa had been placed on the watch list for 1998 and 1999.<sup>256</sup> The U.S. Trade Representative's Report of April 30, 1999 stated that "South Africa's Medicines Act appears to grant the Health Minister ill defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights."<sup>257</sup> Besides calling for compliance before the January 1, 2000 deadline, the U.S. Trade Representative pledged to "continue to address these issues" with the

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on the Trade Agreements Program, available at [http://www.ustr.gov/pdf/1998tpa\\_vii.pdf](http://www.ustr.gov/pdf/1998tpa_vii.pdf) (last visited Mar. 13, 2002).

254. See Nash, *supra* note 46, at 495-96. According to Public Law 105-277:

[N]one of the funds appropriated under this heading may be available for assistance for the central government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997.

Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, 112 Stat. 2681, 2681-155 (1998). Not all the Congressional interest was protectionist. For example, some House members were concerned that the compulsory licensing measure could threaten the health of South Africans by allowing inferior and counterfeit products to be placed on the market. See Ford, *supra* note 39, at 953 (citing H.R. REP. NO. 105-719, at 15 (1998)).

255. Nash, *supra* note 46 at 496 (citing United States', *U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15 (c) of the South African Medicines and Related Substances Act*, available at <http://www.cptech.org/ip/health/sa/stdept-feb51999.html> (last visited Mar. 13, 2002)).

256. Nash, *supra* note 46, at 496.

257. United States Trade Representative, 1999 Report of the United States Trade Representative, available at <http://www.ustr.gov/releases/1999/04/99-41.html> (last visited Mar. 13, 2002) [hereinafter USTR, 1999 Report]. Meanwhile, the South African government was coming under increasing pressure from public health experts and AIDS activists. See *Cash-Strapped S. African Government*, *supra* note 173 (describing activists' efforts to inject the AIDS drug issue into the country's pending elections).

government of South Africa and to “conduct an out-of-cycle review of South Africa’s progress towards addressing these concerns in September 1999.”<sup>258</sup> There was a small silver lining to the extent that South Africa was only placed on the Watch List of less severe offenders, implying that it would only be subject to “out-of-cycle reviews,” but not to trade sanctions.<sup>259</sup>

The South African government, for its part, “affirmed the Act’s validity under international law” and charged that the United States was bringing pressure to bear on South Africa primarily to protect American pharmaceutical interests.<sup>260</sup> The Minister of Health, Ms. Nkosasana Zuma, strongly denied that section 15(c) ends patent rights,<sup>261</sup> or gives her the power to end all pharmaceutical patent rights.<sup>262</sup> She argued that the measure is solely designed to permit parallel importation<sup>263</sup> of much needed HIV/AIDS therapies.<sup>264</sup> In defense of the Act, Alec Erwin, South Africa’s Trade and Industry Minister, averred that “the government had taken a policy decision to stop drug companies from using their patents to prevent affordable health care.”<sup>265</sup> Meanwhile, some contended that as a result of overly aggressive pressure by the pharmaceutical lobby in Washington, the United States was bullying South Africa to adhere to a standard higher than the TRIPS.<sup>266</sup> As Lois Boland of the U.S. Patent and Trademark Office stated, “We acknowledge that our position is more restrictive than the TRIPS agreement but we see TRIPS as a minimum standard of protection.”<sup>267</sup>

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258. USTR, 1999 Report, *supra* note 257.

259. Snyder, *supra* note 36, at 176 n.12.

260. See Nash, *supra* note 46, at 486-87.

261. Snyder, *supra* note 36, at 183.

262. *Id.* at 184-85.

263. *Id.* at 183.

264. See *id.* at 176 (noting that South Africa has one of the highest HIV growth rates in the world, and over six percent of its population has already been infected with the HIV virus).

265. *Id.* at 184.

266. See Ford, *supra* note 39, at 954-55.

267. Nathan Ford & Daniel Berman, *AIDS and Essential Medicines and Compulsory Licensing 2*, available at <http://www.cptech.org/march99-cl/report1.html> (last visited Mar. 13, 2002).

By September 9, 1999, the Pharmaceutical Manufacturers Association of South Africa promised to suspend its legal action against the Act “as a ‘goodwill gesture[,]’ while the Minister of Health consider[ed] legislative amendments that w[ould] make compliance with TRIPS unambiguous.”<sup>268</sup> On September 17, 1999, the U.S. Trade Representative announced that the United States and the Republic of South Africa had worked out their differences and the United States pledged to withdraw the threat of sanctions against South Africa.<sup>269</sup> South Africa, for its part, agreed to enforce the Act’s compulsory licensing and parallel importation requirements as specified in the TRIPS.<sup>270</sup>

However, the controversy continues to simmer, as U.S. policy on compulsory licensing remains unclear.<sup>271</sup> First, it is unclear if the United States side actually acknowledged the legality of compulsory licensing, or whether they “merely backed down due to harsh political pressure.”<sup>272</sup> In addition, some wonder whether the United States’ concession on compulsory licensing was limited solely to AIDS drugs and not for other needed pharmaceuticals.<sup>273</sup> Meanwhile, the apparent face-saving exit by the United States, allowing South Africa to use compulsory licensing, raised questions about how the issue would be resolved with respect to other nations.<sup>274</sup>

Meanwhile, the South African government has continued to take a tough stance toward the drug companies.<sup>275</sup> At the end of April 1999, the Mbeki government asked the manufacturer of AZT, Glaxo Wellcome, to lower the price of the drug but the company replied it was already offering the drug at a discounted

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268. Nash, *supra* note 46, at 496.

269. *Id.* at 496-97.

270. *Id.*

271. Ford, *supra* note 39, at 954-55.

272. *Id.* at 956.

273. *Id.* at 955 n.64. For more on the U.S.-South Africa agreement, see Press Release, Office of the United States Trade Representative, Executive Office of the President, U.S.-South Africa Understanding on Intellectual Property (Sept. 17, 1999), available at <http://www.usinfo.gov/topical/econ/ipr/ipr-africa.htm>.

274. See Ford, *supra* note 39, at 956 n.67.

275. See Steve Sternberg, *Victims Lost in Battle Over Drug Patents*, USA TODAY, May 24, 1999, at 2D.

price.<sup>276</sup> On June 4, 2000, the South African government pledged to lobby international drug companies to implement promised price cuts and provide technical assistance to help combat the pandemic.<sup>277</sup> Even after a UN brokered deal where five drug firms pledged to reduce prices of HIV/AIDS therapies, Manto Tshabalala-Msimang, the South African Health Minister, responded skeptically.<sup>278</sup> Minister Msimang promised to join with others to press the companies to implement the promised price cuts, adding: “If indeed they are thinking of reducing the costs of drugs, they must understand it is not just antiretroviral, it is all drugs, but in particular to manage opportunistic infections.”<sup>279</sup> The task team also believed it was necessary that the companies assist in developing the medical infrastructure.<sup>280</sup>

These settlements and compromises notwithstanding, the confusion at the heart of the compulsory licensing problem remains and some believe it is just a matter of time before the WTO’s dispute settlement body becomes involved in resolving the issue.<sup>281</sup> While the WTO’s dispute settlement body was not involved in the settlement of the United States–South Africa dispute,<sup>282</sup> it appears that the WTO believes compulsory licensing is permitted under the TRIPS.<sup>283</sup> On the other hand,

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276. *Cash-Strapped S. African Government*, *supra* note 173.

277. *South Africa Wants More than Cheap HIV Drug Prices*, MEDICAL INDUSTRY TODAY, June 6, 2000, at World Health.

278. *See id.*

279. *Id.*

280. *Id.*

281. Ford, *supra* note 39, at 944. The dispute settlement body has been successful in addressing the interests of countries at all stages; of 157 requests filed, 88 were filed by developed nations and 29 by developing nations. Ernesto Hizon, *Virtual Reality and Reality: The East Asian NICs and the Global Trading System*, 5 ANN. SURV. INT’L & COMP. L. 81, 120-21 (1999).

282. Ford, *supra* note 39, at 950. As one member of Congress stated, “The State Department does not want to challenge [the South African Government] in the World Trade Organization because they will lose.” 145 CONG. REC. H6027 (daily ed. July 21, 1999) (statement of Rep. Sanders).

283. Ford, *supra* note 39, at 950 n.41 (citing World Trade Organization—Committee on Trade and Development, *Developing Countries and the Uruguay Round: An Overview*, available at [http://www.wto.org/english/docs\\_e/legal\\_e/ldc2\\_512.htm](http://www.wto.org/english/docs_e/legal_e/ldc2_512.htm) (last visited Mar. 13, 2002)).

Rita Hayes, U.S. Ambassador to the WTO, states that “[t]he United States believes that the TRIPs agreement does not permit WTO members to grant compulsory licenses or impose other exceptions or limitations on exclusive marketing rights.”<sup>284</sup> Recently, several developing countries of Africa, including Kenya, Uganda and Zambia, submitted a joint paper to the WTO calling for a review of TRIPS provisions to ensure that they can retain access to pharmaceutical products through compulsory licensing.<sup>285</sup>

The effort to achieve treatment equity through compulsory licensing appears to have collided head-on with the global patent protection system and the interests, preferences and priorities of entrenched actors, including the pharmaceutical companies of the North and the governments that are sworn to defend their national economic interests.<sup>286</sup> This alignment between corporate interests and Northern governments against proposed resource reallocation or redistribution has bedeviled North-South negotiations over the last forty years.<sup>287</sup> Yet this is precisely the wrong time for such actors on both sides of the divide to engage in the grandstanding dominated discussions about resources of speculative value such as moon rocks or minerals on asteroids.<sup>288</sup>

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284. Ford, *supra* note 39, at 955 n.63 (citing *Intellectual Property: U.S. Cites Problems with India's Revised Patent Law; No Plans to File Complaint*, 16 INT'L TRADE REP. 759 (May 5, 1999)).

285. Ford, *supra* note 39, at 944 n.13; see also *Intellectual Property: Seven Developing Nations Urge Trips Review to Ensure Compulsory Licensing for Drugs*, 16 INT'L TRADE REP. 966 (June 9, 1999).

286. See Sternberg, *supra* note 275, at 2D.

287. J.M. Spectar, *The Fruit of the Human Genome Tree: Cautionary Tales About Technology, Investment, and the Heritage of Humankind*, 23 LOY. OF L.A. INT'L & COMP. L. REV. 1, 14 (2001) (arguing the North's concerns over investment security and the development and protection of technology, including the vexing matter of technology transfers associated with common heritage approaches, weakened the prospects for consensus in the seabed and moon regimes). See also J.M. Spectar, *Bridging the Global Digital Gap: Frameworks For Access and the World Wireless Web*, 26 N.C. J. INT'L L. & COM. REG. 57 (2000) (noting that the international telecommunications negotiations of the seventies and eighties were often mired in rancorous North-South debates arising, in part, from conflicting views about the international economic and legal orders).

288. Considerable discussion in the Moon Treaty involved equitably divvying up mineral wealth in some far away celestial body at some future time, if and when it became technologically feasible. Grier C. Raclin, *From Ice to Ether: The Adoption of a*

The immediacy, the exigency of the AIDS pandemic leaves no time, not a moment, for the rhetorical flourishes of North-South diplomatic intercourse. Additionally, if the debate over treatment equity for HIV increasingly becomes a proxy for undermining the global system of patent protection, it is difficult to imagine a scenario whereby the South can prevail, given its present lack of the material and technological resources required to go it alone.<sup>289</sup> Meanwhile, given the urgency of the situation, the pharmaceutical companies of the North and their supporters in government must no longer hide behind legal technicalities and machinations while the death toll mounts. Below, this Article examines some new approaches to break the impasse in the North-South polemic on intellectual property rights in the biotech domain and thereby increase the prospects for treatment equity.

#### IV. TOWARDS TREATMENT EQUITY

Given the patent necessity of North-South cooperation on the matter of treatment equity, policy makers must develop an acceptable framework, albeit ad hoc, for increasing access to affordable therapies without undermining the system of global intellectual property protection. Below, this Article recommends various alternative approaches for attaining treatment equity for developing countries within the context of a global pandemic while preserving the basic framework of intellectual property protection.

##### A. Recommendations

###### 1. *Modifying International Trade Policy: the Pandemic Exception*

Given, the propensity of pandemics to spread death, destruction and instability on a global basis,<sup>290</sup> it is suggested

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*Regime to Govern Resource Exploitation in Outer Space*, 7 J. INT'L L. BUS. 727, 735-36 (1986).

289. See Spectar, *supra* note 287, at 22.

290. Pandemics cover "a wide geographic area" and affect "a large proportion of

that policy makers carve out a specific pandemic exception in the TRIPS and other multilateral trade and intellectual property agreements. For example, a limited *pandemic exception* to TRIPS should *clearly* permit compulsory licensing in close consultation and cooperation with the patent holder.

It appears that U.S. international trade policy is undergoing a shift towards permitting derogation when a pandemic threatens global public health.<sup>291</sup> For example, the United States has offered to cooperate with its trading partners to “assure that U.S. trade policies do not hinder their efforts to respond to health crises.”<sup>292</sup> At the December 1999 WTO meeting in Seattle, President Clinton announced a “cooperative” effort to help poor countries “gain access” to affordable medicines.<sup>293</sup> The approach was designed to ensure that the application of U.S. trade law related to intellectual property “remain sufficiently flexible to respond to legitimate public health crises.”<sup>294</sup>

Already there may be signs that a “pandemic exception” is being recognized by U.S. policy makers in the South Africa case.<sup>295</sup> First, during a Congressional hearing, Joe Popovich, a U.S. Trade Representative official, stated that the Administration was willing to relax its position on compulsory licensing of AIDS drugs, indicating growing recognition of the unique nature of the plague and the need for greater flexibility

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the population.” American Heritage Dictionary of the English Language (4<sup>th</sup> ed. 2000).

291. See Gore UN Remarks, *supra* note 170.

292. *Id.*

293. President Clinton Announces New Cooperative Effort to Help Poor Countries Gain Access to Affordable Medicines, Including for HIV/AIDS Treatment, at <http://clinton3.nara.gov/WH/New/WTO-Conf-1999/factsheets/fs-012.html> (Dec. 1, 1999).

294. The White House, Office of the Press Secretary, *Solidifying Our Partnership with Africa*, available at [http://www.state.gov/www/regions/africa/fs\\_000217\\_africa\\_wh.html](http://www.state.gov/www/regions/africa/fs_000217_africa_wh.html) (Feb. 17, 2000).

295. See Ford, *supra* note 39, at 956 (stating that the United States “agreed to relax its trade pressures on South Africa by acknowledging the special circumstances inherent in the AIDS epidemic”); *Cf. Africa–Caribbean Trade Bill Wins Final Approval in U.S. Congress*, at <http://www.cnn.com/2000/WORLD/africa/05/11/africa.us.trade/> (May 11, 2000) (noting that President Clinton, by signing an executive order “promoting the local manufacturing and distribution of HIV/AIDS drugs in sub-Saharan Africa,” reversed his Administration’s prior policy preventing sub-Saharan nations from licensing and purchasing drug formulas).

in U.S. trade policy.<sup>296</sup> Then, on May 10, 2000, President Clinton issued an executive order promoting the local manufacturing and distribution of HIV/AIDS drugs in sub-Saharan Africa.<sup>297</sup>

Meanwhile, at the international level, the world's leaders meeting at the UN Millennium Summit adopted a promising, if somewhat vague stance on the matter of treatment equity.<sup>298</sup> In their Millennium Declaration, the UN Member States resolved "[t]o encourage the pharmaceutical industry to make essential drugs more widely available and affordable by all who need them in developing countries."<sup>299</sup>

## 2. *The World Health Organization Treatment Equity Resolution*

The WHO and the UN General Assembly and other appropriate international organizations should adopt resolutions urging Member States to adopt the following policy orientation: In the midst of the AIDS pandemic (or any other global health catastrophe of similar magnitude) that threatens not just global health, but international security and the development and survival of nations, public health rather than commercial interests have primacy in pharmaceutical and health policies. To that end, member states of the WHO are urged to review their options under TRIPS and other relevant trade agreements in order to facilitate and safeguard access to essential drugs with the goal of arresting pandemics that destabilize international

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296. Ford, *supra* note 39, at 956 n.67. Regarding the effect of HIV/AIDS on southern Africa, Peter Piot of UNAIDS stated that the region "is facing human disaster on a scale it has never seen before." UNAIDS Press Release, *UNAIDS Executive Director Warns of Unprecedented Emergency in Southern Africa*, available at <http://www.unaids.org/whatsnew/press/eng/pressarc98/sadec98e.html> (Nov. 30, 1998).

297. Exec. Order No. 13,155, 65 Fed. Reg. 30,521 (May 10, 2000) ("[T]here is a critical need for effective incentives to develop new pharmaceuticals, vaccines, and therapies to combat the HIV/AIDS crisis, including effective global intellectual property standards . . .").

298. United Nations Millennium Declaration, G.A. Res 2, U.N. GAOR, 55th Sess., at 5, U.N. Doc. A/55/PV.8 (2000) (resolving to halt, by the year 2015, the spread of HIV/AIDS and "[t]o provide special assistance to children orphaned by HIV/AIDS").

299. *Id.* While this acknowledgement of the problem of treatment inequity is encouraging, much remains to be done to realize the lofty aspirations of the Millennium Declaration. *Id.*

security, imperil development, diminish the right to health of internationally recognized vulnerable persons and the survival of nations.<sup>300</sup>

Although the WHO Assembly has previously refused to support language positing the primacy of global public health over commercial interests with respect to essential drugs,<sup>301</sup> the growing recognition that AIDS threatens international security, development, the human rights of internationally recognized vulnerable persons and the survival of nations should provide impetus for the adoption of the proposed language.

### 3. *Further Voluntary Actions by Pharmaceutical companies to Achieve Treatment Equity*

In light of the scale of the global AIDS pandemic, and particularly its systemic ravaging of the African continent,<sup>302</sup> more pharmaceutical companies should voluntarily rethink and adjust their rigid enforcement of certain patent rights. Support for treatment equity also makes good business sense, at least in the long term. Based on current projections, over forty million Africans may be killed by the global AIDS pandemic assuming an effective vaccine is not found and disseminated within the next twenty years.<sup>303</sup> From a pure business standpoint, these are

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300. The text language builds on a proposal by the WHO Executive Board in January 1998. The WHO's Executive Board recommended that the WHO Assembly adopt a resolution urging Member States "to ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies and to review their options under the Agreement on Trade-Related Aspects of Intellectual Property Rights to safeguard access to essential drugs." World Health Organization Executive Board, *Revised Drug Strategy*, available at [http://www.who.int/gb/EB\\_WHA/PDF/EB101/pdfangl/angr24.pdf](http://www.who.int/gb/EB_WHA/PDF/EB101/pdfangl/angr24.pdf) (Jan. 27, 1998).

301. Fidler, *supra* note 16, at 211 (noting that the World Health Assembly sent the Revised Drug Strategy "back to the Executive Board in May 1998 because the controversy it generated prevented its adoption").

302. *AIDS in Africa*, at <http://www.avert.org/aafrica.htm> (last visited Mar. 13, 2002) (stating that "Africa is home to 70% of the adults and 80% of the children living with HIV in the world," and concluding that "Africa continues to dwarf the rest of the world in how the region has been affected by AIDS.").

303. See Lester R. Brown, *HIV Epidemic Restructuring Africa's Population*, at <http://www.worldwatch.org/chairman/issue/001031.html> (Oct. 31, 2000) (stating that "[e]ach day, 6,000 Africans die from AIDS [and] . . . an additional 11,000 are infected"

dead customers—coffins and mourning attire representing the only growth industries. Yet aggressive efforts to keep these and other victims alive may ensure the survival of potential and even new markets.<sup>304</sup>

Recently, the pharmaceutical industries in the North appear to have come to grips with the internecine scope of the global AIDS pandemic, and they have modified many of their policies on compulsory licensing and treatment equity accordingly.<sup>305</sup> Several pharmaceutical companies are reversing longstanding positions and have offered to reduce the prices of AIDS drugs to Africa.<sup>306</sup> The landmark UN-brokered agreement announced on May 11, 2000 “involve[d] Germany’s Boehringer Ingelheim, Bristol-Myers Squibb of New York, Roche of Switzerland, Glaxo Wellcome in Britain, and Merck and Co. of Whitehouse Station, N.J.”<sup>307</sup> According to Catherine Gavin of the humanitarian group Doctors Without Borders, the proposed plan could reduce overall drug prices by as much as seventy percent.<sup>308</sup> Glaxo Wellcome offered to sell Combivir at a price of \$2 per day in developing countries, as compared to the current U.S. price of \$16.50 per day.<sup>309</sup> Ben Plumley of Glaxo Wellcome also stated that “the company would increase the number of free tablets it was

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and concluding that “[t]hese life expectancies are more akin to those of the Middle Ages than of the modern age.”).

304. Analysts expect increasing trade opportunities for U.S. companies with African nations following the passage of the groundbreaking African-Caribbean Trade Bill. “The Africa trade bill lifts or relaxes U.S. import quotas of apparel manufactured in 25 Caribbean and 48 sub-Saharan countries.” *Africa-Caribbean Trade Bill Wins Final Approval in U.S. Congress*, *supra* note 295. The Africa trade portion of the bill allows African nations “to export apparel to the U.S., amounting to 1.5 percent of total U.S. imports.” *Id.* “That figure would rise to 3.5 percent over eight years.” *Id.* “Trade officials estimate that U.S. imports from Africa will rise from \$250 million . . . to \$4.2 billion by 2008.” *Id.*

305. See Naomi Koppel, *Drug Companies To Slash Prices for AIDS Drugs to Africa*, at [http://www.augustachronicle.com/stories/051300/tec\\_124-2766.shtml](http://www.augustachronicle.com/stories/051300/tec_124-2766.shtml) (May 12, 2000) (quoting a UNAIDS statement which said “[t]he companies are offering, individually, to improve significantly access to, and availability of, a range of medicines”).

306. See *id.*

307. *Id.*

308. *Id.*

309. *Id.*

providing as part of an existing mother-and-child program.”<sup>310</sup>

Meanwhile, Boehringer Ingelheim, one of the five pharmaceutical companies in the UN brokered price-slashing agreement, has astounded many by offering free therapies to certain AIDS victims.<sup>311</sup> On the eve of the International AIDS Conference in South Africa, Boehringer offered to provide, for a five-year period, free doses of nevirapine, an antiretroviral drug that has been shown to reduce mother-child transmissions.<sup>312</sup> As Peter Piot, the Executive Director of UNAIDS, observes, removal of a major obstacle against controlling mother-to-child transmissions is “not just symbolic . . . . It’s quite an effort.”<sup>313</sup>

These actions must be commended and supported by state actors, who can assist by providing infrastructure, organizational support, technical assistance and other resources.

#### 4. *Provide Resources for A Global Pandemic & Disaster Fund*

The international community should seriously consider the idea of developing a Global Pandemic and Disaster Fund through an international taxation scheme or perhaps by a mutual insurance plan. The costs of treating AIDS will exceed \$36 billion worldwide and about \$24 billion dollars in Africa alone.<sup>314</sup> The international community must develop a creative approach to this funding dilemma. France has put forth a bold but “controversial international plan for a global fund to supply AIDS drugs to the developing world.”<sup>315</sup> This approach must not be dismissed off-hand; instead it may be worthwhile to develop creative ways of financing such a fund. Examples include a

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310. *Id.*

311. See David Brown, *Africans Fear Costs of Free AIDS Drug*, WASH. POST, July 9, 2000, at A18.

312. See *id.* Unfortunately, due to the poisoned relationship between pharmaceutical companies and many African governments, even this offer was greeted with suspicion and cynicism. Many African health officials pointed out that the costs of implementation, including counseling and testing, would exceed the cost of the medicine. See *id.*

313. *Id.*

314. *Rich-Poor Divide*, *supra* note 163.

315. *Id.*

global disaster tax or a pandemic insurance fund handled by multinationals such as Lloyds of London.

Despite the paucity of resources, there are signs that the international community is struggling to deploy more resources to the struggle against AIDS.<sup>316</sup> On the eve of the 13th International AIDS Conference in South Africa, the World Bank proposed to set aside \$500 million in grants and loans to fight the pandemic in Africa.<sup>317</sup> The funds scheduled to be approved by the Bank's board of directors by the end of September 2000 would "be available to any African country with a national AIDS program backed by strong government commitment."<sup>318</sup>

5. *Governments, NGOs, PVOs Should Purchase Promising Patents*

Governments, NGOs, private and voluntary organizations (PVOs), universities and other organizations should consider purchasing promising biotech patents with a view towards placing them in the public domain.<sup>319</sup> Michael Kremer, the unconventional Harvard economist, argues that once such patents are placed in the public domain, any company could produce pharmaceuticals at much reduced prices.<sup>320</sup> The system would provide protections against collusion by firms and would be designed to avoid the problem of monopoly holders of patents charging excessive prices.<sup>321</sup>

6. *Encourage, Support & Form Partnerships with NGOs, PVOs, Foundations and other Actors in Private Sector Working for Treatment Equity*

Governments, international organizations and other

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316. See, e.g., *World Bank*, *supra* note 168.

317. *Id.*

318. *Id.*

319. Michael Kremer and other economists/social thinkers on the cutting-edge have put forth this revolutionary approach. See Peter Monaghan, *Of Elephants and O-Rings: An Economist's Unusual Views on Ivory, Taxes, and Population*, CHRON. HIGHER EDUC., Mar. 3, 2000, at A20.

320. See *id.*

321. *Id.*

organizations interested in achieving treatment equity should support the activities of NGOs, PVOs, foundations, universities and other actors in the private sector through a combination of incentives including tax breaks, tax exemptions, subsidies and credits.

Already, many of the efforts to achieve treatment equity are being spearheaded by NGOs, PVOs and pharmaceutical industries.<sup>322</sup> NGOs have “severely criticized” Northern pharmaceutical companies for pricing policies that have placed many effective HIV/AIDS therapies beyond the reach of people in developing countries, where over ninety-five percent of HIV infected people now live.<sup>323</sup>

The involvement of NGOs and other non-state actors on the matter of treatment equity has broken the North-South logjam, giving rise to transnational cooperation on a scale hitherto unknown.<sup>324</sup> NGOs including Medicins Sans Frontiers, Health Action International and ACT-UP have lobbied on behalf of compulsory licensing schemes.<sup>325</sup>

Other groups, such as Treatment Action Campaign have mounted an international effort for treatment equity aimed not directly at governments but at the pharmaceutical industry.<sup>326</sup>

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322. See *International Response*, *supra* note 158, at 51-53, 57.

323. See Fidler, *supra* note 16, at 210.

324. For more analysis of the pivotal role NGOs can play in transforming international law and society, see, e.g., J.M. Spectar, *Saving the Ice Princess: NGOs, Antarctica & International Law in the New Millennium*, 23 SUFFOLK TRANSNAT'L L. REV. 57 96 (1999) (arguing the success of environmental NGOs in securing the protection of Antarctica as a World Park signaled an incipient paradigmatic shift from statecentric international law-making to an increasingly decentralized world system where non-state actors and social movements, aided by the Internet's rapid connectivity, play crucial roles as partners). States and international organizations should allow and/or encourage key NGOs to play a greater role in international policy making, especially in the UN and other multilateral institutions. *Cf. id.* at 58 (supporting the influence of non-state entities on international law).

325. See Ford, *supra* note 39, at 955 n.65 (citing *Drugs: U.S., EU Resistance to Compulsory Drug Licensing Draws Health Care Fire*, BNA INT'L TRADE DAILY NEWS, Mar. 29, 1999 at D8).

326. See, *Protesters Target Drug Firms as AIDS Conference Opens in South Africa*, available at <http://www.cnn.com/2000/HEALTH/AIDS/07/09/aids.conference.01/index.html> (July 9, 2000).

Just prior to the Durban Conference, Treatment Action Campaign, the South African-based umbrella NGO “backed by 230 AIDS organizations from around the world, staged a march in Durban, South Africa . . . to demand that pharmaceutical companies make affordable drugs available” to the poor people in the South.<sup>327</sup> The group of over 4,000 protesters demanded that President Mbeki of South Africa “work to make the drug firms substantially reduce the price of HIV-related drugs.”<sup>328</sup>

Meanwhile, other non-state actors such as the Gates Foundation are spearheading efforts to achieve treatment equity that transcend the worn North-South dynamic.<sup>329</sup> As a founding member of the Global Alliance for Vaccines and Immunizations (GAVI), the Bill and Melinda Gates Children’s Vaccine Program has provided funds to immunize millions of children worldwide.<sup>330</sup> Other members of GAVI working to secure treatment equity include the Rockefeller Foundation, the United Nations Children Emergency Fund (UNICEF), the World Bank and the WHO.<sup>331</sup>

7. *Governments Must take Responsibility: developed and developing countries must work together in partnership to increase treatment equity.*

The AIDS pandemic challenges the entire community of humankind to work in concert and to form new partnerships between state and non-state actors, including NGOs and international organizations. In particular, states must adopt a comprehensive approach to health that, *inter alia*, focuses on the structural and contextual determinants shaping the courses of

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327. *Id.*

328. *Id.* (quoting Treatment Action Committee spokesman, Naghan Geffen).

329. *See, Putting Immunization at the Top of the Global Health Agenda*, at <http://www.childrensvaccine.org/html/act-setting-agenda.htm> (last visited Mar. 13, 2002) (emphasizing the commitment of the Bill and Melinda Gates Children’s Vaccine Program to children’s health worldwide).

330. *See id.* Saving millions of poor children worldwide from premature and painful death, the Bill and Melinda Gates Foundation’s Nobel Prize-quality work deserves the international community’s highest civilian awards.

331. *See id.*

the pandemic, especially the social practices that violate human rights and make citizens more vulnerable to AIDS and other diseases.<sup>332</sup> Elsewhere, this author has also argued in favor of a holistic approach that includes an elaborate plan for eradicating chronic poverty—particularly because extreme poverty has been determined to be a purveyor of pestilence.<sup>333</sup> In this context, creditor nations should tie extensive debt relief and/or debt cancellation to the developing countries making specific and verifiable commitments to allocate funds for treatment of AIDS and the development of infrastructure and organization needed to effectively administer therapy. Developing countries must also adopt the programs and reforms necessary to strengthen the health sector and improve cooperation with relief agencies, NGOs and international organizations working to achieve treatment equity. Additionally, it will be necessary for many developing countries to reallocate funds for treatment purposes by reducing excessive military expenditures.

#### 8. *Development of Cheaper and Alternative Therapies*

In the short term, researchers from both the North and South should work together to develop cheaper therapies suited to the needs of the people. As the costs of antiretrovirals are beyond the reach of the developing countries,<sup>334</sup> achieving treatment equity may require the development of more affordable therapies suited to the needs of the developing countries. Recently, some have expressed hope that antibiotics, which are generally much cheaper than protease inhibitors, can be used to combat infections.<sup>335</sup> For example, the cost of antibiotics for a patient in the United States is \$60 a year, while

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332. See, e.g., J.M. Spectar, *The Hydra Hath But One Head*, *supra* note 186, at 1-2 (noting policies and programs to fight AIDS must be comprehensive in scope and designed to empower women, girls, and other vulnerable populations).

333. See *id.* at 16-17, n.111.

334. See Philip A. Lieder, *Domestic AIDS Vaccine Trials: Addressing the Potential for Social Harm to the Subjects of Human Experiments*, 88 CAL. L. REV. 1185, 1194 (2000).

335. See *International AIDS Conference Offers Good News About Cheap Drug Treatments*, at <http://www7.cnn.com/2000/HEALTH/AIDS/07/11/aids.conference.02/index.html> (July 11, 2000).

drug cocktail treatments can cost as much as \$15,000.<sup>336</sup> Some of these potential “treatments” like Roche’s Bactrim cost as little as nine cents a tablet.<sup>337</sup>

Meanwhile, it is necessary for North and South to begin research and development efforts aimed at discovering how traditional African medicines/herbs and the holistic therapies of the East can slow the pandemic or at least alleviate pain even as humankind awaits a vaccine.

9. *Begin the Planning for Effective Dissemination of an AIDS Vaccine Now*

While there are currently many efforts underway to develop an AIDS vaccine, there is inadequate planning for the eventual delivery of such a vaccine in the remote areas of developing countries.<sup>338</sup> The logistics of rapid global dissemination in remote rural areas would pose a great challenge in the period immediately following the development of an effective and affordable vaccine.<sup>339</sup> Instead of waiting until the problem materializes, hopefully not long from now, the international community under the leadership of the World Health Organization and NGOs such as GAVI should begin planning for the swiftest and the most comprehensive vaccination program today. It is hoped that this task can be enabled by the increasing penetration of new communications technologies.

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336. *Id.*

337. *See, e.g., Drug Prices/Index: Bactrim, at* [http://webrx.com/ode/cstage?eccookie=&eaction=ecpassthru&template=pharmacy\\_index.en.htm&content=didetail&PharmBrandId=122873](http://webrx.com/ode/cstage?eccookie=&eaction=ecpassthru&template=pharmacy_index.en.htm&content=didetail&PharmBrandId=122873).

338. *Cf. Lieder, supra* note 334, at 1192-93 (recognizing that AIDS treatments have been a success in industrialized nations although “the treatments are largely unavailable in developing countries”).

339. *See id.* at 1191, 1196 (noting developing countries have virtually no infrastructure to distribute medication and the “obstacles to . . . dissemination of a vaccine are formidable, if not insurmountable”).