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NOTE

ACCESS TO AFFORDABLE HIV/AIDS DRUGS: THE HUMAN RIGHTS OBLIGATIONS OF MULTINATIONAL PHARMACEUTICAL CORPORATIONS

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INTRODUCTION

The United Nations has characterized the impact of the HIV/AIDS crisis in Africa as "no less destructive than that of warfare itself."[1] In developed nations, the widespread availability of life-prolonging HIV/AIDS drugs has turned AIDS from a death sentence into a manageable and treatable illness.[2] But in developing countries, which account for ninety percent of infected people globally, the overwhelming majority of HIV/AIDS sufferers cannot afford these life-saving treatments.[3] In South Africa, where the average daily

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1. Press Release, United Nations, In Address to Security Council, Secretary-General Says Fight Against AIDS in Africa Immediate Priority in Global Effort Against Disease, SG/SM/7275 AFR/200 SC/6780 (Jan. 6, 2000) (statement of U.N. Secretary-General Kofi Annan), http://www.un.org/News/Press/docs/2000/20000106.sgsm7275.doc.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review). As of December 2001, an estimated 28.1 million people in sub-Saharan Africa alone were infected with HIV. Joint United Nations Programme on HIV/AIDS & WHO, AIDS Epidemic Update at 2, 3, U.N. Doc. UNAIDS/01.74E, WHO/CDS/CSR/NCS/2001.2 (2001), *available at* http://www.unaids.org/worldaidsday/2001/Epiupdate2001/EPIupdate2001_en.pdf [hereinafter UNAIDS Update].

2. *See* James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 Fla. L. Rev. 727, 733-34 (2001) (stating that "drug treatment has quadrupled the median survival time for Americans diagnosed with AIDS from one to four years" and decreased mortality rates by seventy-five percent); Judy Rein, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines*, 21 Nw. J. Int'l L. & Bus. 379, 379 (2001) ("Significant public and private investment, particularly in the United States, converted this killer into a manageable chronic disorder for many in the developed world.").

3. *See* UNICEF et al., Sources and Prices of Selected Drugs and Diagnostics for People Living with HIV/AIDS 5 (2001), *available at* http://www.unaids.org/acc_access/access_drugs/Sources0501.doc [hereinafter Sources & Prices]; Rein, *supra* note 2, at 379. In sub-Saharan Africa, where approximately seventy-five percent of

income is $7, a one-year supply of the most common HIV treatment combination from the major drug companies costs a staggering $1200.[4] The generic equivalent of that same drug combination costs $350 per year.[5]

Developing countries and human rights activists claim that these prohibitively expensive drug prices are the result of strong patent protection, which governments must provide under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[6] While TRIPS is mostly favorable to the rich industrialized world and its multinational corporations,[7] it provides some flexibility for states to address their public health needs by allowing several public interest exceptions to patent protection.[8] Through the use of controversial

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people live on less than two dollars a day, UNAIDS Update, *supra* note 1, at 7, only an estimated 10,000-25,000 Africans are receiving anti-retroviral treatment, Sources & Prices, *supra*, at 5. *See also* Barton Gellman, *An Unequal Calculus of Life and Death: As Millions Perished in Pandemic, Firms Debated Access to Drugs*, Wash. Post, Dec. 27, 2000, at A1 (stating that only "one-tenth of 1 percent" of infected Africans receive HIV/AIDS drug therapy).

4. *AIDS Drugs Case Adjourned*, CNN.com, Apr. 18, 2001, *at* http://www.cnn.com/2001/WORLD/africa/04/18/safrica.drugs.02/ (last visited Nov. 9, 2001) (on file with the Fordham Law Review); Kristen Philipkoski, *S. Africa To Rule on AIDS Drugs*, Wired News, Apr. 14, 2001, *at* http://www.wired.com/news/technology/0,1282,43066,00.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review). HIV drug combinations, known as drug cocktails, "interrupt the cycle of HIV infection, allow an infected person's immune system to rebuild itself, and allow the person to live much longer than the person would without treatment." Gathii, *supra* note 2, at 734.

5. *AIDS Drugs Case Adjourned*, *supra* note 4.

6. *See* Kara M. Bombach, Note, *Can South Africa Fight AIDS? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement*, 19 B.U. Int'l L.J. 273, 288 (2001) ("Some critics argue that, because TRIPS provides for worldwide patent protection, drugs become more expensive in developing countries."); Andrew Pollack, *Defensive Drug Industry: Fueling Clash Over Patents*, N.Y. Times, Apr. 20, 2001, at A6 ("Drug patents are under attack, blamed for high AIDS drug prices that deny life-saving therapy to millions of people in developing countries."); Pharmaceutical Research and Manufacturers of America, Health Care in the Developing World: The Global Challenge of AIDS, *at* http://world.phrma.org/global.challenge.aids.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review) [hereinafter PhRMA Global Challenge]; *see also* Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS]. TRIPS provides an international framework of intellectual property obligations that is binding on World Trade Organization (WTO) member states. See *infra* Part I.A.3 for a thorough discussion of TRIPS.

7. *See* Gathii, *supra* note 2, at 761 ("Substantively, TRIPS came to embody the interests of the . . . Western coalition."); Pollack, *supra* note 6 (quoting the president of a generic drug companies' trade organization characterizing TRIPS as "probably the greatest political economic achievement that the pharmaceutical industry ever had").

8. *See, e.g.*, Gathii, *supra* note 2, at 759-70 (discussing the public interest logic of TRIPS); Rein, *supra* note 2, at 387 (discussing TRIPS and the North American Free Trade Agreement and noting that "the intellectual property provisions of the trade

practices such as compulsory licensing and parallel importing, drug prices in developing countries feasibly could be reduced by ninety percent.[9]

Along with other developing nations, South Africa has attempted to take advantage of this flexibility by adopting a law designed to reduce the prices of HIV/AIDS drugs.[10] Thus, in 1997, the South African Parliament proposed an amendment to its existing Medicines and Related Substances Control Act ("Medicines Act Amendment") to allow the government to take measures to ensure wider access to essential drugs.[11] The multinational drug companies, in tandem with the U.S. government, however, have aggressively opposed such legislation, characterizing it as an infringement on their intellectual property rights by allowing practices such as parallel importing and compulsory licensing.[12] In South Africa, for example, subsidiaries of

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agreements leave substantial room for countries to exercise regulatory control over pharmaceutical pricing").

9. Joint Press Release, Médecins Sans Frontières et al., Generic AIDS Drugs Offer New Lease of Life to South Africans; Importation of Generics Cuts Price in Half (Jan. 29, 2002) ("Our project shows that antiretroviral therapy is feasible in a resource-poor setting."), *at* http://www.msf.org/countries/page.cfm (last visited Nov. 9, 2002) (on file with the Fordham Law Review) [hereinafter Generic Drugs Press Release]; *see also AIDS Drugs Case Adjourned*, *supra* note 4 (citing Médecins Sans Frontières estimate that the price of one HIV/AIDS drug cocktail in South Africa could be reduced by three-quarters if it were purchased from a generic producer).

10. *See* Medicines and Related Substances Control Amendment, Act 90 of 1997 (S. Afr.), *available at* http://www.Policy.org.za/govdocs/legislation/1997/act90.pdf [hereinafter Medicines Act Amendment]; *see also* Joanne Csete, *Several for the Price of One: Right to AIDS Treatment as Link to Other Human Rights*, 17 Conn. J. Int'l L. 263, 264 (2002) (describing Kenya's law); Duane Nash, *South Africa's Medicines and Related Substances Control Amendment Act of 1997*, 15 Berkeley Tech. L.J. 485 (2000) (discussing South Africa's amendment); Rosemary Sweeney, Comment, *The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision*, 9 Pac. Rim. L. & Pol'y J. 445 (2000) (discussing Thailand's statute).

11. *See* Naomi A. Bass, Note, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 Geo. Wash. Int'l L. Rev. 191, 210 (2002).

12. *See* Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 Wis. Int'l L.J. 481, 500-02 (2002) (describing U.S. pressure on South Africa and Thailand, on behalf of the drug industry, to prevent the implementation of laws to make HIV/AIDS drugs cheaper); Bess-Carolina Dolmo, Note, *Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example*, 7 Buff. Hum. Rts. L. Rev. 137, 151 (2001) (discussing responses of U.S. interests to South Africa's law); Submission of PhRMA for the "Special 301" Report on Intellectual Property Barriers (Pharmaceutical Research and Manufacturers of America 2002) (requesting that the United States take action against countries such as South Africa and Brazil), http://www.phrma.org/international/special301 (last visited Nov. 9, 2002) (on file with the Fordham Law Review); *see also* Barbara Larkin, U.S. Department of State, U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(c) of the South African Medicines and Related Substances Act of 1965 (Feb. 5, 1999) (detailing U.S. government's actions to "defend the legitimate interests and rights of U.S. pharmaceutical firms" in South Africa), http://www.cptech.org/ip/health/sa/stdept-feb51999.html (last visited Nov. 5,

the major multinational drug companies filed a lawsuit to prevent implementation of the amended law.[13] While the drug industry and its supporters have defended the intellectual property rights of drug companies, others have framed access to affordable HIV/AIDS drugs as a human rights issue.[14] During the controversy in South Africa, for example, human rights organizations and commentators accused the drug companies of violating human rights.[15]

Part I of this Note presents the background to the debate over laws designed to increase access to drugs, focusing on intellectual property rights, and contextualizes the debate through the South African experience.[16] Section A presents the intellectual property rights issues raised by governments' efforts to make HIV/AIDS drugs more affordable.[17] This section presents the debate over patents and the practices that undermine them, as well as the debate over the TRIPS provisions relevant to HIV/AIDS drugs access.[18] Section B contextualizes this debate by focusing on the Medicines Act Amendment and the drug companies' aggressive opposition to that law.[19]

Part II explores the human rights dimension to HIV/AIDS drugs

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2002) (on file with the Fordham Law Review) [hereinafter Larkin Report]. See *infra* Part I.B and accompanying notes for a discussion of the drug industry's opposition to South Africa's amended law and similar laws.

13. *See* Applicants' Notice of Motion, Pharm. Mfrs.' Ass'n of S. Afr. v. President of the Republic of South Africa, the Honourable Mr. N.R. Mandela N.O. (S. Afr. 1998) (No. 4183/98), http://www.cptech.org/ip/health/sa/pharmasuit.html (last visited Nov. 9, 2002) (on file with the Fordham Law Review) [hereinafter Notice of Motion]; *see also* Nash, *supra* note 10, at 486-87.

14. *See, e.g.*, Barbara Cochrane Alexander, *Lack of Access to HIV/AIDS Drugs in Developing Countries: Is There a Violation of the International Human Right to Health?*, 8 Hum. Rts. Brief 12, 14 (2001); Marjorie Cohn, *The World Trade Organization: Elevating Property Interests Above Human Rights*, 29 Ga. J. Int'l & Comp. L. 427, 435-37 (2001) (arguing that WTO protects intellectual property rights at the expense of human rights and citing access to HIV/AIDS drugs as an example); Csete, *supra* note 10, at 265 (asserting that access to HIV/AIDS treatment "has been recognized as a human right"); Joint Statement, The Allard K. Lowenstein International Human Rights Clinic of the Yale Law School et al., AIDS and Human Rights: A Call for Action (June 26, 2001) ("Under trade agreements, governments and international institutions should . . . interpret pharmaceutical patent and property laws consistent [sic] with the imperative of the right to health—and the right to life."), *at* http://www.hrw.org/press/2001/06/ aids-ngos-0627.htm (last visited Nov. 5, 2002) (on file with the Fordham Law Review) [hereinafter Call for Action]; *AIDS Drug Battle Ends, Clears Way for Cheaper Treatment*, CNNfyi.com, Apr. 19, 2001 (citing World Health Organization official characterizing "access to affordable drugs [as] a 'human rights issue'"), *at* http://www4.cnn.com/ 2001/fyi/news/04/19/africa.aids/ (last visited Nov. 5, 2002) (on file with the Fordham Law Review) [hereinafter *AIDS Drug Battle Ends*].

15. *See, e.g.*, Alexander, *supra* note 14, at 14.

16. *See infra* notes 28-190 and accompanying text.

17. *See infra* notes 28-122 and accompanying text.

18. *See infra* notes 28-122 and accompanying text.

19. *See infra* notes 123-90 and accompanying text.

access.[20] Section A provides the normative framework for understanding fundamental human rights under international law, and the concomitant obligations to ensure those rights.[21] This section then builds on that framework to examine the rights implicated by lack of access to HIV/AIDS treatment.[22] Section B analyzes the human rights obligations of corporations under a form of "soft law" corporate duties, the corporate codes of conduct promulgated by multilateral institutions.[23]

In Part III, this Note argues that access to HIV/AIDS drugs is a human right, and that the drug companies' actions to prevent developing countries from making HIV/AIDS drugs more affordable violate the "soft law" human rights obligations of multinational corporations under the multilateral corporate codes of conduct.[24] Section A builds on the human rights framework established in Part II.A to argue that access to HIV/AIDS drugs is a fundamental human right.[25] Section B argues that the multilateral codes of conduct call on drug companies to respect host states' laws and policies that promote the human right to affordable HIV/AIDS treatment, and to respect states' obligations under international law to protect, promote, and fulfill the right to affordable HIV/AIDS treatment.[26] It further argues that drug corporations violate these "soft law" human rights obligations when they challenge the actions of developing countries to increase access to life-prolonging HIV/AIDS drugs.[27]

I. ACCESS TO HIV/AIDS DRUGS & INTELLECTUAL PROPERTY RIGHTS

A. *The Debate over Intellectual Property Rights & Laws to Increase Access to HIV/AIDS Drugs*

The debate over governments' efforts to widen access to HIV/AIDS drugs has centered around intellectual property rights and their limits.[28] The United Nations (U.N.) and non-governmental human rights organizations claim that patents are a major factor in the lack of access to HIV/AIDS drugs,[29] a point hotly disputed by the drug

20. *See infra* notes 191-287 and accompanying text.
21. *See infra* notes 202-17 and accompanying text.
22. *See infra* notes 218-57 and accompanying text.
23. *See infra* notes 258-87 and accompanying text.
24. *See infra* notes 288-375 and accompanying text.
25. *See infra* notes 292-306 and accompanying text.
26. *See infra* notes 316-75 and accompanying text.
27. *See infra* notes 316-75 and accompanying text.
28. *See infra* notes 29-190 and accompanying text.
29. *See, e.g.*, Carmen Pérez-Casas et al., Accessing ARVs: Untangling the Web of Price Reductions for Developing Countries 3 (Médecins Sans Frontières 2001) (presenting graph showing how generic competition significantly drove down prices of a sample triple-therapy cocktail in Brazil), *available at*

industry and its proponents.[30] The industry promotes strong patent protection for medicines, criticizes compulsory licensing and parallel importing, and accuses developing countries such as South Africa of violating their legal obligations under TRIPS by adopting laws such as the Medicines Act Amendment.[31] Developing countries and their advocates support using compulsory licensing and parallel importing to make drugs more affordable, and argue that laws designed to increase access to drugs are legal under TRIPS' numerous public interest exceptions.[32] This section discusses intellectual property rights as they relate to access to medicines and presents the debate over patents, compulsory licensing and parallel importing, and TRIPS.[33]

1. Patents: The Root of the Problem?

According to the United States International Trade Commission, "[a] patent is a grant issued by a national government conferring the right to exclude others from making, using, or selling the invention within the national territory."[34] By investing exclusive rights in a patent holder, patents give inventors a monopoly for a set period of time; without competition from other manufacturers to drive the price down, patent holders can charge high prices for their inventions.[35] In this way, patent rights function as an incentive for corporations to invest in researching new drugs and to reveal their inventions, as well as a reward for their costly investment.[36]

The drug industry denies that patents are responsible for the lack of affordable HIV/AIDS drugs.[37] Instead, the industry blames other

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http://www.globaltreatmentaccess.org/content/pressreleases/01/100501_MSF_RPT_ARV_Prices.pdf [hereinafter Untangling the Web]; UNAIDS Update, *supra* note 1, at 9 (identifying competition with generic manufacturers as one factor responsible for lowering drug prices); Sources & Prices, *supra* note 3, at 5 (identifying patents and limited competition as factors that may affect drug affordability); Posting of James Love, love@cptech.org, to ip-health@lists.essential.org, Request that WHO Seek Compulsory Licenses for 5 Essential Antiretroviral Products in Sub-Saharan Africa (Oct. 7, 2001), *at* http://lists.essential.org/pipermail/ip-health/2001-October/ 002012.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review).

30. *See, e.g.*, PhRMA Global Challenge, *supra* note 6; *see also* Pollack, *supra* note 6.

31. *See* discussion *infra* Parts II.A, II.B.

32. *See* discussion *infra* Parts II.A, II.B.

33. *See infra* notes 34-122 and accompanying text.

34. International Intellectual Property Law 3 (Anthony D'Amato & Doris Estelle Long eds., 1997).

35. *See* Theodore C. Bailey, Note, *Innovation and Access: The Role of Compulsory Licensing in the Development and Distribution of HIV/AIDS Drugs*, 2001 U. Ill. J.L. Tech. & Pol'y 193, 202-04.

36. *Id.*; *see also* Bombach, *supra* note 6, at 282; Dolmo, *supra* note 12, at 154.

37. *See* Pollack, *supra* note 6; PhRMA Global Challenge, *supra* note 6 ("Notwithstanding claims by developing nations and activists, pharmaceutical patents are not hindering efforts to get more drugs to Africa.").

barriers for the lack of access to HIV/AIDS drugs, such as poverty, poor health infrastructure, the lack of government commitment to fighting HIV/AIDS, and cultural barriers in developing countries.[38] Citing a recent study finding that most HIV/AIDS drugs are not under patent in Africa, the industry maintains that developing countries are thus free to import and manufacture generics.[39] The study, published in the Journal of the American Medical Association ("J.A.M.A."), identifies the paucity of international aid as the main factor responsible for the lack of HIV/AIDS drugs in Africa.[40]

Several commentators have undermined the findings in the studies on which the drug industry bases its claims.[41] They point out, for example, that the survey omits consideration of crucial drugs that are indeed patented in Africa, and does not sufficiently consider the impact of patents on new drug combinations of older drugs.[42] The J.A.M.A. study itself verifies that thirteen of the fifteen HIV/AIDS drugs surveyed are patented in South Africa.[43] One scholar adopts the World Health Organization's ("WHO") distinction among the three different components of access to drugs: "therapeutic access," "physical access," and "financial access."[44] She concludes that, specifically, financial access to drugs "is greatly affected by the ability of pharmaceutical companies to exercise monopoly control of pricing through exclusive patent rights."[45]

The industry's critics also dispute the contention that developing

38. *See, e.g.*, Gellman, *supra* note 3; PhRMA Global Challenge, *supra* note 6; Pharmaceutical Research and Manufacturers of America, Health Care in the Developing World: Overview: Factors Affecting Global AIDS Fight, *at* http://world.phrma.org/factors.affecting.aids.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review). The South African government, for example, has thus far refused to use the tools that the Medicines Act Amendment put at its disposal to provide free drug treatment. *See* Generic Drugs Press Release, *supra* note 9 (describing how "South Africans are mobilizing against a government they say is not doing enough to fight [HIV/AIDS]").

39. Pharmaceutical Research and Manufacturers of America, Health Care in the Developing World: Intellectual Property and Access to AIDS Drugs, *at* http://world.phrma.org/ip.access.aids.drugs.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review) [hereinafter PhRMA Intellectual Property & Access]; *see also* Amir Attaran & Lee Gillespie-White, *Do Patents For Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886 (2001).

40. *See* PhRMA Intellectual Property & Access, *supra* note 39.

41. *See* Bernard Pécoul et al., *Access to Essential Drugs in Poor Countries: A Lost Battle?*, 281 JAMA 361, 366 (1999); Sell, *supra* note 12, at 514-15; Posting of James Love, love@cptech.org, to ip-health@lists.essential.org, Comment on Attaran/Gillespie-White and PhRMA Patent Surveys (Oct. 16, 2001), *at* http://lists.essential.org/pipermail/ip-health/2001-October/002089.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review) [hereinafter Attaran Study Comment].

42. *See* Attaran Study Comment, *supra* note 41.

43. *See* Attaran & Gillespie-White, *supra* note 39, at 1888.

44. Rein, *supra* note 2, at 381.

45. *Id.*

nations lack the infrastructure to properly use HIV/AIDS drugs.[46] Some countries, such as Brazil, Argentina, and Uruguay have successfully implemented free HIV-treatment programs.[47] Additionally, these critics argue that while other factors may impact access to drugs, it would be a mistake to first "await solutions to all of Africa's problems," and posit that the availability of affordable drugs itself may spur the building of health infrastructure.[48]

2. The Limits of Intellectual Property Rights?: The Debate over Compulsory Licensing and Parallel Importing as Tools to Increase Access to HIV/AIDS Drugs

Compulsory licensing and parallel importing are two practices that limit a patent holder's rights.[49] Parallel importing is the government importing of *patented* drugs from other countries where those same patented drugs are cheaper.[50] Patented drugs may be cheaper elsewhere because drug companies sell their products at varying prices in different countries, and because different countries offer varying levels of patent protection.[51] In those countries with weaker levels of patent protection, such as India, competition from generics drives down the price of patented drugs.[52] Parallel importing, including that of pharmaceuticals, is a common practice in many European Union countries and recently was sanctioned by the European Court of Justice and the European Commission.[53]

Compulsory licensing of drugs is a government grant of permission to third parties to manufacture generic versions of medicines under

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46. *See* Generic Drugs Press Release, *supra* note 9 (discussing a project that "shows that antiretroviral therapy is feasible in a resource-poor setting").

47. *See* UNAIDS Update, *supra* note 1, at 9 (noting, however, that in "low-income countries . . . health infrastructures are too frail to bring life-prolonging treatments to the millions who need it").

48. Gellman, *supra* note 3; *see also* Bombach, *supra* note 6, at 286-87.

49. See generally Bailey, *supra* note 35, for a thorough discussion of compulsory licensing, and Shubha Ghosh, *Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights*, 53 Fla. L. Rev. 789 (2001) for a discussion of parallel importing.

50. *See* Nash, *supra* note 10, at 490 ("Parallel imports are goods that are purchased in a foreign market by an independent third party and later resold in the domestic market where their much lower prices compete with those of authorized distributors."). Parallel importing is distinct from the importing of generics.

51. Bailey, *supra* note 35, at 198-99; *see also* Rein, *supra* note 2, at 385 (noting that "there are significant price differentials on the same medicines legally produced in, or exported to, different countries").

52. Bombach, *supra* note 6, at 288; Rein, *supra* note 2, at 396-97. TRIPS provides for a tiered compliance system, granting developing and least-developed countries longer transitional periods. *See* TRIPS, *supra* note 6, art. 65. Thus, some developing countries, such as India, offer weaker patent protection than other countries. *See* Rein, *supra* note 2, at 390, 396-97.

53. Dolmo, *supra* note 12, at 147-49. In the United States, Congressional members of the Democratic Party have been pursuing legislative measures to allow parallel imports of drugs in the United States. *Id.* at 147.

patent without the patent holder's authorization.[54] In practice, the introduction of several manufacturers of the drug promotes market competition and reduces the drug's price; ultimately, compulsory licensing can cut the prices of some drugs up to ninety percent.[55] For example, if South Africa were to issue a compulsory license to a generic manufacturer to produce an HIV/AIDS drug, the government could then purchase the cheaper generic version of that HIV/AIDS drug from the generic manufacturer.

According to the drug industry, the drug development process is lengthy, costly, and risky.[56] Patent rights, which allow the inventors of new drugs to charge high prices, are necessary to provide incentives for the research and development ("R&D") of new drugs.[57] The drug industry argues that compulsory licensing and parallel importing, by undermining the drug companies' exclusive patent rights, greatly reduce the incentives for companies to invest in the R&D of new drugs to treat diseases like HIV/AIDS.[58] As a result, drug companies will no longer allocate their resources to finding new HIV/AIDS drugs.[59] The drug industry claims that generic competition alone already diminishes its profits by three billion dollars.[60]

Ultimately, the pharmaceutical industry's fundamental concern is that lower prices in the more peripheral markets of developing countries will have a negative effect on the much more significant European and American markets.[61] Lower prices in the developing

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54. Bombach, *supra* note 6, at 276-77.

55. *Id.*

56. *See* Dolmo, *supra* note 12, at 154. A successful AIDS drug takes fourteen years and costs over $360 million to develop and market, and a drug only has a one in 4,000 chance of actually making it to the market. Bailey, *supra* note 35, at 197; Dolmo, *supra* note 12, at 154. According to PhRMA, in 2001 the industry invested over $30 billion in the R&D of new drugs. Press Release, Pharmaceutical Research and Manufacturers of America, Health Care Advocates to Fight Efforts by Generic Industry to Jeopardize the Progress in Medical Research (Feb. 25, 2002), *at* http://www.phrma.org/mediaroom/press/releases/ 25.02.2002.347.cfm (last visited Nov. 5, 2002) (on file with the Fordham Law Review). Additionally, the cost of the rare drug that makes it onto the market must include the cost of researching and applying for FDA approval for the thousands of unsuccessful drugs. *See* Bailey, *supra* note 35, at 197.

57. Andrea M. Curti, Note, *The WTO Dispute Settlement Understanding: An Unlikely Weapon in the Fight Against AIDS*, 27 Am. J.L. & Med. 469, 476 (2001).

58. *See* Bailey, *supra* note 35, at 210-11; Bombach, *supra* note 6, at 282; Pollack, *supra* note 6 ("The Canadian experience suggests that protecting [patents] may prompt greater investments by drug companies and even the development of a homegrown industry.").

59. *See* Bombach, *supra* note 6, at 282.

60. *See* Curti, *supra* note 57, at 477 (accounting for differences in market sales in developing world); Dolmo, *supra* note 12, at 155 (noting that Adock Ingram and Glaxo-Wellcome blame parallel importing for, respectively, decline in stock value and loss of profits).

61. *See* Bombach, *supra* note 6, at 287; Gellman, *supra* note 3; Pollack, *supra* note 6 (quoting the executive of a major drug company as stating that "[t]here was a feeling that if a country deliberately went against Trips, there would be a castle-of-

countries may undermine the willingness of Western consumers to pay higher prices, and thus lead to pressure to lower prices in the major drug markets.[62] Another possibility is that developed countries may import cheaper patented HIV/AIDS drugs from developing countries.[63] Either way, the industry argues, this scenario would decrease worldwide profits and substantially reduce the incentives for companies to invest in researching new HIV/AIDS drugs.[64]

Since the pharmaceutical industry traditionally has failed to disclose its R&D investments, many accuse the drug industry of inflating the R&D costs that form the basis for the industry's opposition to compulsory licensing and parallel importing.[65] The industry's critics assert that the drug industry spends twice as much on marketing than on R&D efforts.[66] Some critics also assert that the industry's very high profitability itself belies any claims about the riskiness of developing new drugs.[67] Additionally, they point out that the development of new drugs frequently is subsidized heavily by the taxpayer's money and performed in publicly-funded laboratories.[68] Thus, critics not only question the R&D claims that the industry uses to attack compulsory licensing and parallel importing, but some also argue that it is unfair for drug companies to reap huge profits from the inflated prices they charge for products developed using taxpayer money.[69]

Many activists and scholars dispute the industry's contention that compulsory licensing and parallel importing will eliminate the

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cards effect").

62. *See* Bombach, *supra* note 6, at 287; *see also* Pollack, *supra* note 6.

63. Gellman, *supra* note 3.

64. *Id.*

65. *See* Bombach, *supra* note 6, at 284; Charlotte Denny & James Meek, *Drug Giants Made to Swallow Bitter Pill: Global Opinion Won in South Africa, But Will it Triumph When the US Fights Brazil's Cheap Aids Medicine?*, The Guardian, Apr. 19, 2001, 2001 WL 19602587 (referring to "the big pharmaceutical companies' lack of financial transparency").

66. Nitya Nanda & Ritu Lodha, *Making Essential Medicines Affordable to the Poor*, 20 Wis. Int'l L.J. 581, 584, 592 (Figure 2) (2002) (citing 1989 figures).

67. Treatment Action Campaign, TAC's Questions and Answers on its Friends of the Court Status, *at* http://www.cptech.org/ip/health/sa/TACfoc.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review [hereinafter TAC Q&A].

68. *See* James Orbinski, *Health, Equity, and Trade: A Failure in Global Governance*, *in* The Role of the World Trade Organization in Global Governance 223, 226 (Gary P. Sampson ed., 2001) (noting that, according to Médecins Sans Frontières, the research for the majority of patented anti-retrovirals was publicly funded by the tax money of Europeans and Americans); Bombach, *supra* note 6, at 282 (noting that the American government holds the patent rights to many anti-retrovirals; pharmaceutical companies then purchase exclusive rights to market those drugs).

69. *See, e.g.*, Denny & Meek, 2001 WL 19602587, *supra* note 65. The pharmaceutical companies have also been criticized for advancing this defense when they spend "disproportionate" amounts of money on the marketing and researching of drugs for the "lifestyle problems" of the developing world. *Id.*

incentives for research.[70] They point out that since most people cannot afford the high-priced brand-name drugs, profits from selling drugs in developing countries are relatively miniscule.[71] While seven industrialized nations account for eighty percent of total revenues from drug sales, the entire continent of Africa only accounts for one percent.[72] Thus, commentators conclude that Africa is not a major factor in the R&D of the multinational drug companies.[73]

Supporters of generic competition also argue that compulsory licensing may ultimately *increase* revenues for patent holders by generating higher sales levels, since more people will be able to afford the previously prohibitively expensive drugs.[74] Furthermore, compulsory licensing provides patent holders with revenue in the form of royalties, since generic producers that are granted compulsory licenses must typically pay the patent holder royalties.[75]

Even assuming that generic competition reduces the incentives to invest in R&D, as one commentator argues, "it does not [necessarily] follow that . . . [this] will lead to a significant reduction from present levels of research or even that such a reduction would be socially undesirable."[76] Instead, Bailey argues that "the present incentives to invest are so strong that they would have to be weakened considerably before there would be any reduction in the amount of pharmaceutical research."[77] Furthermore, while agreeing that the R&D of new drugs is socially beneficial, Bailey argues that broad access to drugs is equally or more socially desirable.[78] Framing the conflict as one between "the relative value of extensive research and development" which leads to new drugs and "broad access to existing technology,"[79] Bailey concludes that the "compulsory licensing of HIV/AIDS drugs in developing countries contributes to a socially optimal balance between discovery and distribution."[80] TRIPS, which attempts to balance intellectual property rights with the public interest, appears to

70. *See, e.g.*, Bailey, *supra* note 35, at 215-16.

71. *See* Gellman, *supra* note 3.

72. *Id.* (citing data of IMS Health which "supplies market data to the industry"); *see also* Médecins Sans Frontières Access to Essential Medicines Campaign & The Drugs for Neglected Diseases Working Group, Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases 8 (2001) (stating that the developing world makes up 80% of the population but only purchases 20% of global sales), *available at* http://www.msf.org/source/access/2001/fatal/fatalshort.pdf [hereinafter Fatal Imbalance]; Bombach, *supra* note 6, at 283.

73. A related issue is the pharmaceutical industry's lack of R&D investment for neglected diseases, such as malaria and schistosomiasis, that afflict mostly the Third World. *See* Fatal Imbalance, *supra* note 72, at 10-11.

74. *See* Dolmo, *supra* note 12, at 160-61.

75. *See id.*; Bombach, *supra* note 6, at 285.

76. Bailey, *supra* note 35, at 216.

77. *Id.* at 215.

78. *See, e.g., id.* at 201.

79. *Id.*

80. *Id.* at 195.

support Bailey's conclusion, since it allows compulsory licensing under certain conditions.[81]

3. The International Framework for Intellectual Property: TRIPS

The national laws of each country govern patent protection domestically, including the practices of parallel importing and compulsory licensing.[82] Since 1994, however, the domestic laws of member states of the World Trade Organization ("WTO") must now conform to TRIPS, a WTO treaty that establishes minimum standards of copyright, trademark, and patent protection.[83] The pharmaceutical industry was instrumental in bringing about TRIPS.[84] "At the behest of the private sector," the U.S. government "engaged in extensive coercive economic diplomacy leading up to and during the [negotiation of TRIPS]."[85] For example, during the negotiation of TRIPS at the Uruguay Round of the General Agreement on Trade Tariffs, the developing and developed nations disagreed on several key issues.[86] The United States then threatened sanctions against those developing nations opposed to the agreement and exerted bilateral pressure for a strongly protectionist document.[87] As a result, the terms of TRIPS are widely perceived as favorable to developed countries and the large corporations that originate from them.[88]

The pharmaceutical industry was active not only in pushing for TRIPS, but also in the drafting of TRIPS itself, and was ultimately successful in its lobbying efforts for strong protectionist provisions.[89]

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81. *See* TRIPS, *supra* note 6, art. 31.

82. For example, the Patents Act, Act 57 of 1978 (S. Afr.), provides for patent protection in South Africa.

83. *See* TRIPS, *supra* note 6; Abdulqawi A. Yusuf, *TRIPS: Background, Principles and General Provisions*, *in* Intellectual Property and International Trade: The TRIPS Agreement 3, 13 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998). TRIPS also establishes enforcement standards for intellectual property protection, and provides a binding dispute-settlement procedure for conflicts. *See* TRIPS, *supra* note 6, Part III ("Enforcement of Intellectual Property Rights"), Part V ("Dispute Prevention and Settlement") of TRIPS, *supra* note 6; *see also* Curti, *supra* note 57, at 473-74 (describing TRIPS' dispute-resolution procedure).

84. *See* Sell, *supra* note 12, at 481, 484-89 ("If it had not been for the twelve American-based transnational corporations of the Intellectual Property Committee (IPC), there would be no Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) today.").

85. *Id.* at 489; *see also* Gathii, *supra* note 2, at 753-57.

86. Nash, *supra* note 10, at 485.

87. *Id.*; *see also* Gathii, *supra* note 2, at 757 ("The bilateral pressures of the United States . . . were critical in leveling opposition to TRIPS in the Uruguay Round."); Rein, *supra* note 2, at 393 (citing example of U.S. threats against Brazil).

88. *See* Gathii, *supra* note 2, at 761; Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 Wake Forest L. Rev. 89, 108-09 (1993).

89. Sell, *supra* note 12, at 484-89; Bombach, *supra* note 6, at 277-78, 290; Curti, *supra* note 57, at 473 (describing successful industry lobbying for favorable "pipeline protection").

Before TRIPS, countries were required only to afford foreign drug companies the same treatment that they provided their domestic companies.[90] Thus, some developing countries did not offer patent protection for drug products, allowing generic manufacturers to provide more affordable drugs than would have been possible if patents for drugs were required.[91] TRIPS requires that, for the first time, the developing countries that belong to the WTO provide patent protection to drug products.[92] As a result, many developing countries and their supporters argue that TRIPS' protections for the drug industry have impeded the developing world's efforts to cope with the HIV/AIDS epidemic.[93]

Nevertheless, TRIPS contains several provisions that provide developing countries with flexibility to address their HIV/AIDS epidemics.[94] Article 8(1), for example, provides a general public interest exception to TRIPS that allows member states "to adopt measures necessary to protect public health and nutrition, and to promote the public interest."[95] While Article 28 confers exclusive rights on the inventor to manufacture, use, sell, or import its invention,[96] Article 30 allows states some room to limit such exclusive rights and to take into account "the legitimate interests of third parties."[97]

Although TRIPS does not directly address parallel imports, Article 6 provides that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[98] According to one scholar, the "[e]xhaustion of rights doctrine holds

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90. *See* Gathii, *supra* note 2, at 760-61 (referring to the required protection as "the principle of national treatment"); Sell, *supra* note 12, at 481-82.

91. *See* Gathii, *supra* note 2, at 762; Rein, *supra* note 2, at 386; Sell, *supra* note 12, at 481-82.

92. Sell, *supra* note 12, at 481, 482 ; *see also* TRIPS, *supra* note 6, art. 27(1).

93. *See, e.g.*, Bass, *supra* note 11, at 193 ("The TRIPS Agreement as it stands now will hamper efforts to . . . [provide] access to essential new medicines at affordable prices.").

94. *See, e.g.*, TRIPS, *supra* note 6, art. 7.

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Id.; *see also* Gathii, *supra* note 2, at 729 (referring to the tension between the dual logics of TRIPS: the commodity logic and the public policy logic); Curti, *supra* note 57, at 469-72 (noting that TRIPS attempted to balance the promotion of innovation with the promotion of the public interest).

95. *See* TRIPS, *supra* note 6, art. 8(1).

96. *See id.* art. 28.

97. *See id.* art. 30; *see also* Curti, *supra* note 57, at 479-86 (discussing use of article 30 of TRIPS for compulsory licensing in detail).

98. TRIPS, *supra* note 6, art. 6. While Article 28(1)(a) grants the patentee the exclusive right of importing its product, a footnote to that Article references Article 6. *Id.* art. 28(1)(a) n.6.

that once a rights holder introduces protected goods into the stream of commerce, there is no restriction on how the goods may be further distributed."[99] Developing countries and their supporters argue that, by leaving exhaustion to the discretion of the WTO member states, TRIPS allows states to determine that a patent holder loses the exclusive right to import goods after the first sale of the patented goods; as such, TRIPS sanctions parallel importing.[100] The drug industry opposes parallel importing and has lobbied the U.S. government to punish countries that allow parallel importing.[101]

Article 31 of TRIPS allows for domestic legislation permitting compulsory licensing, subject to eight conditions, including "adequate remuneration" to the patent holder.[102] Many countries regularly engage in compulsory licensing, which is legal under several American laws.[103] TRIPS specifies five grounds for granting compulsory licenses, including a "national emergency or other circumstances of extreme urgency."[104] In the case of a national emergency, TRIPS relaxes the conditions for issuing compulsory licenses by waiving the requirement that countries attempt to get permission from the patent holder.[105] Nevertheless, TRIPS fails to define what constitutes a national emergency.[106] Commentators argue that TRIPS does not limit compulsory licenses to those grounds specified in Article 31.[107] As a result, they argue, member states may issue compulsory licenses on other grounds consistent with the public interest exceptions found

99. Rein, *supra* note 2, at 384; *see also* Bombach, *supra* note 6, at 278.

100. *See* Carlos M. Correa, *Patent Rights*, *in* Intellectual Property and International Trade: The TRIPS Agreement, *supra* note 83, at 189, 204-05; Gathii, *supra* note 2, at 764; Nash, *supra* note 10, at 491 (noting that "the issue of parallel importation [is] . . . an entirely domestic legal concern"); Bombach, *supra* note 6, at 289-90. *But see* Dolmo, *supra* note 12, at 142 (interpreting TRIPS to bar parallel importing without the permission of the patent holder); Sweeney, *supra* note 10, at 455-56 (interpreting TRIPS as ambiguous on parallel importing).

101. *See* Submission of PhRMA for the "Special 301" Report on Intellectual Property Barriers: Priority Watch List Country: South Africa (Pharmaceutical Research and Manufacturers of America 2002) ("[W]idespread parallel importation would pose a serious threat to the viability of American pharmaceutical investment in South Africa."), http://www.phrma.org/international/special301/safrica.cfm (last visited Nov. 9, 2002) (on file with the Fordham Law Review) [hereinafter PhRMA Special 301 Submission: South Africa].

102. TRIPS, *supra* note 6, art. 31; *see also* Correa, *supra* note 100, at 208-16.

103. Dolmo, *supra* note 12, at 144 (accusing the United States of "bad faith" for opposing South Africa's trade practices). Under the Bayh-Dole Act, the U.S. government has permission to issue compulsory licenses for public health purposes and the U.S. government regularly issues such licenses for several products. *Id.* at 146; *see also* Matthew Kramer, Comment, *The Bolar Amendment Abroad: Preserving the Integrity of American Patents Overseas After the South African Medicines Act*, 18 Dick. J. Int'l L. 553, 563-64 (2000) (indicating assertions that Hatch-Waxman Act allowing special exception for pharmaceuticals may violate TRIPS).

104. TRIPS, *supra* note 6, art. 31(b); *see also* Correa, *supra* note 100, at 210.

105. TRIPS, *supra* note 6, art. 31(b).

106. *Id.*

107. *See, e.g.*, Correa, *supra* note 100, at 210; Nash, *supra* note 10, at 489.

in other TRIPS provisions.[108]

The pharmaceutical industry and the United States consistently challenge laws designed to make HIV/AIDS drugs more affordable as violations of TRIPS.[109] Developing nations that have passed laws to make HIV/AIDS drugs more widely available argue that such laws are valid under TRIPS' public interest exceptions.[110] Their supporters also endorse a flexible approach to TRIPS for developing nations seeking to promote public health goals, asserting that TRIPS allows compulsory licensing.[111]

The drug companies and the U.S. government have consistently pushed for "TRIPS-plus" patent protection, forcing developing countries to provide greater protection than the minimum standards that TRIPS requires.[112] Under 19 U.S.C. § 2411, for example, the United States Trade Representative has the discretion to sanction countries for an "act, policy, or practice . . . which (i) denies fair and equitable . . . provision of adequate and effective protection of intellectual property rights *notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights.*"[113] Critics accuse the United States of hypocrisy, since several of its national laws allow parallel importing and compulsory licensing.[114] Critics point out, for example, that during the anthrax scare following the September 11, 2001 terrorist attacks in America, the U.S. government considered the compulsory licensing of Cipro, an anthrax antibiotic.[115] Although, ultimately, the United States did not issue compulsory licenses for Cipro, the U.S. government has been accused of using the threat of compulsory licensing as leverage to negotiate favorable terms from Bayer, Cipro's patent holder.[116]

At a conference in Doha, Qatar in November 2001, the WTO's Ministerial Council issued a declaration agreeing with the developing countries' interpretation of TRIPS as allowing developing countries to

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108. *See* Correa, *supra* note 100, at 210; Nash, *supra* note 10, at 489.

109. *See* Bombach, *supra* note 6, at 280 (describing policy "to pressure countries to provide patent protection stronger than that afforded by the TRIPS Agreement").

110. *See* Bass, *supra* note 11, at 199-200 (stating that developing countries adopt a broad interpretation of TRIPS' "concessions").

111. *See, e.g.*, Sources & Prices, *supra* note 3, at 7 ("[I]ntellectual property standards . . . should take protection of public health into account. . . . Developing countries can therefore use the flexibility of TRIPS provisions and its safeguards to protect public health. This means that, under certain conditions, the TRIPS Agreement enables governments to authorize the use . . . of patented drugs against the will of the patent owner.").

112. Sell, *supra* note 12, at 482.

113. 19 U.S.C. §§ 2411(d)(3)(b), 2411(b) (2000) (emphasis added).

114. *See* Kramer, *supra* note 103, at 563-64.

115. *See* Sell, *supra* note 12, at 495; Denise Gellene, *Anthrax Cases Reshape Drug Price Debate*, L.A. Times, Nov. 9, 2001, at C1 .

116. Sell, *supra* note 12, at 515-16.

take various measures to make HIV/AIDS drugs more affordable.[117] Specifically, the Doha Declaration asserted that developing countries have "the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted,"[118] to define the HIV/AIDS epidemic as a national emergency,[119] and to utilize parallel importing of drugs.[120] Although developing countries pushed for a legally binding interpretation of TRIPS, the Doha Declaration is a ministerial declaration and does not supercede TRIPS.[121] The status of the Doha Declaration is unclear, and interpretations of its import range from that of a "political statement" to that of "persuasive authority in the interpretation of TRIPS in the event of a dispute."[122]

B. *Case Study: The Battle over South Africa's Medicines Act Amendment*

The issues at stake in the debate over developing countries' efforts to make HIV/AIDS drugs more affordable are well-illustrated by South Africa's attempts to widen access to HIV/AIDS drugs and by the lawsuit that the drug industry brought against the government to challenge that law.[123] The post-apartheid Constitution guarantees

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117. *See* Declaration on the TRIPS Agreement and Public Health, para. 4, WT/MIN(01)/DEC/2 (Nov. 20, 2001) (asserting that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to . . . promote access to medicines for all"), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf [hereinafter Doha Declaration].

118. *Id.* para. 5(b).

119. *Id.* para. 5(c) ("Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS . . . can represent a national emergency or other circumstances of extreme urgency.").

120. *Id.* para. 5(d) ("The effect of the provisions in the TRIPS Agreement . . . [on] the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge.").

121. Sell, *supra* note 12, at 517-18; Alan O. Sykes, *Trips, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 Chi. J. Int'l L. 47, 54 (2002) (stating that "ministerial declarations within the WTO are not legally binding in the dispute resolution process, and in the event of a dispute the language of the treaties as approved by national governments would prevail over any contradictory declaration by the ministers").

122. *See* Sell, *supra* note 12, at 517-18 (citation omitted); Sykes, *supra* note 121, at 54.

123. First, the HIV/AIDS crisis in South Africa has reached astronomical proportions, and UNAIDS estimates that the devastating impact of AIDS has reduced the average life expectancy in South Africa from sixty-six to forty-seven years. *See* UNAIDS Update, *supra* note 1, at 8, 16-18. Second, the overwhelming majority of South Africans lack effective access to HIV/AIDS drugs: only one percent of HIV-infected South Africans can afford potentially life-prolonging treatment. *See* Philipkoski, *supra* note 4. As of October 2001, only 20,000 South Africans were being treated with anti-retrovirals. Treatment Action Campaign, Bredell Consensus Statement on the Imperative to Expand Access to Anti-Retroviral (ART) Medicines for Adults and Children with HIV/AIDS in South [Africa] (released Nov. 19, 2001),

South Africans the right to health care.[124] To meet its constitutional duty, South Africa adopted a national policy of promoting access to essential drugs.[125] To further that policy, in 1997, the South African Parliament passed the Medicines Act Amendment, granting the Minister of Health broad power to ensure access to affordable drugs.[126]

1. The Legal Challenge: The Contours of South Africa's Law

Among other provisions to make HIV/AIDS drugs more affordable, the new law authorizes the Minister of Health to adopt regulations requiring pharmacists to prescribe generic versions of drugs.[127] The amendment further authorizes the Minister to create a pricing committee empowered to recommend a transparent pricing system for medicines.[128] This provision would force pharmaceutical companies to justify the prices they charge and prevent pharmacists from over-pricing drugs.[129]

The most controversial provision of the amendment is section 10, which provides,

> The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may—
>
> *(a)* notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any 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;
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> *(b)* prescribe the conditions on which any medicine which is

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available at www.tac.org.za/Documents/ Statements/bredell3.pdf. Third, the pharmaceutical companies' opposition to South Africa's attempts to make HIV/AIDS drugs affordable took the drastic form of a lawsuit and was particularly well-documented. *See* sources *infra* note 181.

124. *See* S. Afr. Const. ch. II, § 27 ("Everyone has the right to have access to . . . health care services, including reproductive health care. . . . The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.").

125. *See* National Drug Policy for South Africa (1996), *available at* http://196.36.153.56/doh/docs/policy/drugsjan1996.pdf.

126. *See* Medicines Act Amendment, *supra* note 10, §§ 10, 14.

127. *Id.* § 14 (inserting section 22F into original Medicines Act); *see also* Statement, Treatment Action Campaign, An Explanation of the Medicines Act Amendment and the Implications of the Court Victory (Apr. 24, 2001) (describing generic substitution), http://www.tac.org.za/newsletter/ns010424.txt (last visited Nov. 5, 2002) (on file with the Fordham Law Review) [hereinafter TAC Statement].

128. Medicines Act Amendment, *supra* note 10, § 14 (inserting section 22G into original Medicines Act).

129. *See* TAC Statement, *supra* note 127.

> 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;
>
> *(c)* prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph *(b)*.[130]

There has been considerable debate over the scope of the Health Minister's powers and the precise meaning of the provisions of section 10.[131] On the one hand, South Africa intended the law only to provide for parallel importing and generic substitution.[132] The pharmaceutical industry, on the other hand, interpreted the amendment to give the government much broader power.[133] According to the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the law appears to allow the Minister of Health to revoke pharmaceutical patents in violation of South African law and TRIPS.[134] Considering the amendment a violation of both the South African Constitution and TRIPS, the industry brought suit against the South African government.[135]

The drug industry attacked the law as unconstitutional because it interpreted Section 10 to give the Minister of Health overly broad powers of implementation, thereby effectively allowing her to deprive the drug companies of their constitutional right to property.[136] The drug industry also specifically attacked the constitutionality of, among other provisions, the law's sections providing for generic drug substitution[137] and a drug pricing committee.[138] The South African

130. Medicines Act Amendment, *supra* note 10, § 10 (inserting section 15C into original Medicines Act).

131. *See infra* text accompanying notes 132-57.

132. *See* Posting of James Love, love@cptech.org, to pharm-policy@lists.essential.org, Report on Court Case Over South Africa Medicines [Act] (Mar. 4, 2001), *at* http://lists.essential.org/pipermail/pharm-policy/2001-March/000740.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review) [hereinafter Court Case Report].

133. *See* PhRMA Special 301 Submission: South Africa, *supra* note 101.

134. *Id.*

135. *See* Notice of Motion, *supra* note 13.

136. *See id.*, *supra* note 13, para. 4.3; *see also id.* paras. 2.1-2.3, 4.1, 7; Court Case Report, *supra* note 132.

137. *See* Notice of Motion, *supra* note 13, paras. 4.1-4.5; Posting of James Love, love@cptech.org, to pharm-policy@lists.essential.org (Mar. 5, 2001), March 5, 1st Day of the Medicines Act Trial, *at* http://lists.essential.org/pipermail/pharm-policy/2001-March/000744.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review) [hereinafter Trial First Day].

138. *See* Notice of Motion, http://www.cptech.org/ip/health/sa/pharmasuit.html, *supra* note 13, paras. 5.1, 5.2.

government argued that it has an express constitutional duty to provide health care to its citizens, and that the Medicines Act Amendment is critical to meeting that duty.[139] As an adviser to the South African government during the lawsuit framed the government's stance, "[t]he South African government is defending its right to establish its own health care policy within the limits established by international law."[140]

The drug industry claimed that the South African law violated TRIPS on several grounds. In their complaint, the drug companies asserted that the law was inconsistent with Article 27 of TRIPS, because it discriminated against drug patents by providing lesser protections for drugs than for other inventions.[141] The industry further argued that, as written, the law delegated broad powers to the Minister of Health that would enable her to import generic versions of patented drugs, as well as to issue compulsory licenses for the local manufacture of generics under conditions beyond those that TRIPS specifies.[142] Outside the courtroom, the industry also leveled broader challenges to the law's validity under TRIPS, claiming, for example, that the amendment violated Article 28 of TRIPS by allowing parallel importing.[143]

Prior to the passage of the Medicines Act Amendment, South Africa already had limited power to issue compulsory licenses under the Patents Act of 1978.[144] Thus, the South African government

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139. *See AIDS Drugs Case Adjourned*, *supra* note 4. In a thoughtful analysis of the application of South Africa's constitutionally guaranteed socioeconomic rights to private actors, one scholar concludes that "the terrible force of the patients' rights at stake in the context of AIDS drug prices, and the links pharmaceutical companies' power has to the state, suggest that these companies might rightly be found to have a constitutional duty to provide access to their drugs." Stephen Ellmann, *A Constitutional Confluence: American "State Action" Law and the Application of South Africa's Socioeconomic Rights Guarantees to Private Actors*, 45 N.Y.L. Sch. L. Rev. 21, 53-61, 74 (2001).

140. Philipkoski, *supra* note 4.

141. Notice of Motion, *supra* note 13, para. 2.4.

142. *See* Nash, *supra* note 10, at 493 (asserting that the drug industry believed the Medicines Act Amendment was inconsistent with TRIPS because it empowered the Minister of Health with broad discretion to grant licenses under conditions beyond those specified in TRIPS); David Pilling & Nicol Degli Innocenti, *Drug Companies Still Seeking Patents Law Deal*, Fin. Times, Apr. 19, 2001, at 10 (describing drug companies as asserting that "clause 15c of the 1997 legislation would, if passed, give the health minister sweeping powers to buy or import the cheapest drugs available, overriding existing patents without due process"); *see also* Trial First Day, *supra* note 137; Court Case Report, *supra* note 132.

143. Pharmaceutical Research Manufacturers of America, Watch List: South Africa (Feb. 18, 2000) (PhRMA's "Special 301" Submission for 2000) ("Furthermore, the new law, at 15C(b) allows for the parallel importation, a violation of TRIPS Article 28."), http://www.cptech.org/ip/health/phrma/301-00/safrica.html (last visited Nov. 9, 2002) (on file with the Fordham Law Review).

144. *See* Patents Act, Act 57 of 1978, §§ 4, 56 (S. Afr.). Section 4 provides that,

> [A] Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of

argued that its existing Patents Act already provided for compulsory licensing,[145] that the amendment was not designed to permit compulsory licensing, and that the government only intended to use the law for parallel importing.[146] South Africa appears to have kept its promise, since in the proposed regulations that the government later issued pursuant to the amended law, the government only provided for parallel importing.[147] In response to the claim that the law's breadth allowed for practices beyond those specified under TRIPS, the government argued that the law complied with TRIPS.[148] Some scholars agreed with South Africa, arguing that "[s]o long as the Minister of Health interprets the Act within the context of TRIPS, and abides by the conditions described in Article 31, any activity taken under the Act's compulsory licensing provision is valid under international law."[149]

The debate over the law's validity under TRIPS spilled out of the courtroom and into the global community, and was taken up by scholars, activists, government officials, and multilateral organizations.[150] The U.S. government initially adopted the industry's stance, opposing the law because it was "potentially" in violation of

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agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee.

Id. § 4.

145. Court Case Report, *supra* note 132.

146. Press Release, S. Afr., Medicines Control Act Regulations Ready for Public Comment (June 4, 2001) ("There is a common misperception that the Medicines Control Amendment Act deals with the importation or manufacture of generic alternatives to drugs that are still patent-protected in South Africa."), *at* http://196.36.153.56/doh/docs/pr/ (last visited Nov. 9, 2002) (on file with the Fordham Law Review) [hereinafter South Africa Regulations Press Release]; *see also* Trial First Day, *supra* note 137; Court Case Report, *supra* note 132. At least one generic manufacturer, Cipla, has applied to South Africa for compulsory licenses to produce HIV/AIDS drugs, claiming that the patent-owners have "abused their dominance" by "charg[ing] an exorbitant price . . . to the detriment of consumers." Posting of James Love, love@cptech.org, to ip-health@lists.essential.org, CIPLA-Medpro Complaint to RSA Competition Commission (reproducing Complaint to the Competition Commission by Cipla-Medro (PTY) Limited) (Oct. 8, 2001), *at* http://lists.essential.org/pipermail/ip-health/2001-October/002026.html (last visited Nov. 9, 2002) (on file with Fordham Law Review).

147. *See* South Africa Regulations Press Release, *supra* note 146; *see also* Posting of James Love, love@cptech.org, to ip-health@lists.essential.org, South Africa Proposes New Parallel Import Regs, But No New Comp[ul]sory Licensing [Procedures] (June 9, 2001) (noting that the government dropped an earlier proposal to include provisions for compulsory licenses), *at* http://lists.essential.org/pipermail/ip-health/2001-June/ 001423.html (last visited Nov. 9, 2002) (on file with the Fordham Law Review).

148. *See* Pilling & Innocenti, *supra* note 142 (stating that the South African government has "consistently argued" that Section 15(c) complies with TRIPS); Denny & Meek, *supra* note 65.

149. *See, e.g.*, Nash, *supra* note 10, at 493-94.

150. *See, e.g.*, *id.* (discussing the law's validity); Larkin Report, http://www.cptech.org/ip/health/sa/stdept-feb51999.html, *supra* note 12 (discussing U.S. involvement).

TRIPS, was overly broad, and gave the Minister of Health excessive power.[151] Consistent with its TRIPS-plus policy, the U.S. repeatedly sought assurances from South Africa that the Medicines Act Amendment would not be implemented to allow parallel imports or compulsory licensing of pharmaceuticals.[152] According to a group of organizations that met with representatives of the U.S. government, however, the United States failed to articulate the precise TRIPS provisions it believed that South Africa's law violated.[153]

Supporters of the legislation argue that it is valid under TRIPS' exceptions for public policy decisions, such as Article 8, which allows "measures necessary to protect public health."[154] Other advocates of the amendment argue that the AIDS epidemic in South Africa falls within the TRIPS definition of a national health emergency, and is valid under that provision.[155] The general consensus is that the Medicines Act Amendment is valid, so long as South Africa complies with the provisions of TRIPS in its *implementation*.[156] Notably, the drug companies eventually dropped their claim that the Medicines Act Amendment violated TRIPS and limited themselves to challenging the law on constitutional grounds.[157]

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151. *See* Larkin Report, *supra* note 12; Press Statement, Aids Law Project, Meeting with Representatives of the Government of the United States of America (Aug. 4, 1999), *at* http://wwwserver.law.wits.ac.za/cals/OLDalp/press/gore-press.shtml (last visited Nov. 5, 2002) (on file with the Fordham Law Review) [hereinafter U.S Meeting Press Release].

152. Larkin Report, *supra* note 12.

153. U.S. Meeting Press Release, *supra* note 151 (stating that when questioned during a meeting, the U.S. government failed to indicate exactly how Section 15(c) of Medicines Act violates international trade laws). Notably, the United States did not use the WTO dispute-resolution mechanism TRIPS provides to challenge South Africa's law, leading commentators to speculate that the United States feared a decision for South Africa. *See* Bombach, *supra* note 6, at 281; Dolmo, *supra* note 12, at 146 (noting that the United States failed to challenge South Africa's practices under the WTO dispute-resolution mechanisms and speculating that the United States realized that South Africa's practices were consistent with WTO rules).

154. Nash, *supra* note 10, at 489.

155. Denny & Meek, *supra* note 65 (noting that, in South Africa, "campaigners argued that the [HIV/AIDS] crisis was an emergency" under the TRIPS definition).

156. *See, e.g.*, Nash, *supra* note 10, at 493-94, 501 (noting that "[g]iven its ambiguous wording, *implementation* of the Act may or may not comply with South Africa's obligations under TRIPS") (emphasis added); Bombach, *supra* note 6, at 275 (concluding that "the use of compulsory licensing and parallel imports provided for in the Bill are consistent with international law obligations, and in particular with the TRIPS Agreement").

157. *See* Ghosh, *supra* note 49, at 814-15; *Drug Companies Drop S. Africa Suit*, CNN.com, Apr. 19, 2001, *at* http://www.cnn.com/2001/WORLD/africa/04/18/safrica.drugs.03/index.html (last visited Nov. 9, 2002) (on file with the Fordham Law Review).

2. Outside the Courtroom: The Drug Companies' Campaigns

While pursuing their lawsuit against South Africa, the pharmaceutical companies began to offer drugs at discounted prices and to make drug donations of their expensive HIV/AIDS drugs to South Africa and other developing countries.[158] GlaxoSmithKline, for example, announced that it would not enforce its patent on its HIV/AIDS drug, Zerit, in South Africa.[159] In October 2001, GlaxoSmithKline also voluntarily granted a local South African drug manufacturer a license to produce and market generic versions of three of its HIV/AIDS drugs.[160] The industry claims that its "programs to improve public health . . . are some of the most effective."[161] In 2000, the drug industry came together under the aegis of the U.N. to coordinate direct negotiations, for discounted drugs, between the drug companies and the governments of participating nations.[162] Critics, however, have labeled this U.N. initiative a "public relations gimmick."[163]

Activists have also criticized the drug companies' independent initiatives as flawed, inadequate, and unsuccessful.[164] The fatal problems with these programs, activists argue, are that they are of limited geographical scope and duration, reach a miniscule percentage of the twenty-five million HIV-positive people in need of drugs, and depend on the goodwill of the companies offering them.[165] The programs' critics claim that even at reduced prices, patented drugs still remain unaffordable to the majority of HIV/AIDS sufferers in the developing world, particularly to those most in need of treatment.[166]

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158. *See* Bristol-Myers Squibb Co., Secure the Future: Care and Support for Women and Children with HIV/AIDS (2001), *available at* http://www.securethefuture.com/; Untangling the Web, *supra* note 29, at 8; Pharmaceutical Research and Manufacturers of America, Global Partnerships: Humanitarian Programs of the Pharmaceutical Industry in Developing Nations (2000), *available at* www.world.phrma.org [hereinafter PhRMA Global Partnerships]; Sources & Prices, *supra* note 3, at 30-31.

159. *See* PhRMA Global Partnerships, *supra* note 158, at 16.

160. *See GlaxoSmithKline is First South African HIV/AIDS Generic Drugs License Deal*, Marketletter, Oct. 14, 2001, 2001 WL 9081276.

161. PhRMA Global Partnerships, *supra* note 158, at 6 (claiming that a World Bank report supports this assertion).

162. Sources & Prices, *supra* note 3, at 5, 16; Gellman, *supra* note 3 (listing the five companies involved in the initiative as Bristol-Meyers Squibb, Merck, Boehringer Ingelheim, Hoffman-La Roche, and Glaxo Wellcome).

163. *See* Gathii, *supra* note 2, at 769.

164. *See, e.g.*, Gellman, *supra* note 3 (quoting World Bank economist characterizing the programs as "expensive boutiques . . . available to a lucky few").

165. *See id.*; International Gay and Lesbian Human Rights Commission, *Pfizer Betrays Promises, Puts Profits Before People: "Drug Donation" Scheme a Scam*, June 23, 2000, *at* http://www.iglhrc.org/world/africa/ SouthAfrica2000Jun.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review); TAC Statement, *supra* note 127.

166. *See* Csete, *supra* note 10, at 265 (noting that, even at reduced prices,

Skeptics also suggest that drug companies are cutting their prices so that they can argue that generic versions of drugs are unnecessary and thereby preserve their patent rights.[167] According to one commentator, "maximal effective access to HIV/AIDS drugs depends on adequate supply at near-production-cost prices which arguably are not, and will not, be provided by pharmaceutical firms bearing patent-based monopolies in these drugs because such behavior would not maximize profits for these firms."[168] As a result, many activists see generic competition as superior to the drug companies' voluntary programs.[169]

While pursuing these programs, however, the drug industry, one of the largest lobbyists in the United States, simultaneously lobbied the U.S. government to exert pressure on South Africa to change or repeal its law.[170] As a result, high-ranking U.S. officials met repeatedly with South African representatives to express the U.S. government's condemnation of the law and to request its repeal, Vice President Al Gore personally lobbied South African officials for the repeal of the law, and the U.S. Congress threatened to withhold foreign aid.[171] Also as a direct result of the influence of the American pharmaceutical industry, the U.S. government placed South Africa on a "Special 301 Watchlist," sanctioned South Africa by denying it trade privileges under the Generalized System of Preferences, and later conducted a Section 301 investigation.[172] The United States eventually reached a bilateral understanding with South Africa in

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HIV/AIDS drugs remain too expensive for poor countries); Gellman, *supra* note 3 (stating that interviews and examination of records "suggest that nothing fundamental has changed in the calculus of access to AIDS treatment").

167. *See* Pollack, *supra* note 6.

168. Bailey, *supra* note 35, at 209.

169. *See* Pollack, *supra* note 6.

170. Sell, *supra* note 12, at 501-02 ("At PhRMA's behest, the U.S. government threw its full weight behind the South African case to press South Africa to revoke the offending provisions of its law."). One American pharmaceutical company also threatened to withdraw all of its operations from South Africa. 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, 177 (1999).

171. Sell, *supra* note 12, at 501-02; Dolmo, *supra* note 12, at 151; Marcus Mabry, *Give Us This Day Our Daily Meds*, Newsweek Int'l, July 5, 1999, 1999 WL 8074144; *see also* Larkin Report, *supra* note 12.

172. *See* Larkin Report, *supra* note 12. Under the amended Trade Act of 1974, the United States must identify countries without effective patent protection for U.S. intellectual property. United States Trade Representative, Special 301 Report 13-14 (2001), *available at* http://www.ustr.gov/enforcement/special.pdf. Those countries with the most inadequate protection are published in the Federal Register as "Priority Foreign Countries;" the United States also publishes a "priority watch list" and "watch list" of countries. *Id.* at 16-32. Under "Special 301," the U.S. typically conducts investigations of intellectual property protection in those countries identified as a "Priority Foreign Country." *Id.* at 14.

December 1999.[173]

The controversy between South Africa and the multinational pharmaceuticals was highly publicized in the international media and sparked domestic and international discussion and mobilization.[174] Several international institutions, including the U.N., the World Health Assembly ("WHA") and the European Parliament, supported South Africa's efforts to make drugs affordable.[175] The WHA, for example, passed a resolution declaring that public health concerns are "paramount" to intellectual property rights.[176] Public opinion was overwhelmingly against the pharmaceutical companies, as people understood the drug industry's actions to be a choice of patents and profits over lives.[177]

In April 2001, after widespread negative publicity, the drug companies withdrew their lawsuit and reached an out-of-court settlement with South Africa.[178] The companies agreed to cooperate

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173. *See* Posting of James Love, love@cptech.org, to pharm-policy.essential.org, Press Statement, S. Afr. Dep't of Trade and Industry, Joint Understanding Between the Governments of South Africa and the United States of America (Sept. 17, 1999), *at* http://lists.essential.org/pharm-policy/msg00244.html (last visited Nov. 5, 2002) (on file with the Fordham Law Review). South Africa assured the United States that "in the implementation of provisions of the Medicines Act . . . it will honour its obligations under the TRIPS Agreement." *Id.* Subsequently, in May 2000, President Clinton issued an Executive Order asserting that the United States would not challenge the policies of sub-Saharan African countries to increase access to HIV/AIDS medications, as long as they complied with TRIPS. *See* Gathii, *supra* note 2, at 750.

174. *See, e.g.*, *AIDS Drug Battle Ends*, *supra* note 14 (noting opposition by public and human rights advocates to the drug companies' policies); *AIDS Drugs Case Adjourned*, *supra* note 4 (citing former South African President Nelson Mandela's criticism of the companies as exploitive for using the lawsuit to protect their profits); Denny & Meek, *supra* note 65 (describing how "[i]nternational public opinion and a worldwide web of activists" played a role in changing the corporations' minds).

175. *See* Pollack, *supra* note 6; Posting of UNAIDS, to treatment-access@hivnet.ch Press Statement, UNAIDS, UNAIDS Welcomes Outcome of South African Court Case (Apr. 19, 2001) (indicating that "UNAIDS has consistently supported" the intent of the Medicines Act Amendment), *at* http://www.hivnet.ch:8000/topics/treatment-access/ (last visited Nov. 5, 2002) (on file with the Fordham Law Review) [hereinafter UNAIDS Welcomes Outcome].

176. *See* Dolmo, *supra* note 12, at 143 (attributing WHA resolution to lobbying by public health and consumer interest groups).

177. *See, e.g.*, Pilling & Innocenti, *supra* note 142 (noting that "public opinion turned against" the drug companies); *AIDS Drug Battle Ends*, *supra* note 14 (noting opposition by public and human rights advocates); *AIDS Drugs Case Adjourned*, *supra* note 4 (citing an Oxfam executive referring to this as the "'Vietnam of the drug industry'"); Denny & Meek, 2001 WL 19602587, *supra* note 65 ("[T]he public perception was that the companies were more interested in protecting their intellectual property rights than in the health crisis in the continent.").

178. *See* In the Matter Between: The Pharmaceutical Manufacturers' Association of South Africa et al., and the President of the Republic of South Africa et al., Joint Statement of Understanding Between the Republic of South Africa and the Applicants (Apr. 19, 2001), *available at* www.canadapharma.org/Media_Centre/News_Releases/2001/JointStatementIndustrySAGovt-April19-01_e.pdf (last visited Nov. 9, 2002) [hereinafter Drug Company Settlement]; *see also* Dolmo, *supra* note 12,

with South Africa to provide HIV/AIDS drugs at lower costs, and South Africa agreed both to honor TRIPS and to consult with the pharmaceutical industry on the proposed amendment.[179] While PhRMA claims that the legal challenge was dropped because the South African Minister of Health promised to redraft the law,[180] many commentators attribute the resolution of the legal challenge to the negative publicity that surrounded the lawsuit.[181] Across the globe, many people and organizations welcomed the end of the litigation,[182] which has been characterized as "one of the great corporate PR disasters of all time."[183]

Although the South African lawsuit was resolved and some programs have been implemented to provide wider access to HIV/AIDS drugs in developing countries,[184] HIV/AIDS drugs still remain unaffordable to the majority of HIV-infected people in developing countries.[185] The drug donations and discounts offered by pharmaceutical companies are not permanent solutions to the lack of affordable HIV/AIDS drugs.[186] Moreover, the pharmaceutical corporations and the American government continue to exert their substantial influence to prevent developing countries from implementing laws like South Africa's Medicines Act Amendment.[187] For example, the pharmaceutical industry recently opposed the enactment of Kenyan legislation that would allow compulsory licensing and parallel importing to make HIV/AIDS drugs cheaper.[188] Despite enacting laws permitting compulsory licensing, developing

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at 145; *AIDS Drug Battle Ends*, *supra* note 14.

179. *See* Drug Company Settlement, *supra* note 178; *see also* Dolmo, *supra* note 12, at 145 (stating that the settlement was perceived as considering industry "as a partner rather than [as] an antagonist").

180. *See* Gumisai Mutume, *Trade: U.S. Drug Companies Ease Up on South Africa*, Inter Press Service, Sept. 12, 1999, 1999 WL 27373954.

181. *See, e.g.*, Curti, *supra* note 57, at 477; Pilling & Innocenti, *supra* note 142 ("Cast in the role of villains . . . pharmaceutical companies have opted for damage limitation."); Rachel L. Swarns, *Drug Makers Drop South Africa Suit Over AIDS Medicine*, N.Y. Times, Apr. 20, 2001, at A1 (stating that, by dropping the lawsuit, the drug industry was "[b]owing to mounting public pressure"); Denny & Meek, 2001, *supra* note 65; *Drug Companies Drop S. Africa Suit*, *supra* note 157 (characterizing the withdrawal of the lawsuit as "the end of a public relations disaster").

182. *See, e.g.*, UNAIDS Welcomes Outcome, *supra* note 175 (stating that UNAIDS further recommended that other countries enact similar legislation to make HIV/AIDS drugs more affordable).

183. Denny & Meek, *supra* note 65.

184. *See* Drug Company Settlement, *supra* note 178; *see also supra* notes 158-62 and accompanying text (discussing drug companies' humanitarian programs).

185. *See* Csete, *supra* note 10, at 265; Gellman, *supra* note 3.

186. *See supra* notes 163-69 and accompanying text (discussing the flaws of the drug industry's humanitarian programs).

187. *See, e.g.*, Samuel Siringi, *Generic Drugs Battle Moves from South Africa to Kenya*, The Lancet, May 19, 2001, 2001 WL 10158786.

188. *See id.* (noting that "officials from the main pharmaceutical companies have been lobbying government ministers and committees involved in drafting the Bill").

countries are reluctant to follow through and issue compulsory licenses for HIV/AIDS drugs because of pressure from the pharmaceutical industry and the American government it lobbies.[189] Thus, developing nations continue to struggle with the problem of ensuring affordable HIV/AIDS drugs to their populations, while the pharmaceutical industry and the United States continue to challenge their efforts, arguing that these efforts undermine intellectual property rights and international obligations under TRIPS.[190]

II. ACCESS TO HIV/AIDS DRUGS & HUMAN RIGHTS

At stake in the debate over measures to increase access to HIV/AIDS drugs are not only the intellectual property rights of drug companies, but also the human rights of those people in developing countries infected with HIV/AIDS who cannot afford high-priced patented drugs.[191] Thus, scholars and human rights activists argue that TRIPS is being interpreted and implemented in violation of the rights to life and health.[192] Activists and commentators further argue that donor nations are violating their duties, under international law, to engage in international cooperation to protect the human right to health.[193] One commentator suggests that developed nations also may violate human rights by failing to prevent those multinational drug companies in their jurisdictions from impeding the efforts of developing nations to fulfill their human rights obligations to ensure access to HIV/AIDS drugs.[194]

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189. *See* Pollack, *supra* note 6; Human Rights Watch, WTO Summit: Don't Undercut AIDS Drug Access (Nov. 7, 2001) (noting that, while developed countries have used compulsory licensing, "no low-income developing country has succeeded in obtaining a compulsory license for generic AIDS drugs" and that "[t]he United Nation's Development Programme's 'Human Development Report 2001' attributes this disparity to threats from Europe and the United States"), *at* http://www.hrw.org/press/2001/11/wto-aids1107.htm (last visited Nov. 9, 2002) (on file with the Fordham Law Review).

190. *See, e.g.*, Sell, *supra* note 12, at 495 (noting that, in sanctioning Argentina, "the USTR 'admitted that it had decided to enforce these patent law related sanctions based entirely on information and data supplied by PhRMA'" (citations omitted)).

191. *See, e.g.*, Sam Ricketson, *Intellectual Property and Human Rights*, *in* Commercial Law and Human Rights 187, 208-09 (Stephen Bottomley & David Kinley eds., 2002) (outlining "the possible countervailing human rights claims that may arise where patents are granted and exploited"); Sell, *supra* note 12, at 497 (describing how AIDS activists framed the issue in public health terms); *AIDS Drug Case Adjourned*, *supra* note 4 (citing an AIDS activist as stating that "'[t]he right to life, dignity and health supercedes the right of drug companies to profiteer'"). *See generally* Csete, *supra* note 10 (describing set of human rights implicated by lack of HIV/AIDS treatment).

192. *See, e.g.*, Cohn, *supra* note 14, at 437; Call for Action, *supra* note 14.

193. *See, e.g.*, Call for Action, *supra* note 14 (stating that states have a duty to engage in international cooperation to promote human rights and that donor nations are violating "their obligations to protect the right to health through cooperative, supportive activities").

194. *See* Alexander, *supra* note 14, at 13 (asserting that a human rights treaty binds

During the controversy in South Africa, human rights activists also accused the drug companies themselves of violating human rights.[195] Activists argue, for example, that drug corporations violate fundamental human rights when they prevent developing countries from fulfilling their international obligations to provide their populations with affordable medicines.[196] While human rights law developed primarily to hold states accountable for human rights violations, globalization forced international law and institutions to reckon with the emergence of multinational corporations as major actors in human rights violations.[197] As a result, today corporations have human rights obligations under international law, and there are a multitude of mechanisms to enforce and regulate those obligations.[198] This part explores the human rights that may be implicated by the lack of access to HIV/AIDS drugs, and examines one source of corporate human rights obligations: the "soft law" of multilateral corporate codes of conduct.[199]

A. *Access to HIV/AIDS Drugs: Defining the Human Rights at Stake*

According to one scholar, "[i]nternationally recognized human rights are those included in the International Bill of Human Rights or those elaborated on in subsequent instruments adopted by the UN General Assembly."[200] The International Bill of Human Rights (International Bill) consists of the Universal Declaration and the two primary human rights conventions, the International Covenant on Civil and Political Rights ("ICCPR") and the International Covenant

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signatory states to "prevent third parties from violating the right [to health] in other countries, if they are able to influence these third parties by way of legal or political means").

195. *See, e.g.*, *AIDS Drugs Case Adjourned*, *supra* note 4; Press Release, Oxfam, Drug Giants Set to Cause Violation of Human Rights: Oxfam Calls for Urgent UN Investigation (Nov. 4, 2001), *at* http://www.oxfam.org.uk/whatnew/press/cutcost6. htm (last visited Nov. 2, 2002) (on file with the Fordham Law Review) [hereinafter Drug Giants Press Release].

196. *See, e.g.*, Alexander, *supra* note 14, at 14; Drug Giants Press Release, *supra* note 195 (["T]he companies' court action against the South African government over its attempts to get cheap drugs to its people, prevent[s] the South African government from fulfilling its international human rights obligations.").

197. *See generally* Barbara A. Frey, *The Legal and Ethical Responsibilities of Transnational Corporations in the Protection of International Human Rights*, 6 Minn. J. Global Trade 153 (1997); Stephan Hobe, *The Era of Globalisation as a Challenge to International Law*, 40 Duq. L. Rev. 655, 659-60 (2002); Jordan J. Paust, *Human Rights Responsibilities of Private Corporations*, 35 Vand. J. Transnat'l L. 801 (2002).

198. *See, e.g.*, Paust, *supra* note 197, at 802-03 (asserting that "human rights law can reach private corporations"). *See generally* Sidney Dell, The United Nations and International Business (1990) (discussing the regulation of business by the U.N.).

199. *See infra* notes 200-87 and accompanying text.

200. Asbjørne Eide, *Economic, Social and Cultural Rights as Human Rights*, *in* Economic, Social and Cultural Rights: A Textbook 21, 21 (Asbjørne Eide et al. eds., 1995).

on Social, Economic and Cultural Rights ("ICESCR").[201]

1. The Normative Framework

Adopted in 1948, the Universal Declaration of Human Rights "contains the whole range of human rights within one consolidated text."[202] While it is not a formal treaty, the Universal Declaration has a special legitimacy in international law.[203] The ICCPR and the ICESCR are legally binding on those states that ratify them, obligating those states to respect, protect, and fulfill the rights enshrined in the conventions.[204] United Nations resolutions further elaborate on the human rights guaranteed in the International Bill, as well as on the concomitant obligations of states, but are not legally binding.[205]

Within this framework, specific human rights have generally been divided into two categories, tracking the two major human rights conventions: civil and political rights and economic, social and cultural rights.[206] Traditionally, economic, social, and cultural rights, such as the right to health, have attracted less attention and hold a weaker status than civil and political rights.[207] The marginalization of

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201. *See* Matthew C.R. Craven, The International Covenant on Economic, Social, and Cultural Rights: A Perspective on its Development 1 (1995); Eide, *supra* note 200, at 21; *see also* International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3, 6 I.L.M. 360 [hereinafter ICESCR]; International Covenant on Civil and Political Rights, Dec. 16, 1966, 999 U.N.T.S. 171, 6 I.L.M. 368 [hereinafter ICCPR]; Universal Declaration of Human Rights, G.A. Res. 217A, U.N. GAOR, 3rd Sess., at 71, U.N. Doc. A/810 (1948) [hereinafter Universal Declaration].

202. Eide, *supra* note 200, at 22; *see also* Universal Declaration, *supra* note 201.

203. Mark E. Wojcik, *AIDS and International Human Rights Law*, 35 J. Marshall L. Rev. 423, 426 n.140 (2002) (asserting that nations "have endowed it with great legitimacy through their actions, including its legal and political invocation at the national and international levels" (citing Jonathan M. Mann et al., *Health and Human Rights*, *in* Health and Human Rights: A Reader 9 (Jonathan M. Mann et al. eds., 1999))); Geoff Larson, *The Right of International Intervention in Civil Conflicts: Evolving International Law on State Sovereignty in Observance of Human Rights and Application to the Crisis in Chechnya*, 11 Transnat'l L. & Contemp. Probs. 251, 264 (2001) (stating that the Universal Declaration "has, in the minds of many highly regarded international law scholars, attained the status of customary law").

204. *See* Craven, *supra* note 201, at 109 ("According to the tripartite typology, all human rights entail three forms of State obligation, *viz.* the obligation to respect, protect and fulfil."); Asbjørne Eide & Allan Rosas, *Economic, Social and Cultural Rights: A Universal Challenge*, *in* Economic, Social and Cultural Rights: A Textbook, *supra* note 200, at 15, 15.

205. Eide, *supra* note 200, at 21.

206. Eide & Rosas, *supra* note 204, at 15.

207. *Id.*; *see also* Craven, *supra* note 201, at 9, 16 (concluding that "there are no really convincing arguments either for denying economic, social, and cultural rights the status of human rights or for maintaining absolute distinctions between them and civil and political rights"); Brigit C.A. Toebes, The Right to Health as a Human Right in International Law 5-6 (1999) (asserting that "in practice, particularly Western States and NGOs have tended to treat economic, social and cultural rights as if they were of less importance than civil and political rights").

economic, social, and cultural rights rests in part on the perception that they "lack the essential characteristics of universality and absoluteness."[208] An additional basis of distinction between these two categories of rights is the nature of states' obligations with respect to implementation.[209] Unlike the ICCPR, the ICESCR allows states to implement the rights "progressively" and "to the maximum of... available resources."[210] For these reasons, "many authors are of the opinion that economic and social rights, because of their very nature, are not 'justiciable' in the sense that they are not capable of being invoked in courts of law and applied by judges."[211]

Academics debate whether the human rights instruments discussed above bind corporations.[212] One view is that "[a] number of international instruments make it clear that rights exist between private individuals or bodies."[213] For example, the Universal Declaration specifies that everyone has duties to the community.[214] Furthermore, its Preamble specifies that "every organ of society... shall strive... to promote respect for these rights and... to secure their universal and effective recognition and observance."[215] Thus, some commentators argue that corporations are "organs of society" and, therefore, have an obligation under the Universal Declaration to respect human rights.[216] As one commentator argues, "if the drafters

208. Craven, *supra* note 201, at 10.

209. *See id.* at 106.

210. ICESCR, *supra* note 201, art. 2(1).

211. Martin Scheinin, *Economic and Social Rights as Legal Rights*, *in* Economic, Social and Cultural Rights: A Textbook, *supra* note 200, at 41, 41; *see also* Craven, *supra* note 201, at 10.

212. *See, e.g.*, David Kinley, *Human Rights as Legally Binding or Merely Relevant?*, *in* Commercial Law and Human Rights, *supra* note 191, at 25, 37-38; Alexander, *supra* note 14, at 13-14. *But see* Frey, *supra* note 197, at 163 (stating that "it is unclear whether [corporations] are bound to respect the[] rights" guaranteed in the Universal Declaration); Stephen G. Wood & Brett G. Scharffs, *Applicability Of Human Rights Standards To Private Corporations: An American Perspective*, 50 Am. J. Comp. Law 531, 544-45 (2002) (Section IV) (asserting that "[o]n their face, international human rights instruments do not appear to apply to corporations").

213. Kinley, *supra* note 212, at 37-38.

214. *See* Universal Declaration, *supra* note 201, art. 29.

215. *Id.* at Pmbl.

216. *See, e.g.*, Amnesty International Human Rights Principles for Companies, ACT 70/01/98 (1998) (discussing the Universal Declaration and asserting that "[c]ompanies and financial institutions are organs of society.... All companies have a direct responsibility to respect human rights in their own operations"), *available at* http://www.web.amnesty.org/ai.nsf/index/ACT700011998 [hereinafter Amnesty International Principles]; U.N. Comm'n on Hum. Rts., Human Rights Principles and Responsibilities for Transnational Corporations and Other Business Enterprises, 54th Sess., pmbl., U.N. Doc. E/CN.4/Sub.2/2002/XX, E/CN.4/Sub.2/2002/WG.2/WP.1 (February 2002 for discussion in July/August 2002) (acknowledging that "transnational corporations and other business enterprises, as organs of society, are also responsible for promoting and securing the human rights set forth in the Universal Declaration of Human Rights"), http://www1.umn.edu/humanrts/principlesW-OutCommentary5final.html (last visited

of the [Universal Declaration] intended to limit the scope of who should promote and recognize human rights to public, state actors, they could have used the phrase 'every State' rather than 'every organ of society.'"[217]

2.The Specific Human Rights at Stake

Human rights activists and commentators argue that access to affordable HIV/AIDS drugs is a human right or is a component of other internationally guaranteed human rights, such as the rights to health, life, development, and enjoying the benefits of scientific progress.[218] In 1946, WHO declared the right to health a fundamental human right.[219] Subsequently, the Universal Declaration enshrined the right to health as a fundamental human right, and the ICESCR later legally obligated signatory states to respect, protect, and fulfill the right to health.[220] The Universal Declaration guarantees all persons "the right to a standard of living adequate for the health and well-being of himself and of his family, including . . . medical care."[221] Article 12 of the ICESCR obligates state parties to "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[222]

The contours of the right to health are ill-defined in international law.[223] As a result, it is unclear whether the right to health under international law specifically encompasses the right to affordable drugs.[224] The Universal Declaration recognizes that "[e]veryone has the right to . . . medical care."[225] Additionally, the ICESCR requires

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Oct. 30, 2002) (on file with the Fordham Law Review) [hereinafter U.N. Draft Code]; Alexander, *supra* note 14, at 14 (asserting that "[a] pharmaceutical corporation arguably is an 'organ of society'"); *Globalise This: Human Rights*, OECD Observer 38, May 1, 2002, 2002 WL 100074990 ("The universal declaration . . . calls upon 'every individual and every organ of society' to promote respect for these rights and freedoms and to ensure their observance.").

217. Alexander, *supra* note 14, at 14.

218. *See, e.g.*, Csete, *supra* note 10, at 265; Nanda & Lodha, *supra* note 66, at 581.

219. Mary Ann Torres, *The Human Right to Health, National Courts, and Access to HIV/AIDS Treatment: A Case Study from Venezuela*, 3 Chi. J. Int'l L. 105, 105 (2002) (citing WHO Constitution, Pmbl., 62 Stat 2679, 14 U.N.T.S. 185 (1948)).

220. *See* ICESCR, *supra* note 201, art. 12(1); Universal Declaration, *supra* note 201, art. 25(1); *see also* Craven, *supra* note 201, at 109-14 (describing states' obligations under the ICESCR as including the duties to respect, protect, and fulfill human rights).

221. Universal Declaration, *supra* note 201, art. 25(1).

222. ICESCR, *supra* note 201, art. 12(1).

223. *See, e.g.*, Toebes, *supra* note 207, at 4 (asserting that "the precise content of the right to health as a socio-economic right allows for much confusion" and that "the term is used without being clear what the exact meaning of the right to health exactly entails"); Torres, *supra* note 219, at 108.

224. *See* Katarina Tomaševski, *Health Rights*, *in* Economic, Social and Cultural Rights: A Textbook, *supra* note 200, at 125, 125 (noting that "[a]ccess to health care as an individual right does not enjoy global recognition").

225. Universal Declaration, *supra* note 201, art. 25(1).

states to "assure to all medical service and medical attention in the event of sickness" and to take steps towards the treatment of epidemic diseases.[226] Thus, many activists and scholars argue that "access to medicines is an essential part of access to health."[227]

Several recent developments suggest that the right of access to medical treatment may be a component of the right to health.[228] For example, the U.N. committee that supervises the implementation of the ICESCR has interpreted the right to health guaranteed in the ICESCR to include the rights to treatment of epidemic diseases, access to affordable health services, and the provision of essential drugs.[229] In its General Comment 14, the committee further specifies that states' duties to *protect* the right to health include "the duties . . . to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties," as well as to "ensure that third parties do not limit people's access to health-related information and services."[230] The committee's interpretations are not legally binding, but they "may be said to have considerable legal weight."[231] Thus, some scholars argue that state signatories to the ICESCR have a binding obligation to protect and promote the right to health by guaranteeing affordable health care, including drugs.[232]

Moreover, the U.N. Commission on Human Rights has passed a resolution acknowledging that access to HIV/AIDS medications is "one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[233] The resolution

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226. ICESCR, *supra* note 201, arts. 12(2)(c)-(d).

227. Nanda & Lodha, *supra* note 66, at 581; *see also* Toebes, *supra* note 207, at 116-17 (asserting that "accessibility of health care services is a crucial element of the right to health" and categorizing accessibility as financial, geographic and cultural); Csete, *supra* note 10, at 265.

228. *See* Gathii, *supra* note 2, at 736 (noting that "there have been significant developments that have already laid a rights framework to facilitate access to essential medicines").

229. *See* ESCOR, Comm. on Econ., Soc., and Cultural Rts., The Right to the Highest Attainable Standard of Health, U.N. (CESCR General Comment 14), 22nd Sess., paras. 16, 12(b), 17, U.N. Doc. E/C.12/2000/4 (2000) (defining economic accessibility as one of the elements of the right to health and specifying that "health facilities, goods and services must be affordable for all"), *available at* http://www.publichealthlaw.net/Reader/ [hereinafter Comment 14]; *see also* Craven, *supra* note 201, at 4 (referring to the Committee on Economic, Social, and Cultural Rights (CESCR) as the "primary supervisory body" of the ICESCR).

230. Comment 14, *supra* note 229, para. 35.

231. Craven, *supra* note 201, at 4.

232. *See, e.g.*, Alexander, *supra* note 14, at 14.

233. Access to Medication in the Context of Pandemics such as HIV/AIDS, Hum. Rts. Comm'n Res. 2001/33, U.N. ESCOR, 57th Sess., Supp. No. 3, 71st mtg. at 169, para. 1, U.N. Doc. E/CN.4/2001/167 (2001) [hereinafter U.N. Medicines Access Resolution]; *see also* Human Rights Watch, World Report 2002: Special Issues and Campaigns: HIV/AIDS and Human Rights (2002),

further calls on states to adopt policies to ensure the availability of HIV/AIDS medications.[234] Most recently, the U.N. revised its guidelines to states on HIV/AIDS and human rights "to reflect new standards in HIV treatment and evolving international law on the right to health."[235] The new Guideline 6 specifically asserts that states should "take measures necessary to ensure for all persons . . . the availability and accessibility of [HIV/AIDS treatment] . . . including antiretroviral and other safe and effective medicines."[236]

In addition to these developments under international law, there is also recent domestic case law defining the right to health to include the right to affordable HIV/AIDS treatment.[237] In *Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social*, the Venezuelan Supreme Court held that the national government violated the right to access HIV/AIDS drugs by failing to provide its citizens with those drugs.[238] According to one commentator, the court reached its holding that the right to health included the right to access to treatment by taking into account both the Venezuelan Constitution and unspecified "international legal principles."[239] Similarly, the South African High Court held that the government breached the right to health by failing to provide HIV/AIDS treatment to pregnant women who are HIV-positive, in order to prevent mother-to-child HIV transmission.[240] Unlike the court in *Cruz Bermúdez*, however, the South African court reached its holding that access to HIV/AIDS drugs was a right on the basis of the South African constitution alone, and did not explicitly recognize access to HIV/AIDS treatment as an internationally guaranteed right.[241]

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http://www.hrw.org/wr2k2/hivaids.html (last visited Oct. 30, 2002) (on file with the Fordham Law Review).

234. *See* U.N. Medicines Access Resolution, *supra* note 233, para. 2.

235. Office of the United Nations High Commissioner for Human Rights & Joint United Nations Programme on HIV/AIDS, HIV/AIDS and Human Rights: International Guidelines: Third International Consultation on HIV/AIDS and Human Rights, at 5 (2002) (pre-publication edition), *available at* http://www.unaids.org/humanrights/ [hereinafter U.N. HIV Guideline 6].

236. *Id.* at 13.

237. *See* Torres, *supra* note 219, at 106 (discussing "the 1999 decision of the Venezuelan Supreme Court in *Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social*, in which the Court held the government's failure to provide . . . access to ARV therapies violated their right to health"); *see also* Treatment Action Campaign v. Minister of Health, Case No. 21182/2001, at 60 (S. Afr. 2001), *available at* http://www.tac.org.za/ [hereinafter TAC Lawsuit].

238. *See* Torres, *supra* note 219, at 106 (citing Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social, *Corte Suprema de Justicia*, Republica de Venezuela, Expediente Numero: 15.789 (1999), *available at* http://www.csj.gov.ve/sentencias/SPA/spa15071999-15789. html).

239. *Id.* at 111 (citing Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social, *Corte Suprema de Justicia*, Republica de Venezuela, Expediente Numero: 15.789 (1999), *available at* http://www.csj.gov.ve/sentencias/SPA/spa15071999-15789. html).

240. TAC Lawsuit, *supra* note 237, at 60.

241. *Id.* at 49, 60.

In addition to the right to health, other internationally guaranteed human rights may be linked to access to affordable HIV/AIDS treatment.[242] During the controversy in South Africa, for example, human rights activists linked the right to HIV/AIDS drugs to the right to life.[243] Under Article 3 of the Universal Declaration, "everyone has the right to life, liberty and the security of person."[244] Article 6 of the ICCPR states that "[e]very human being has the inherent right to life. This right shall be protected by law."[245] In its general comment interpreting the right to life in the ICCPR, the U.N. Human Rights Committee adopts a broad interpretation of the right to life, requiring states to "adopt positive measures . . . to eliminate . . . epidemics."[246] The European Human Rights Convention provides a more detailed description of the right to life.[247]

Access to HIV/AIDS drugs may also be tied to the right to development.[248] The right to development is guaranteed in the Universal Declaration, which specifies that "[e]veryone is entitled to a social and international order in which the rights . . . set forth in this Declaration can be fully realized."[249] The Declaration on the Right to Development ("Development Declaration") further defines the right to development, recognizing the right to development as "an inalienable human right,"[250] and giving states the right and duty "to formulate appropriate national development policies . . . on the basis of . . . the fair distribution of the benefits resulting."[251] Specifically, the Development Declaration urges states to take all of the necessary steps to ensure "equality of opportunity for all in their access to . . . health services."[252] Thus, as one commentator concludes, "the right to development may provide a further basis for national patent systems making . . . provision [for compulsory licensing] in developing countries."[253]

Similarly, some argue that "[t]o give effect to [the rights to share in

242. Ricketson, *supra* note 191, at 208-09 (citing the "rights to share in scientific advancement and its benefits" and the "rights to development").

243. *See, e.g.*, Call for Action, *supra* note 14.

244. Universal Declaration, *supra* note 201, art. 3.

245. ICCPR, *supra* note 201, art. 6(1).

246. Report of the Human Rights Committee: General Comments Under Article 40, paragraph 4 of the Covenant, General Comment 6 (16), U.N. GAOR, 37th Sess., Supp. No. 40, Annex V, at 93-94, paras. 5, 37, U.N. Doc A/37/40 (1982).

247. *See* Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, art. 2, 213 U.N.T.S. 221, 224.

248. *See, e.g.*, Declaration on the Right to Development, G.A. Res. 41/128 (Annex), U.N. GAOR, 41st Sess., Supp. No. 53, at 186, U.N. Doc. A/41/53 (1986) [hereinafter Development Declaration]; Universal Declaration, *supra* note 201, art. 28; Ricketson, *supra* note 191, at 209.

249. Universal Declaration, *supra* note 201, art. 28.

250. Development Declaration, *supra* note 248, art. 1(1).

251. *Id.* art. 2(3).

252. *Id.* art. 8(1).

253. Ricketson, *supra* note 191, at 209.

scientific advancement and its benefits] dictates, at the very least, the need for reasonable exceptions to protection that allow for research and development by third parties."[254] The right to share in scientific progress is also guaranteed under international law.[255] The Universal Declaration, for example, states that everyone "has the right . . . to share in scientific advancement and its benefits."[256] Similarly, the ICESCR guarantees all persons the right "[t]o enjoy the benefits of scientific progress and its applications."[257]

B. *Source of Corporate Responsibility for Human Rights: Corporate Codes of Conduct*

The U.N. and other multilateral institutions, non-governmental organizations, national governments, and corporations themselves have all sought to regulate the human rights activities of multinational corporations through a variety of mechanisms.[258] One popular form of corporate regulation is the use of codes of conduct.[259] Several corporations, most notably Gap and Levi Strauss, have adopted their own corporate codes of conduct, which set out policies and mechanisms for addressing human rights violations internally.[260]

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254. *Id.* at 208; *see also* Lawrence O. Gostin & Zita Lazzarini, Human Rights and Public Health in the AIDS Pandemic 31 (1997) ("The right to share in the benefits of scientific progress has particular import in the HIV/AIDS pandemic.").

255. *See* ICESCR, *supra* note 201, art. 15(1)(b); Universal Declaration, *supra* note 201, art. 27(1).

256. Universal Declaration, *supra* note 201, art. 27(1).

257. ICESCR, *supra* note 201, art. 15(1)(b).

258. *See, e.g.*, Foreign Corrupt Practices Act, 15 U.S.C. 78dd-2 (1994) (prohibiting bribing of foreign officials); Dell, *supra* note 198 (describing U.N. regulation of transnational corporations); Sustainability Reporting Guidelines on Economic, Environmental, and Social Performance (Global Reporting Initiative 2000) (using disclosure as a mechanism to regulate corporate human rights abuses), *available at* http://www.globalreporting.org/GRIGuidelines/June2000/June2000GuidelinesDownload.htm. For a more complete discussion of disclosure and multinational corporations, see generally S. J. Gray et al., Information Disclosure and the Multinational Corporation (1984).

259. *See, e.g.*, Model Business Principles (United States Dep't of Commerce 1996), http://www.itcilo.it/english/actrav/telearn/global/ilo/guide/usmodel.htm (last visited Nov. 2, 2002) (national government code); Amnesty International Principles, *supra* note 216 (non-governmental organization code). For a more complete discussion of the regulation of transnational corporations through codes of conduct, see Judith Richter, Holding Corporations Accountable: Corporate Conduct, International Codes, and Citizen Action (2001).

260. *See* Frey, *supra* note 197, at 177 (classifying internal codes into three categories: "vendor standards regarding forced and child labor; standards in support of civil and political rights; and criteria for investment"); *see, e.g.*, Email from Gap Customer Service, to Lissett Ferreira, Symposium Editor, Fordham Law Review (11/2/2002, 5:40:22 PM) (including Gap Code of Vendor Conduct) (on file with the Fordham Law Review); Levi Strauss & Co., Social Responsibility/Global Sourcing & Operating Guidelines, *at* http://www.levistrauss.com/responsibility/conduct/guidelines.htm (last visited Nov. 2, 2002) (on file with the Fordham Law Review). While these corporate codes of conduct reflect a positive trend in the

Many corporations have also participated in voluntary, industry-wide human rights and ethical standards and codes, promulgated by private actors, governments, and other institutions.[261]

Multilateral institutions have also promulgated codes of conduct defining and regulating the human rights obligations of transnational corporations.[262] The Global Compact, for example, is a U.N. initiative consisting of nine principles in three areas of international agreement: human rights, labor standards, and the environment.[263] United Nations Secretary-General Kofi Annan has vigorously advocated for businesses to "embrace and enact" the nine principles.[264] Specifically, the two human rights principles in the Global Compact are that businesses should "support and respect the protection of internationally proclaimed human rights within their sphere of influence" and "make sure that they are not complicit in human rights abuses."[265]

The International Labour Organization's declaration for multinational corporations ("ILO Declaration") recommends that governments and multinational corporations operating in member states observe a set of principles, relating mostly to employment practices.[266] It calls on transnational corporations to "take fully into account established general policy objectives of the [host] countries"[267] and to affirmatively *harmonize* their activities with their

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corporate acceptance and enforcement of human rights obligations, *see* Douglass Cassel, *Corporate Initiatives: A Second Human Rights Revolution?*, 19 Fordham Int'l L.J. 1963, 1964 (1996), they also have been criticized for being generally unenforced and ineffective because of their voluntary nature, *see, e.g.*, Lucinda Saunders, Note, *Rich and Rare Are the Gems They War: Holding De Beers Accountable for Trading Conflict Diamonds*, 24 Fordham Int'l L.J. 1402, 1436-37 (2001).

261. *See, e.g.*, Amnesty International Principles, *supra* note 216; *see also* Saunders, *supra* note 260, at 1468-70 (discussing the Sullivan Principles and the MacBride Principles, two initiatives that were directed at regulating corporate activity in specific turbulent areas).

262. *See* Organization for Economic Co-Operation and Development, The OECD Guidelines for Multinational Enterprises: Revision 2000 (2000), *available at* www.union-network. org/UNIsite/ In_Depth/ Interna_Relations/ OECDGuidelines.pdf [hereinafter OECD Guidelines]; ILO, Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy, http://www.ilo.org/public/english/standards/norm/sources/mne.htm (last visited Oct. 30, 2002) (on file with the Fordham Law Review) [hereinafter ILO Declaration]; U.N. Global Compact, http://65.214.34.30/un/gc/unweb.nsf/ content/thenine.htm (last visited Nov. 9, 2002) (on file with the Fordham Law Review) [hereinafter Global Compact]; U.N. Draft Code, *supra* note 216.

263. Global Compact, *supra* note 262 (noting that the principles are derived from, among other instruments, the Universal Declaration); *see also* William H. Meyer & Boyka Stefanova, *Human Rights, the UN Global Compact, and Global Governance*, 34 Cornell Int'l L.J. 501 (2001).

264. Global Compact, *supra* note 262.

265. *Id.*

266. *See* ILO Declaration, *supra* note 262, at Pmbl.

267. *Id.* para. 10.

host state's social and development policies.[268] The ILO Declaration further asserts that multinational corporations should "respect the sovereign rights of States, obey the national laws and regulations, give due consideration to local practices and respect relevant international standards."[269] Specifically, the ILO Declaration calls on transnational corporations to respect the International Bill of Rights.[270]

The Organisation for Economic Co-Operation and Development's guidelines for multinational corporations ("OECD Guidelines") is a "multilaterally endorsed and comprehensive code" addressed to business that articulates the "shared values" of the developed states from which most multinational corporations originate.[271] First promulgated by the OECD in 1977, the code is periodically updated; the last update was in 2000.[272] The Guidelines specify a minimum set of obligations that multinationals should strive to achieve on a range of rights, including labor rights and environmental rights.[273] There is general agreement that, of all the "soft law" standards for multinational corporations, the OECD Guidelines have the most potential for effective implementation.[274]

The newly revised OECD Guidelines now obligate corporations to "[r]espect the human rights of those affected by their activities consistent with the host government's international obligations and commitments."[275] The OECD Guidelines also specify that multinational corporations should "take fully into account established policies in the countries in which they operate" and, specifically, ensure that their activities are consistent with their host country's technology policies.[276] Additionally, the OECD Guidelines exhort corporations to contribute to economic and social progress, and specify the affirmative obligations of multinational corporations in the

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268. *Id.*

269. *Id.* para. 8.

270. *Id.*

271. OECD Guidelines, *supra* note 262, at 5 (Statement by the Chair of the Ministerial). The Guidelines include specific chapters on disclosure, employment, the environment, bribery, and consumer interests, as well as on science and technology. *See id.*, *supra* note 262; *see also* Marinus Sikkel, *A Reinvigorated Instrument for Global Investment*, OECD Observer 29, Mar. 1, 2001, 2001 WL 22296403 (describing the guidelines as "compris[ing] recommendations, to multinational corporations, from thirty-three governments covering areas from respect of human rights to environmental protection wherever companies operate").

272. OECD Guidelines, *supra* note 262, at 5 (Statement by the Chair of the Ministerial); *see also* Sikkel, *supra* note 271.

273. *See* Sikkel, *supra* note 271. *See generally* OECD Guidelines, *supra* note 262.

274. For a description of the implementation of the OECD Guidelines, see The OECD Guidelines for Multinational Enterprises, 5 OECD Working Papers 21 (1997). Other scholars are skeptical about the guidelines' effectiveness. *See, e.g.*, Cassel, *supra* note 260, at 1970 (stating that OECD guidelines are "limited" and "[broke] little new ground").

275. OECD Guidelines, *supra* note 262, at II.2.

276. *Id.* at II, VIII.1

area of science and technology.[277] Thus, they suggest that when practicable or appropriate, multinational corporations should "contribute to the development of local and national innovative capacity"[278] and "[a]dopt . . . practices that permit the transfer and rapid diffusion of technologies and know-how, with due regard to the protection of intellectual property rights."[279] The commentary to the OECD Guidelines further specifies that "[w]hen selling or licensing technologies . . . the terms and conditions negotiated [should] be reasonable."[280]

Finally, the draft U.N. code of conduct for transnational corporations ("U.N. Draft Code") is an ongoing U.N. effort to define the human rights obligations of transnational corporations.[281] The most recent version of the U.N. Draft Code asserts that "within their respective spheres of activity and influence, transnational corporations and other business enterprises have the obligation to respect, ensure respect for, prevent abuses of, and promote human rights recognized in international as well as national law."[282] The U.N. Draft Code further calls on transnational corporations to respect and "contribute to [the] realization" of human rights, including the right to health, and to "refrain from actions which obstruct the realization of those rights."[283] The U.N. Draft Code calls on multinational corporations to respect state sovereignty, including "applicable norms of international law; national laws; . . . [and] social, economic, and cultural policies."[284]

Scholars debate the usefulness and effectiveness of the multilateral codes.[285] While these multilateral codes are voluntary, as one scholar asserts, "transnational codes with a moral dimension . . . are embodiments of law in the broadest sense, because they are enforceable by a source of control."[286] These codes may be characterized as "soft law" instruments, which, in contrast to legally binding and judicially enforceable instruments such as the human rights treaties, are not mandatory and are not enforced by judicial mechanisms.[287]

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277. *Id.* at II.1, VIII.1.
278. *Id.* at VIII.1
279. *Id.* at VIII.2.
280. OECD Guidelines, *supra* note 262, at Commentary, para. 54.
281. U.N. Draft Code, *supra* note 216. For a complete discussion of the history and content of the U.N. Draft Code, see Dell, *supra* note 198, at 73-90.
282. U.N. Draft Code, *supra* note 216, art. A.1.
283. *Id.* art. E.12.
284. *Id.* art. E.10.
285. *See, e.g.*, Steven R. Salbu, *True Codes Versus Voluntary Codes of Ethics in International Markets: Towards the Preservation of Colloquy in Emerging Global Communities*, 15 U. Pa. J. Int'l Bus. L. 327, 341, 342 (1994) (criticizing the codes as vague and "so general as to provide little practical or useful guidance").
286. *Id.* at 332-33 (citations omitted).
287. *See, e.g.*, Steven R. Ratner, *Corporations and Human Rights: A Theory of*

III. THE HUMAN RIGHTS VIOLATIONS OF DRUG CORPORATIONS: A THEORY OF LIABILITY

Today, while there is considerable debate about the scope of their obligations, it is virtually universally recognized that multinational corporations, including the major pharmaceutical companies, do indeed have obligations to respect human rights.[288] Substantial evidence documents the role of patents in rendering HIV/AIDS treatment unaffordable to citizens of developing countries, as well as the success of generic competition and parallel importing at broadening access to those life-saving treatments.[289] Drug companies, however, have aggressively opposed the use of compulsory licensing and parallel importing for HIV/AIDS drugs, and successfully lobbied and pressured the U.S. government to sanction countries that seek to promote more affordable HIV/AIDS drugs.[290] These actions violate the human rights of HIV/AIDS patients in developing countries, which drug companies have an obligation to respect under the "soft law" multilateral codes of conduct.[291]

A. *Access to HIV/AIDS Drugs Is a Human Right*

The right to affordable HIV/AIDS treatment is a fundamental human right under international law, and states have an obligation to respect, protect, and fulfill that right.[292] Several recent developments in international law reflect an emerging consensus that access to HIV/AIDS treatment is a human right.[293] United Nations bodies have

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Legal Responsibility, 111 Yale L.J. 443, 486-87 (2001) (characterizing the ILO Declaration and the OECD Guidelines as "soft law instruments" recognizing corporate duties). For a thoughtful discussion and analysis of "soft law," see Pierre-Marie Dupuy, *Soft Law and the International Law of the Environment*, 12 Mich. J. Int'l L. 420 (1991).

288. *See, e.g.*, Kinley, *supra* note 212, at 40 ("The horizontal application of human rights law—or the 'privatisation' of human rights—is now well recognised, if not yet having reached its full potential."); Cassel, *supra* note 260, at 1980-84 (analyzing codes of conduct for transnational corporations and suggesting continuum of human rights responsibilities of corporations); Jonathan I. Charney, *Transnational Corporations and Developing Public International Law*, 1983 Duke L.J. 748, 748 (asserting that "one of the most significant developments in public international law is the apparent creation of law applicable to transnational corporations").

289. *See, e.g.*, Sources & Prices, *supra* note 3, at 5; Untangling the Web, *supra* note 29, at 3 ("Generic competition appears currently to be the most efficient way to lower the price of ARVs").

290. *See supra* notes 170-73, 187-90 and accompanying text.

291. *See infra* notes 292-375 and accompanying text.

292. *See* Csete, *supra* note 10, at 265 (asserting that access to HIV/AIDS treatment "has been recognized as a human right"); Nanda & Lodha, *supra* note 66, at 581.

293. *See, e.g.*, U.N. Medicines Access Resolution, *supra* note 233; Comment 14, *supra* note 229; U.N. HIV Guideline 6, *supra* note 235; Torres, *supra* note 219, at 106 (citing Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social, *Corte Suprema de Justicia*, Republica de Venezuela, Expediente Numero: 15.789 (1999), *available at* http://www.csj.gov.ve/sentencias/SPA/spa15071999-15789.html).

issued interpretative comments, resolutions, and a guideline declaring affordable HIV/AIDS treatment a fundamental human right and obligating states to ensure that right.[294] While these instruments are not legally binding per se, because the U.N. reflects the views of the majority of the world's states, these instruments supplement the human rights conventions.[295] Furthermore, national case law, such as the *Cruz Bermúdez* case in Venezuela, has also interpreted the right to HIV/AIDS treatment to be an internationally protected right and has obligated the state to ensure that right.[296] Cumulatively, these developments are evidence of an emerging consensus in the international community that all persons have the right to affordable HIV/AIDS drugs and that states have an affirmative obligation to ensure that right.[297]

In addition, the right to affordable life-saving drugs is linked closely to various fundamental rights guaranteed under international law, such as the rights to life, development, and to share in scientific progress.[298] Numerous scientific studies have proven that HIV/AIDS drugs are capable of prolonging the life of HIV-positive people.[299] Thus, denying or withholding these life-prolonging HIV/AIDS drugs from people effectively violates their right to life.[300] Since the right to life is guaranteed in the key human rights instruments, states have a basic obligation under international law to guarantee the right to life for all people by ensuring equitable access to life-saving HIV/AIDS drug treatment.[301] Therefore, laws such as the Medicines Act Amendment, which seek to bring HIV/AIDS drugs to those who cannot afford them, are consistent with a state's international obligation to protect the right to life.[302]

Additionally, in its Development Declaration, the U.N. further obligates states to ensure equal opportunity to all people in the effective availability of health services.[303] As such, equitable access to

294. *See* U.N. Medicines Access Resolution, *supra* note 233; Comment 14, *supra* note 229; U.N. HIV Guideline 6, *supra* note 235.

295. *See* Eide, *supra* note 200, at 21.

296. *See* Torres, *supra* note 219, at 106 (citing Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social, *Corte Suprema de Justicia*, Republica de Venezuela, Expediente Numero: 15.789 (1999), *available at* http://www.csj.gov.ve/sentencias/SPA/spa15071999-15789. html).

297. *See supra* notes 228-41 and accompanying text (discussing the recent developments suggesting that access to affordable HIV/AIDS treatment is a human right).

298. *See supra* notes 242-58 and accompanying text.

299. *See supra* note 2 and accompanying text.

300. *See, e.g.*, Call for Action, *supra* note 14.

301. *See* ICCPR, *supra* note 201, art. 6(1); Universal Declaration, *supra* note 201, art. 3; *see also supra* notes 243-47 and accompanying text (discussing the right to life under international law).

302. *See* Medicines Act Amendment, *supra* note 10, § 10; *supra* notes 243-47 and accompanying text.

303. *See* Development Declaration, *supra* note 248, art. 8(1).

the "health service" of HIV/AIDS drugs is a component of the right to development guaranteed under international law.[304] Furthermore, equitable access to scientific advancements, in the form of new HIV/AIDS drugs, is also encompassed within the internationally guaranteed right to share in the benefits of scientific progress.[305] Thus, equitable access to HIV/AIDS drugs is not only an emerging independent human right, but is already encompassed within a bundle of other human rights guaranteed under international law.[306]

B. *Corporate Accountability Under "Soft Law": Multilateral Codes of Conduct*

The "soft law" multilateral codes of conduct for transnational corporations are an important source of human rights obligations for corporations, including drug companies.[307] The body of international human rights law includes a broad range of sources of norms and obligations, beyond just treaties, including "soft law."[308] Because these norms were developed and promulgated by multilateral institutions composed of many of the world's states, they reflect a broad international consensus on the human rights obligations of corporations.[309] Thus, the cumulative effect of these "soft law" standards is to embody a set of international norms to govern the actions of corporations which impact the social sphere.[310] In particular, those obligations that are consistently defined throughout the several multilateral standards indicate a powerful consensus on the minimum human rights obligations of transnational corporations.[311] While differing in their specific content, the multilateral codes of conduct and standards overlap in their definition of several general human rights norms for transnational corporations.[312]

The fact that the "soft law" standards lack formal judicial mechanisms under which to prosecute the drug corporations for their human rights violations does not make the drug companies'

304. *See* Ricketson, *supra* note 191, at 209; *supra* notes 248-53 and accompanying text (discussing the right to development under international law).

305. *See supra* notes 254-57 and accompanying text (discussing the right to share in the benefits of scientific progress).

306. *See* Csete, *supra* note 10, at 266-71 (discussing the connections between access to HIV/AIDS treatment and other human rights).

307. *See* Ratner, *supra* note 287, at 486-87; *supra* notes 262-87 and accompanying text (discussing the multilateral codes).

308. See generally Dupuy, *supra* note 287, for a discussion of "soft law."

309. *See* Ratner, *supra* note 287, at 486-87.

310. *See id.* (asserting that soft law instruments recognizing corporate duties reflect the expectations of states and discussing the ILO Declaration and the OECD Guidelines).

311. *See supra* notes 262-87 and accompanying text (detailing the human rights duties of corporations under the multilaterally endorsed codes of conduct).

312. *See infra* notes 316-19, 346-50 and accompanying text.

obligations any less compelling.[313] In fact, public pressure has proven effective in forcing drug companies to stop challenging countries trying to make HIV/AIDS drugs cheaper and to lower their drug prices.[314] As such, continuing public pressure has a potential key role to play in enforcing the norms recommended in the multilateral codes of conduct.[315]

1. The "Soft Law" Corporate Obligation to Respect Host State's Sovereignty, Laws, and Policies

Both the U.N. Draft Code and the ILO Declaration specifically urge transnational corporations to respect the sovereignty and laws of their host countries.[316] Several of the standards, such as the OECD Guidelines, U.N. Draft Code and ILO Declaration, also impose a duty on transnational corporations to respect the social policies of their host countries.[317] Furthermore, the ILO Declaration adds that corporations have an affirmative duty to take into consideration their host countries' policies, and to *harmonize* their operations with those countries' social and development goals.[318] Thus, "soft law" imposes a minimum obligation on drug corporations operating in developing countries to respect their host countries' sovereignty, policies, and laws.[319] South Africa and other developing countries with severe HIV/AIDS epidemics have exercised their sovereignty to establish national public health policies to promote affordable HIV/AIDS medicines.[320] Developing countries have further exercised their sovereignty to enact laws, such as the Medicines Act Amendment, to implement these HIV/AIDS drugs policies.[321] Thus, drug companies violate their obligations under the "soft law" standards when they fight laws such as the Medicines Act Amendment, through litigation; lobbying of the U.S. government; threats to move their operations out of the offending country; and other exertions of the drug industry's substantial political and economic power to prevent developing countries from implementing those laws.[322]

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313. *See supra* note 287 and accompanying text.

314. *See* UNAIDS Update, *supra* note 1, at 9 (identifying public pressure as one factor contributing to decreasing drug prices); *see also* sources cited *supra* note 181.

315. *See* sources cited *supra* note 181.

316. *See* ILO Declaration, *supra* note 262, para. 8; U.N. Draft Code, *supra* note 216, art. E.10.

317. *See* U.N. Draft Code, *supra* note 216, art. E.10; OECD Declaration, *supra* note 262, at II; ILO Declaration, *supra* note 262, para. 10.

318. *See* ILO Declaration, *supra* note 262, para. 10.

319. *See* OECD Declaration, *supra* note 262, at II; ILO Declaration, *supra* note 262, paras. 8, 10; U.N. Draft Code, *supra* note 216, art. E.10.

320. *See, e.g.*, National Drug Policy for South Africa, *supra* note 125.

321. *See* Medicines Act Amendment, *supra* note 10.

322. See discussion *supra* Part I.B.2 for a detailed description of the drug

Some may argue that advocating that multinational corporations respect state sovereignty, policies, and laws poses a dilemma in the case of companies operating in repressive regimes that permit or encourage human rights abuses.[323] However, the norms in these multilateral standards logically must be read to incorporate international human rights law.[324] It is implicit that, as efforts to encourage socially responsible corporate activity in the human rights sphere, the standards for corporate conduct do not stand for the proposition that corporations obey laws that violate international human rights.[325]

In fact, as discussed below, the standards also impose simultaneous obligations on corporations to respect the human rights obligations of countries and to themselves respect and support international human rights.[326] Reading these multiple obligations together, therefore, suggests that corporations have a duty to respect those national laws and policies *which are consistent with human rights standards.*[327] Either way, in the case at hand, because the Medicines Act Amendment and similar legislation are efforts to actively promote important human rights, drug companies cannot avail themselves of this argument.[328]

To the contrary, in light of the staggering magnitude of the HIV/AIDS epidemic in developing nations, state policies and laws that seek to make life-saving drugs available to those dying of HIV/AIDS reflect particularly legitimate and weighty goals worthy of the respect and cooperation of the drug corporations.[329] Furthermore, since the right to affordable HIV/AIDS treatment is a human right that states are obligated to protect, laws to promote access to life-prolonging drugs accord with international human rights law.[330] The Medicines Act Amendment and similar laws directly promote human rights by more equitably distributing life-prolonging drugs among

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companies' actions against countries that proposed laws to make HIV/AIDS drugs more affordable.

323. For an example of corporate complicity with states in human rights violations, see Cassel, *supra* note 260, at 1964-68 (discussing Royal Dutch Shell's complicity with the Nigerian government in human rights abuses).

324. See *supra* notes 202-17 and accompanying text for a description of the normative framework for international human rights.

325. *See, e.g.*, Preface to OECD Guidelines, *supra* note 262, para. 1 (asserting that the guidelines "provide voluntary principles and standards for *responsible business conduct consistent with applicable laws*" (emphasis added)).

326. *See infra* notes 346-51 and accompanying text.

327. See *supra* notes 218-57 and accompanying text for a discussion of the relevant human rights standards for drug companies.

328. *See supra* notes 124-26 (describing the context of the Medicines Act Amendment, *supra* note 10).

329. *See supra* notes 1-3 and accompanying text.

330. *See supra* notes 292-306 and accompanying text (arguing that access to HIV/AIDS drugs is a human right).

HIV-positive people.[331]

Even accepting that this corporate duty only extends to those laws that are consistent with international law, some may argue that drug companies do not have any obligation to respect laws to increase access to HIV/AIDS drugs because such laws violate developing countries' international obligations under TRIPS.[332] While the drug industry and its supporters continue to oppose laws such as South Africa's Medicines Act Amendment, the consensus is that the Medicines Act Amendment is valid under TRIPS.[333] Additionally, in the recent Doha Declaration, the WTO interpreted TRIPS to allow developing countries to make HIV/AIDS drugs more affordable, including through the use of compulsory licensing and parallel importing.[334] As a WTO ministerial pronouncement, the Doha Declaration is a "persuasive authority" that asserts that TRIPS does indeed allow such practices, which laws like the Medicines Act Amendment seek to introduce in order to make HIV/AIDS drugs more broadly accessible.[335]

Furthermore, the drug industry's interpretation of those laws is based on a TRIPS-plus approach, which seeks to force developing countries to offer their products greater patent protection than TRIPS requires.[336] The WTO member states, however, signed on to the standards in TRIPS, not the TRIPS-plus obligations that the drug industry seeks to impose.[337] Drug companies are not obligated to respect laws that violate TRIPS, but the drug industry has failed to prove that laws like the Medicines Act Amendment violate TRIPS.[338] As such, there is little merit to the argument that drug companies do not have an obligation to respect laws like South Africa's Medicines Act Amendment because they violate TRIPS.[339]

Additionally, there is some suggestion in the multilateral codes of conduct that corporations have an affirmative obligation to cooperate with their host states.[340] The ILO Declaration specifically recommends that corporations affirmatively *harmonize* their activities with their host states' social and development policies.[341] The drug companies' multi-faceted attack on laws such as the Medicines Act

331. *See* Medicines Act Amendment, *supra* note 10, § 10.

332. See *supra* notes 94-122 and accompanying text for a presentation of the TRIPS provisions relevant to access to HIV/AIDS medicines and the debate over their interpretation.

333. *See* sources cited *supra* note 156.

334. *See* Doha Declaration, *supra* note 117; *see also supra* notes 117-20 and accompanying text.

335. *See supra* note 122 and accompanying text.

336. *See supra* notes 101, 112-13 and accompanying text.

337. *See supra* note 83 and accompanying text.

338. *See* sources cited *supra* note 156 and accompanying text.

339. *See* sources cited *supra* note 156 and accompanying text.

340. *See* ILO Declaration, *supra* note 262, para. 10.

341. *Id.*

Amendment is inconsistent with this obligation to cooperate with, and conform their activities to, state efforts to make HIV/AIDS drugs affordable.[342]

Moreover, the drug companies may also violate their obligation to respect and cooperate with state policies to promote the right to medical treatment when they charge prices so high that only one-tenth of one percent of worldwide HIV/AIDS sufferers can buy their drugs.[343] The consistently high prices drug companies charge directly conflict with the shared goal of many developing states to ensure treatment to those dying of HIV/AIDS.[344] As such, the prices drug corporations charge for their patented drugs in the developing world may not only be unreasonable and unethical, but also a violation of their obligations under the multilateral codes of conduct not to interfere with the legitimate policies of host governments.[345]

2. The "Soft Law" Corporate Obligation to Respect and Support the Protection of Human Rights

There is a broad consensus in the multilateral corporate standards that corporations have an additional duty to both respect and support the international obligations of their host countries to protect human rights.[346] For example, the U.N. Draft Code calls on corporations to "respect, ensure respect for, prevent abuses of, and promote human rights;"[347] the Global Compact urges corporations to both support and respect the protection of human rights;[348] the ILO Declaration recommends that corporations respect "relevant international standards," specifying the International Bill of Rights;[349] and the newly revised OECD Guidelines now also obligate corporations to respect the human rights of those people affected by the corporation's activities.[350] The U.N. Draft Code further suggests that corporations may also have an independent duty themselves to respect, support, and promote human rights.[351]

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342. *See supra* notes 170-73, 187-89 (describing drug companies' opposition to laws seeking to make HIV/AIDS drugs more affordable).

343. *See supra* notes 3-4 and accompanying text.

344. *See supra* notes 124-25 (describing South Africa's constitutional obligations to ensure the right to health and its national drug policy to ensure that right).

345. *See* ILO Declaration, *supra* note 262, para. 10.

346. *See, e.g.*, ILO Declaration, *supra* note 262, para. 8; Global Compact, *supra* note 262; U.N. Draft Code, *supra* note 216, art. A.1.

347. U.N. Draft Code, *supra* note 216, art. A.1.

348. Global Compact, *supra* note 262. The right to HIV/AIDS treatment should be understood as within the "sphere of influence" of pharmaceutical corporations, who have the power to set the prices they charge for their drugs and to either support or challenge states' efforts to protect the right to health of their citizens by making drugs affordable.

349. *See* ILO Declaration, *supra* note 262, para. 8.

350. *See* OECD Guidelines, *supra* note 262, at II.2.

351. *See* U.N. Draft Code, *supra* note 216.

As argued in Part II.A, all states have a legal obligation to respect and promote the right to affordable medical treatment, which is linked to the rights to life, health, sharing in the benefits of scientific progress, and development; the lack of affordable HIV/AIDS drugs impinges on all of these rights.[352] The drug companies violate their "soft law" obligations to respect and support states' human rights obligations when they obstruct the efforts of developing countries to promote and fulfill the human rights to health, life, medical treatment, development, and an equitable distribution of the benefits of scientific progress.[353]

In practice, the actions of the drug companies have resulted in the direct loss of millions of lives that could have been saved through the availability of generic drugs.[354] South Africa's law explicitly sought to make HIV/AIDS drugs more widely available through generic competition.[355] If South Africa had proceeded with the implementation of its law as planned, a great number of HIV-positive South Africans would have been able to buy HIV/AIDS drugs that they could not have otherwise afforded.[356] By bringing a lawsuit that delayed the implementation of South Africa's provisions for more affordable medicines, the drug industry effectively prevented those people from gaining access to treatment that would have significantly enhanced and prolonged their lives.[357]

Furthermore, the industry has consistently misused its considerable influence to cause the United States to pressure countries such as South Africa to forego generic competition, often resulting in the U.S. government sanctioning those countries.[358] Although many countries have promulgated laws promoting generic competition, countries have been hesitant to implement those laws because they fear retaliation by the U.S. government at the behest of the major drug companies.[359] Thus, millions of people in the developing world continue to perish, even though studies confirm that the availability of generic HIV/AIDS drugs could save lives.[360] Although other factors, such as the lack of health infrastructure in developing countries, admittedly play a role in determining the effective access to drugs, it is absurd to

352. *See supra* notes 292-306 and accompanying text.

353. *See supra* notes 170-73, 187-88 (describing drug companies' actions to interfere with states' efforts to promote access to HIV/AIDS drugs).

354. *See supra* note 2 and accompanying text (describing success of HIV/AIDS drugs at prolonging life).

355. *See* Medicines Act Amendment, *supra* note 10, § 10.

356. *See supra* note 2 and accompanying text.

357. See discussion *supra* Part II.B.1 for a detailed account of the drug industry's lawsuit against South Africa.

358. *See* Sell, *supra* note 12, at 495.

359. *See supra* note 189 and accompanying text (describing developing countries' fear of enacting laws allowing compulsory licensing).

360. *See supra* note 2 and accompanying text.

suggest that patents are not to blame for the lack of access to drugs.[361] As such, the pharmaceutical industry's aggressive lobbying of the U.S. government, to take action against countries which enact measures that limit drug patent rights in order to save lives, violates the emerging human right to affordable HIV/AIDS drugs.[362]

The drug companies' rights to intellectual property, and thus the right to charge the prices they choose, are appropriately limited to those rights that are consistent with internationally recognized human rights.[363] As the World Health Assembly, a multilateral institution representative of the international community, has asserted, the right to health should be paramount to intellectual property rights.[364] Thus, the multilateral standards effectively call on drug companies to interpret their intellectual property rights under TRIPS in a manner that is consistent with human rights.[365] The Doha Declaration confirmed that TRIPS can and should be interpreted consistently with human rights.[366] Particularly in light of the Doha Declaration, drug companies should interpret TRIPS consistently with their human rights obligations.[367]

Just as TRIPS imposes obligations on states to offer the specified patent protection, international law imposes an even more critical obligation on states: the duty to fulfill the rights of their populations to life-saving medical care.[368] These two obligations should be read consistently with each other, and not as mutually exclusive.[369] The purpose of TRIPS could not be to subordinate the human rights obligations of states to their trade imperatives, particularly given the vast array of public interest exceptions that TRIPS affords WTO member states.[370]

Human rights activists have criticized the pharmaceutical industry for trying to have it both ways, i.e., benefiting from the strong patent protection provisions of TRIPS, while challenging countries that seek to take legal advantage of other TRIPS provisions, namely compulsory licensing and parallel importing.[371] Large corporations are the major beneficiaries of the strong protectionist regime for

361. See *supra* notes 34-48 and accompanying text for a discussion of the debate over whether patents are responsible for impeding access to HIV/AIDS drugs.

362. *See supra* notes 170-73 and accompanying text (describing negative consequences that drug company lobbying of U.S. government had for South Africa).

363. *See supra* notes 218-57 and accompanying text.

364. *See supra* notes 175-76 and accompanying text.

365. *See* Cohn, *supra* note 14, at 435-37; Call for Action, *supra* note 14; *see also* supra notes 218-57 (defining the human rights at stake).

366. Doha Declaration, *supra* note 117.

367. *Id.*

368. *See supra* notes 292-306 and accompanying text.

369. Human rights and intellectual property rights should be understood as complementary rights.

370. *See* sources cited *supra* note 94.

371. *See, e.g.*, Call for Action, *supra* note 14.

intellectual property embodied in TRIPS.[372] The strong patent protection that developing nations must provide drug companies under TRIPS carries high social and economic costs to the state and its citizens.[373] The quid pro quo for the strong patent protection afforded pharmaceutical corporations by WTO member states is, at the minimum, respect for state policies consistent with TRIPS.[374] Thus, pharmaceutical companies violate their obligations under the "soft law" standards when they challenge states that invoke the explicit TRIPS provisions that allow states to address health crises such as the HIV/AIDS epidemic.[375]

CONCLUSION

Intellectual property rights are important to the research and development of HIV/AIDS drugs, and deserve protection. But intellectual property rights do not, and should not, trump human rights. Through its various public interest exceptions to patent protection, TRIPS makes clear that, under certain circumstances, it is legal and appropriate to limit intellectual property rights to achieve broader societal goals. Given the magnitude of the AIDS pandemic in developing countries and the widespread lack of financial access to HIV/AIDS drugs in those countries, laws like the Medicines Act Amendment are an appropriate limitation on intellectual property rights.

International human rights law is catching up with the HIV/AIDS epidemic, and is increasingly acknowledging the human rights of HIV/AIDS patients, including the right to affordable HIV/AIDS treatment. Developing countries have an obligation under international law to provide their citizens with affordable HIV/AIDS drugs, and drug companies have a "soft law" obligation under the multilateral corporate codes of conduct to respect developing states' efforts to protect the right to affordable HIV/AIDS treatment.

372. *See supra* note 88 and accompanying text.

373. *See supra* note 93 and accompanying text.

374. *See supra* note 125 and accompanying text (discussing South Africa's drug policy).

375. See generally Part I.B for a description of the ways in which drug companies impeded South Africa and other countries from making HIV/AIDS drugs more affordable.