Balancing Intellectual Property Protection with the Human Right to Health

By

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"We must not tolerate the current policy that dictates that life with a manageable illness is possible if you are wealthy, but death from AIDS is certain if you are poor."¹

~ U.S. Congresswoman Barbara Lee

In 2003, the Human Immunodeficiency Virus (HIV) newly infected an estimated five million people worldwide; three million died of complications related to Acquired Immunodeficiency Syndrome (AIDS).² Since its discovery in the 1980s, AIDS has killed twenty-two million people worldwide, leaving thirteen million AIDS orphans.³ The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates that between thirty-four and forty-six million people around the world are living with the condition.⁴ While sub-Saharan African states have suffered the worst epidemics to date, UNAIDS and the World Health Organization (WHO) predict new outbreaks in North Africa, India, China, states in Central Asia, and the Baltic states.⁵ HIV/AIDS rates in Latin America are also rising.⁶ Globally, costly anti-retroviral drugs that

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^{1.} Press Release, Barbara Lee, Congresswoman Barbara Lee Supports Pharmaceutical Companies' Decision to Drop Lawsuit Against South Africa (Apr. 19, 2001), at http://www.house.gov/lee/releases/01Apr19.htm (last visited Apr. 11, 2005).

^{2.} UNAIDS - WHO, AIDS Epidemic Report 3 (Dec. 2003), at http://www.unaids.org/Unaids/EN/Resources/Publications/corporate+publications/aids+epidemic+u pdate+-+december+2003.asp (last visited Apr. 11, 2005).

^{3.} Gregor Adams et al., Consensus Statement on Anti-retroviral Treatment for AIDS in Poor Countries, 3 (Mar. 2001), at http://www.hsph.harvard.edu/hai/conferences_events/2001/consensus_aids_therapy.pdf (last visited Apr. 11, 2005).

^{4.} UNAIDS - WHO, supra note 2, at 2-3.

^{5.} Id. at 7, 14, 18-19, 21, 26.

^{6.} Id. at 23 ("More than 2 million people are now living with HIV in Latin America and the Caribbean, including the estimated 200,000 that contracted HIV in the past year."). A 2003 Health GAP report estimated two million HIV-positive individuals in Latin America. See Press Release,

prolong the lives and improve the health of infected individuals do not reach the almost 90% of HIV/AIDS patients living in the poorest 10% of the world's countries.7

South Africa's experience with the AIDS crisis provides a representative example of the deadly combination of poverty and patent protection in the context of public health disasters. With less than 2% of the global population, South Africa is home to 30% of the world's HIV/AIDS-infected people and to 80% of those patients who cannot afford their own healthcare.⁸ Though effective generic anti-retroviral drug therapies can sell for as little as \$140 for one year's supply, patent protections prevent their sale in most developing countries.⁹ According to a lawyer for South Africa's Aids Law Project, "[i]n South Africa, tens of thousands of people are dying every year because excessive prices are charged for life-saving anti-retroviral medicines."¹⁰ The worst is probably yet to come for South Africa, where lack of access to effective medication will facilitate the rapid spread of AIDS-related deaths over the next five years.¹¹ In 2003, UNAIDS and the WHO determined that the immediate implementation of a national anti-retroviral program in South Africa would "significantly cushion the country against the impact" of the AIDS crisis.¹² Nevertheless, as of October 2003, no generic anti-retrovirals were available in South Africa, despite the plentitude of successful generic versions produced in India and Brazil.¹³

HIV/AIDS patients in South Africa and throughout the global South would substantially benefit from the increased affordability of generic anti-retroviral drug therapies. Yet in 2002, out of an estimated twenty-eight million people in sub-Saharan Africa living with HIV/AIDS, only 50,000 people, or less than 0.2%, had access to such treatment.¹⁴ This limited access largely results from patent protections held by multinational pharmaceutical corporations that maintain inflated drug prices and severely restrict the generic manufacture of anti-retrovirals.15

10. Nawaal Deane, SA Generic Aids Drugs Breakthrough, MAIL & GUARDIAN, Oct. 16, 2003, available at http://www.journ-aids.org/reports/16102003f.htm (last visited Apr. 11, 2005).

11. UNAIDS - WHO, supra note 2, at 9.

Health GAP, HGAP on FTAA Miami Ministerial (Nov. 3, 2003), at http://www.healthgap.org (last visited Apr. 11, 2005) [hereinafter Health GAP].

^{7.} John A. Harrelson, TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion, 7 SPG WIDENER L. SYMP. J. 175, 176 (2001). Anti-retroviral drugs block the retroviral replication of HIV and are the only known effective treatment for HIV/AIDS. See BBC News World Edition, Q&A: Anti-Retroviral Drugs (Oct. 24, 2003), at http://news.bbc.co.uk/2/hi/health/3210669.stm (last visited Apr. 11, 2005).

^{8.} Adams, supra note 3, at 15; UNAIDS - WHO, supra note 2, at 8.

^{9.} Adams, supra note 3, at 14; Health Gap, supra note 6, at 1 ("Generic competition has driven down the price of AIDS drugs by more than 98 percent, from \$10,000 to \$140 per person, per year.").

 ^{12.} Id. at 13.
 13. See Deane, supra note 10.

^{14.} UNAIDS - WHO, supra note 2, at 5, 13.

^{15.} See Harrelson, supra note 7, at 175-77.

Drug-patent supporters argue that patents guarantee profit returns, which in turn enable continuing research and development. Public health advocates counter that the unfolding AIDS catastrophe requires a more immediate palliative than the distant hope of discovering a cure or treatment, neither of which would likely be any more accessible to infected populations than current patented drug therapies. Tensions between intellectual property protection and the health needs of their impoverished people plague the leaders of developing states, who fear endangering trade relations with wealthy states should they violate the patent rights enforced through various international agreements.¹⁶

This paper will explore whether existing international law creates a right to health that includes a right to generic, or at least affordable, anti-retroviral treatment, enforceable against state and non-state actors seeking to maintain patent protection. It will further consider whether relaxing patent protection is a feasible means toward the ultimate goal of substantially increasing access to anti-retroviral treatment. AIDS is a global threat with unique impacts on many regions; this paper will focus primarily on the impact of U.S. patent-protection policy in sub-Saharan Africa.¹⁷ Part I presents the need for increased access to anti-retroviral treatment. Part II examines patent-related barriers to access. Part III summarizes sources of international law that suggest the existence of a right to health that would be enforceable against both domestic governments and third parties, such as other states and multinational corporations. Part IV turns to policy arguments that might encourage wealthier states to take proactive measures to increase access, even at the expense of patent protection. Part V suggests methods for easing patent restrictions that would be consistent with the goal of immediately increasing access to anti-retroviral drug therapy for the world's poorest and most vulnerable HIV/AIDS victims.

I.

MAKING THE CASE FOR INCREASED ACCESS TO TREATMENT

A daily cocktail of anti-retroviral medication has transformed HIV/AIDS into a "treatable and chronic" condition for individuals who can afford the treatment.¹⁸ An effective anti-retroviral regimen reduces the viral load, diminishes the virus's ability to replicate itself in the bloodstream of infected patients, decreases the risk of transmission, and encourages participation in

^{16.} See, e.g., James Thuo Gathii, Rights, Patents, Markets, and the Global AIDS Pandemic, 14 FLA. J. INT'L L. 261, 326 (2002) [hereinafter Gathii, Global AIDS Pandemic] (describing the "coercive bargaining framework within which TRIPS [Trade-Related Aspects of Intellectual Property Rights Treaty] was accepted").

^{17.} This is not to suggest that U.S. policy is solely responsible for enforcing patent protection; European countries, for example, have also imposed intellectual property protection in developing countries. See Debora Halbert, Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs, 1 SEATTLE J. FOR SOC. JUST. 257, 266 (2002) (noting that both U.S. and European pharmaceutical companies sell patented drugs in Africa at "brand name" prices).

^{18.} Adams, supra note 3, at 3.

prevention efforts.¹⁹ The WHO reports that since its introduction nine years ago, anti-retroviral therapy has led to significant reductions in morbidity and mortality rates where the treatment is widely available.²⁰ In wealthy states, rates of AIDS-related deaths and mother-to-child transmissions have dropped by as much as 50% with the introduction of anti-retroviral treatment.²¹ Consistent access to anti-retroviral treatment can significantly prolong life expectancy and increase productivity and quality of life, while concomitantly decreasing the rate of hospitalization and related public health care costs.²² With adequate access, anti-retroviral therapy can transform AIDS into a treatable condition rather than an early death sentence.²³

Despite the proven efficacy of anti-retroviral treatment in stabilizing infection and prolonging life expectancies, donor states and international organizations often choose to focus on prevention, at the expense of treating those who are already infected.²⁴ Prevention is obviously crucial to ending the epidemic, but a one-pronged approach is destined to fail, in no small part because prevention efforts rely on individuals' voluntary agreement to be tested; little such incentive exists when people know that treatment is unavailable should they test positive.²⁵ According to a joint UNAIDS – WHO report, "[i]ncreased access to treatment is one of the most powerful incentives for individuals to learn their HIV status," which in turn assists prevention measures.²⁶

Additionally, while the crisis of course destroys individual lives, it also undermines societal stability. Many sub-Saharan states ravaged by HIV/AIDS stand to lose substantial portions of their populations to early AIDS-related deaths.²⁷ USAID has predicted that average life expectancy in eleven sub-Saharan countries by the year 2010 will be thirty.²⁸ Alex de Waal, director of

23. Adams, supra note 3, at 3 ("Until a few years ago, HIV infection led almost inevitably to an early death from AIDS. However, ... the disease has been transformed into a treatable and chronic condition for ... those with access to this treatment.").

24. See, e.g., the Washington Office on Africa, Health and Human Welfare: Confronting the AIDS Pandemic in Africa, available at http://www.woaafrica.org/AIDSmill.htm (last visited Apr. 11, 2005) (noting that while a recent report in Science found that "the world's poorest countries will need \$9.2 billion annually-\$4.4 billion for treatment, and \$4.8 billion for prevention," the USAIDS administrator has argued that U.S. financial resources should only fund prevention, not treatment.).

25. Id. at 4. 26. UNAIDS - WHO, supra note 2, at 33.

 Id. at 4, 13.
 USAID, Remarks by Dr. Anne Patterson, Confronting AIDS in 2002: Moving Forward XIV International AIDS Conference (July 24, 2002), at the from http://www.usaid.gov/press/spe test/speeches/2002/sp020724_1.html (last visited Apr. 11, 2005).

^{19.} Id. at 1, 4, 6.

^{20.} HIV/AIDS Treatment: Anti-Retroviral Therapy, Fact Sheet Euro/06/03, World Health (Dec. 1, 2003), available at Europe Organization http://www.euro.who.int/mediacentre/FactSheets/20031201 2 (last visited Apr. 11, 2005).

Adams, supra note 3, at 6.
 In Brazil, for example, the integration of treatment and prevention strategies effected a dramatic reduction in HIV/AIDS-related hospitalizations. James Thuo Gathii, The Structural Power of Strong Pharmaceutical Patent Protection in U.S. Foreign Policy, 7 J. GENDER RACE & JUST. 267, 288 (2003) [hereinafter Gathii, Structural Power].

Justice Africa and the United Nations Commission on HIV/AIDS and Governance in Africa, has identified a variety of structural dangers likely to flow from the rapidly shrinking life expectancy in AIDS-rayaged countries. including diminished savings rates, concurrent increases in the cost of capital. costly increases in the turnover of employed staff, reduced returns from investments in higher education and employment training, diminished intergenerational accumulation of capital and knowledge transmission, and an adverse shift in dependency ratios.²⁹ According to de Waal, shrinking life expectancies will cripple the labor forces of impacted states, effecting an "early death payroll tax" that will inflate the cost of goods and services.³⁰ Local and national capital markets will suffer as households fail to accumulate capital. resulting in a downward spiral of decreased productivity, especially for agrarian sectors.³¹ As agricultural production declines and communities lose their ability to respond, famine could foreseeably lead to political instability and violence that, in an increasingly globalized world, would certainly have ripple effects that extend far beyond the borders of sub-Saharan Africa.³²

The proven success of anti-retroviral medications in prolonging life expectancy and increasing productivity for HIV/AIDS patients indicates that increasing access would help to counteract the otherwise decimating toll AIDS has and will continue to inflict on the political, social, and economic structures of developing states. As I explore in the next Part, however, the current state of international patent protection for intellectual property rights serves as a stubborn barrier to increased access to affordable anti-retroviral drugs.

II.

PATENT-RELATED BARRIERS TO ACCESS

A. The Illogic of the "Poverty, not Patents" Argument

With as little as \$8 to spend on health care per person annually, the governments of most sub-Saharan states cannot afford the \$10,000 price tag for a year's supply of name-brand anti-retrovirals.³³ Some patent supporters point

32. Id. at 14.

Patterson comments, "In 2010, 11 countries in sub-Saharan Africa will see life expectancies fall to near 30 years, levels not seen since the end of the 19th century. In a region that would have estimated life expectancies to reach 70 years of age by 2010, Botswana's life expectancy will be 27 years, Swaziland, 33 years and Namibia and Zambia, 34 years." Id.

^{29.} Alex de Waal, Why the HIV/AIDS Pandemic Is a Structural Threat to Africa's Governance and Economic Development, 27 FLETCHER F. WORLD AFF. 6, 8-9 (2003), available at http://fletcher.tufts.edu/forum/27-2pdfs/deWaal.pdf (last visited Apr. 11, 2005). A "dependency ratio" is the ratio of dependents to those in the "productive" sector; de Waal relies on a cutoff age of sixteen. See id. at 10 (noting that "[t]he distortions to the age structure within the adult population mean that there are many in the age category of 16 to 25 and fewer mature adults").

 ^{30.} Id. at 11.
 31. See id.

^{33.} Adams, supra note 3, at 15 ("Ghana, Nigeria, and Tanzania have . . . public-sector health

to the limited public health resources of these countries to argue that domestic poverty levels alone explain the lack of access to treatment.³⁴ Surely poverty and under-resourced public health infrastructure are major barriers to access to costly medications. But it is also true that prices remain high, and therefore out of reach, because of patent protection. In pitting poverty as the sole culprit for the crisis, this "poverty, not patents" argument simultaneously, and paradoxically, urges continued patent protection to ensure further research that will somehow increase availability through the discovery of new treatments.³⁵ However, the logic of this argument does not add up; these new treatments will likely also enjoy strong patent protection and remain out of reach for the world's poor, making this an empty bargain for the millions of HIV/AIDS patients who cannot even afford existing treatment.

Advocates of the "poverty, not patents" perspective point to skeletal public health programs in many AIDS-ravaged countries to argue that even if access to affordable generics increased, no infrastructure exists for proper disbursement and monitoring.³⁶ The argument goes as follows: without substantial public health infrastructure, patients will not be able to adhere to the treatment cycle, rendering the drugs ineffective and facilitating drug-resistant viral strains.³⁷ Yet recent studies have concluded otherwise. Patients in Brazil, Kenya, Senegal, and India have adhered to treatment programs as strictly as patients in wealthy western states.³⁸ Research has also attested to the quality and efficacy of generically manufactured anti-retrovirals.³⁹

James Thuo Gathii argues that western governments, in cohort with pharmaceutical corporations, have over-emphasized the role of poverty in restricting access to anti-retrovirals.⁴⁰ The Executive Vice President of Bristol Myers-Squib, which produces the AIDS drug Zerit, for example, denied the impact of patent-based profits on the AIDS crisis, claiming that "[AIDS] is

budgets [of] \$8/patient-year or less-far too little to deal with basic health needs, much less AIDS treatment."); Health GAP, *supra* note 6 (pricing non-generic anti-retrovirals at \$10,000); James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently With Facilitating Access to Affordable AIDS Drugs to Low-End Customers*, 53 FLA. L. REV. 727, 734 (Sept. 2001) [hereinafter Gathii, *Intellectual Property*].

^{34.} See, e.g., Gathii, Structural Power, supra note 22, at 268 (analyzing U.S. foreign policy with regards to AIDS initiatives).

^{35.} Id. at 301.

^{36.} Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Scrutiny*, 25 HUM. RTS. Q. 425, 444 (2003), *available at* http://muse.jhu.edu/journals/human_rights_quarterly/v025/25.2 joseph.pdf (last visited Apr. 11, 2005).

^{37.} Id.

^{38.} Id. at 445.

^{39.} See id. at 444 (observing that "Western government healthcare providers have shown a marked increase in their faith in generics by purchasing cheaper generic alternatives once patents expire"). See also Ben Hirschler, Cheap Indian AIDS Pill as Good as Pricey Brands, available at http://www.natap.org/2004/Bangkok/bangkok_01.htm (last visited Apr. 11, 2005) (announcing the joint research findings of the French National Agency for AIDS Research and Médecins Sans Frontières).

^{40.} Gathii, Structural Power, supra note 22, at 273.

about poverty."⁴¹ Such arguments should come as no surprise, as pharmaceutical corporations have a financial interest in framing this humanitarian crisis as one of poverty rather than affordability. They also cast AIDS as a strictly social condition rather than an infectious disease, a notion not unique to pharmaceutical conglomerates. South African President, Thabo Mbeki, for example, misguidedly asserted that "extreme poverty" is the primary culprit of sub-Saharan Africa's public health ravages, not the HIV virus.⁴²

The circular "poverty, not patents" argument assumes that high prices are a given and that poverty is synonymous with an inability to afford medication. But high prices are not a given; based on the examples of India and Brazil, relaxing patent standards for developing countries by condoning generic manufacture and parallel imports⁴³ dramatically lowers prices and increases access to anti-retroviral treatment.⁴⁴ Instead of poverty, the true barrier to access is unaffordability. This idea should empower those who are truly concerned with combating the AIDS epidemic because, while poverty is a multi-dimensional problem with no immediate solution, current technology already allows for the manufacture of affordable generic treatment. Yet patent protections presently suppress the production of effective generic anti-retrovirals, to the detriment of the world's poorest HIV/AIDS patients.

B. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights Treaty (TRIPS)

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the first international treaty to establish a minimum international standard of intellectual property protection.⁴⁵ The concept that intellectual property merits patent protection is not universally accepted.⁴⁶ Prior to TRIPS, countries were only legally obliged to honor patents reciprocally and could opt to exempt certain inventions from patent protection altogether.⁴⁷ Since 1995, however, TRIPS has transformed patent law, traditionally a "national prerogative," into an internationally enforceable

^{41.} Karen DeYoung & Bill Brubaker, Another Firm Cuts HIV Drug Prices, WASH. POST, Mar. 15, 2001, at A1.

^{42.} Emelia Sithole, *Mbeki Opens AIDS Conference Stressing Poverty*, REUTERS NEWMEDIA, July 9, 2000, *at* http://www.aegis.com/news/re/2000/RE000714.html (last visited Apr. 11, 2005) (quoting Mbeki as saying that he "could not blame everything on a single virus").

^{43.} Carlos Correa defines "parallel import" as the "importation, without the authorization of the owner of an intellectual property right, of a protected product marketed abroad by the patentee or by an authorized party." CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES xiv (2000), available at http://www.southcentre.org/publications/publichealth/ toc.htm (last visited Apr. 11, 2005). See also infra note 60 and accompanying text.

^{44.} See Deane, supra note 10; Gathii, Structural Power, supra note 22, at 288.

^{45.} Gathii, Structural Power, supra note 22, at 278.

^{46.} Harrelson, supra note 7, at 176.

^{47.} Gathii, Intellectual Property, supra note 33, at 760-61; Gathii, Structural Power, supra note 22, at 278.

institution through rigid treaty terms and a compulsory, binding dispute resolution procedure.⁴⁸ TRIPS may even impose more restrictive patent protections than traditional U.S. domestic patent law: leaders of member states have little choice over the scope of patent rights they can grant, whereas a federal employee of the U.S. government may legally use or authorize use of a patent or copyright at her discretion.49

Facially, TRIPS allows some flexibility in pharmaceutical manufacturing. Article 7 appears to promote the transfer of the fruits of intellectual property to developing countries, asserting that 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."⁵⁰ Article 8 grants members the right to "adopt measures necessary to protect public health and nutrition" and to "prevent the abuse of intellectual property rights ... or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."⁵¹ Article 31 explicitly provides for compulsory licensing⁵² if the patent-holder receives fair compensation for this derogation of patent rights and if the use is non-commercial, non-exclusive, non-assignable, and limited to the domestic market. All license-issuing decisions remain subject to review by a higher authority than the member state.⁵³

TRIPS undercuts the flexibility these provisions might otherwise afford developing states, however, by simultaneously requiring that such measures be consistent with the patent-protection provisions of the agreement. Exactly what measures a member state might adopt that would be consistent with other TRIPS provisions has engendered a debate between developing states and wealthier states seeking to enforce patent protection. Additionally, TRIPS has created confusion as to what constitutes a "national emergency" under Article 31(b), whether individual members have the right to define such an emergency, and how much discretion developing states enjoy to utilize any patent-related flexibilities TRIPS appears to grant.54

The Declaration on the TRIPS Agreement and Public Health (Doha

^{48.} Gathii, Structural Power, supra note 22, at 278.

Id. at 281 (citing 28 U.S.C. § 1498(a) (1996)).
 Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 31 Marrakesh Agreement Establishing the World Trade Organization, Annex IC, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994), available at http://www.wto.org/english/docs e/ legal e/27-trips 01 e.htm (last visited Apr. 11, 2005) [hereinafter TRIPS].

^{51.} Id. at art. 8(1)-(2).

^{52.} A compulsory licensing agreement permits a country facing a public health crisis to manufacture a generic drug before the expiration of the brand name's patent. See WTO, MINISTERIAL CONFERENCE 4th Sess. Doha (Nov. 9-14, 2001).

^{53.} TRIPS, supra note 50, at art. 31(a)(i).

^{54.} That a member's decision to issue compulsory licenses based on national-emergency grounds are subject to higher review suggests individual members do not have the right to declare such an emergency on its own.

Declaration), created at the fourth session of the WTO Ministerial Conference, seeks to clarify these facially conflicting obligations.⁵⁵ The domestic-use restriction, for example, withholds the utility of these licensing flexibilities from the very poorest of countries that lack their own manufacturing capabilities. For this reason, the drafters of the Doha Declaration favor an interpretation of Article 6—which explicitly declines to address patent exhaustion—that would allow for parallel imports.⁵⁶

U.S. HIV/AIDS policy tends to prioritize the protection of intellectual property rights.⁵⁷ Intellectual property firms have driven the U.S. economy and political machine for many years, leading to a concentration of knowledgeintensive sectors with significant political influence.⁵⁸ Pharmaceutical companies are powerful lobbying entities in the United States and other western countries: the Pharmaceutical Research and Manufacturing Association (PhRMA) and its member companies contributed over \$50 million to Republican Congressional candidates in the 2002 U.S. elections.⁵⁹ Their platform is that, rather than a barrier, patents are crucial to public health initiatives because they offer the promise of a cure.⁶⁰ Again, the unlikelihood that the world's poor would enjoy access to this distant cure deflates the appeal of this argument to public health advocates.

U.S. HIV/AIDS policy reflects the PhRMA perspective, however, with U.S. leaders asserting that intellectual property protection is the best means for facilitating later access to affordable HIV/AIDS medications and that TRIPS does not impose unfair restrictions.⁶¹ President Clinton, for example, while giving lip-service to the sovereignty of member states to declare health emergencies, in his Executive Order removing South Africa from the infamous United States Trade Representative (USTR) Section 301 Watch List, required AIDS-ravaged states to honor intellectual property rights as consistent with TRIPS in order to benefit from U.S. support.⁶² Since the final Uruguay round of the TRIPS agreements, the United States has forced even stricter patent-related bilateral agreements with members who can neither afford to lose the United States as a trading partner nor risk being placed on the Section 301 Watch List.⁶³ Such a strong U.S. commitment to intellectual property

^{55.} See generally Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, 4th Sess., Doha Ministerial Conference, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration].

^{56.} Id. at \P 6 ("For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.").

^{57.} Gathii, Structural Power, supra note 22, at 294.

^{58.} Susan K. Sell, Trade Issues and HIV/AIDS, EMORY INT'L L. REV. 933, 942 (Summer, 2003).

^{59.} Id. at 947.

^{60.} Id. at 938.

^{61.} Gathii, Structural Power, supra note 22, at 295-96.

^{62.} Exec. Order No. 13,155, 65 Fed. Reg. 30,521, 30,522 (May 10, 2000).

^{63.} Sell, *supra* note 58, at 934-35, 944. Many commentators have noted the coercive bargaining environment of the TRIPS negotiations, citing the fact that developing countries in need

protection and patents comes directly at the expense of increasing access to lifeprolonging anti-retrovirals for the world's poor.

In addition to these supplemental bilateral agreements, the United States has pursued legal action through the WTO to enforce various TRIPS provisions against developing states.⁶⁴ The United States has threatened both Brazil and South Africa, for example, with trade sanctions for making efforts to pursue generic pharmaceutical manufacturing.⁶⁵ Susan Sell explains that such "[a]symmetrical power relationships effectively have reduced choices available to developing countries."⁶⁶ Other strong-arm tactics include severely limiting the compulsory licensing right established in TRIPS. ⁶⁷ These provisions enforce patent-like barriers to generic anti-retroviral medication entering the market, even where no patent law had existed before.

Several factors interweave to limit access to anti-retroviral therapy, including poverty, insufficient public health infrastructure and resources, individual countries' failure to pass anti-discrimination legislation, and sociocultural resistance to implementing prevention programs aimed at mother-tochild transmissions.⁶⁸ Patent protection, which keeps prices inflated up to one hundred times the cost of manufacture, is also a particularly influential factor. A variety of international responses could increase access to treatment. Whereas poverty is harder to eradicate, the global community can immediately target affordability by relaxing patent protection and allowing generic manufacture through compulsory licenses and parallel imports. If a legal duty to provide affordable, accessible treatment exists under international law—as I suggest it does in the following Part—then an effective international response to the AIDS crisis must include an insistence that all states cooperate to create ready accesss to treatment through such patent-relaxing measures.

III.

RIGHT TO TREATMENT UNDER INTERNATIONAL LAW

Human rights advocates concerned with increasing access to treatment point to customary international law and numerous international treaties that declare a justiciable right to health. But if such a right does exist under current international law, does it include access to medication? Do TRIPS and other

of international market access had little choice but to become a TRIPS party. In addition, a country cannot enter a reservation to any TRIPS provision without the express consent of all signatory parties. Developing countries would incur high costs to comply with these legal and policy changes. On the coercive bargaining framework of TRIPS, see Gathii, *Intellectual Property, supra* note 33, at 756-57, 765 ("[T]he United States... unilaterally single[d] out countries opposed to the TRIPS agreement for punitive action unless they complied with United States law."); Sell, *supra* note 58, at 944.

^{64.} Id. at 945.

^{65.} Joseph, supra note 36, at 445.

^{66.} Sell, supra note 58, at 935.

^{67.} Id. at 946.

^{68.} See UNAIDS - WHO, supra note 2, at 13.

patent-protection treaties force poor countries to violate their legal obligation to provide for their citizens' health, as critics of patent protection assert? Do citizens have a cause of action against third parties that impede their own governments' public health efforts? This Part explores whether the right to health established in multiple sources of international law encompasses a right to life-saving medication and whether a country's material incapability to fulfill such a right implicates its treaty partners.

A. Access to Medication as Part of the Right to Health

Alicia Ely Yamin argues that a broad interpretation of the right to life arguably the most basic human right, to which some international tribunals have granted *jus cogens* standing—should include access to life-saving medication if withholding such treatment would otherwise deprive life.⁶⁹ The Universal Declaration of Human Rights (UDHR) establishes "the right to a standard of living adequate for [] health and well-being . . . including . . . medical care and necessary social services."⁷⁰ As a General Assembly declaration, the UDHR is not legally binding, but international legal scholars have suggested that unanimous General Assembly declarations reflect international consensus that might rise to the level of customary international law.⁷¹ In any case, the tenets enunciated in the UDHR surely reflect basic principles that resonate universally.

International legal documents also address the right to health. The Constitution of the WHO, for example, provides for the "enjoyment of the highest attainable standard of health" as a fundamental right, with health defined as a "state of complete physical, mental and social well-being."⁷² Article 6(1) of the International Covenant on Civil and Political Rights (ICCPR) establishes a right to life, which, as Yamin interprets, could require states' affirmative efforts to enable "conditions that permit, at a minimum, survival and ... [promote] dignity and well-being."⁷³ The International Covenant on Economic,

^{69.} Alicia Eli Yamin, Not Just a Tragedy: Access to Medications as Right Under International Law, 21 B.U. INT'L L.J. 325, 330-31 (Fall, 2003). On the right to life as a peremptory norm, Yamin cites the "Street Children Case." Street Children Case (Morales v. Guatemala), Judgment of Nov. 19, 1999, Case No. 63 Inter-Am. C.H.R. 139 (Ser. C) P 139, available at www.corteidh.or.cr/seriecpdf_ing/seriec_77_ing.pdf (last visited Apr. 11, 2005).

^{70.} Universal Declaration of Human Rights, pmbl., G.A. Res. 217A, U.N. GAOR, 3d Sess., U.N. Doc. A/810 (1948) [hereinafter UDHR] ("Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including... medical care and necessary social services."). I argue that this obligation would require special care for vulnerable health populations such as impoverished HIV/AIDS patients.

^{71.} On the relationship between unanimous General Assembly declarations and customary international law, see Gregory J. Kerwin, *The Role of United Nations General Assembly Declarations in Determining Principles of International Law in United States Courts*, 1983 DUKE L.J. 876 (Sept. 1983).

^{72.} Constitution of the World Health Organization, *opened for signature* July 22, 1946, 14 U.N.T.S. 185, 186, pmbl., *available at* http://whqlibdoc.who.int/hist/official_records/constitution.pdf (last visited Apr. 11, 2005).

^{73.} Yamin, supra note 69, at 331 (referring to the International Covenant on Civil and Political Rights, G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No. 16, at 52, U.N. Doc. A/6316

Social, and Cultural Rights (ICESCR) expressly addresses the right to health.⁷⁴ Article 15 guarantees all individuals the right to the benefits of scientific progress, which could include access to break-through medications.⁷⁵ The Committee on Economic, Social, and Cultural Rights (ESCR) has interpreted health as addressed in the ICESCR to be "a fundamental human right indispensable for the exercise of other human rights" and concluded that "[e]very human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity."⁷⁶

Current debate is challenging an older understanding of rights that did not consider social rights, like the right to health under the ICESCR, to bind states legally. It is well settled that a civil-political right is immediately justiciable against one's government regardless of state resources, but an economic, social, or cultural right is still generally thought to be non-justiciable and therefore subject to the limitations of a state's available funds.⁷⁷ Under the ICESCR, states have a progressive, rather than immediate, obligation to honor the non-justiciable rights articulated therein.⁷⁸ Vague language on rights to "scientific progress," "highest attainable standards," and "dignity" further weakens an argument on the existence of a right to health under the ICESCR. While one could read provisions to indicate a right to health, their openness leaves interpretative questions and ambiguity that parties on either side of the right-to-treatment debate can exploit to support their position.

In 2000, the ESCR sought to elucidate and fortify the original treaty language on the right to health. Its General Comment Number 14 (Comment 14) specifies that the right to health under Article 12.1 is not simply a right to be healthy but rather a requirement that a state provide "a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health."⁷⁹ Comment 14 also addresses economic accessibility, asserting that "[e]quity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer

^{(1966), 999} U.N.T.S. 3, 6 I.L.M. 368, available at http://www.unhchr.ch/html/menu3/b/a_ccpr.htm (last visited Apr. 11, 2005)).

^{74.} International Covenant on Economic, Social, and Cultural Rights, G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N. Doc A/6316 (1966), 993 U.N.T.S. 3, 6 I.L.M. 360, available at http://www.unhchr.ch/html/menu3/b/a_cescr.htm (last visited Apr. 11, 2005) (recognizing "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health") [hereinafter ICESCR].

^{75.} Id. at art. 15.

^{76.} General Comment No. 14: The Right to the Highest Attainable Standard of Health, U.N. Committee on Economic, Social and Cultural Rights, 20th Sess., U.N. Doc. E/C.12/2000/4, ¶ 1 (2000), *available at* http://www.law.washington.edu/courses/kuszler/H540_Sp05/Documents/general_comment_14.pdf (last visited Apr. 11, 2005) [hereinafter Comment 14].

^{77.} See Jeanne M. Woods, Justiciable Social Rights as Critique of the Liberal Paradigm, 38 TEX. INT'L L.J. 763, 767 (2003) (describing "economic, social, and cultural rights remain the normatively underdeveloped stepchild of the human rights family").

^{78.} ICESCR, *supra* note 74, art. 2(1).

^{79.} Comment 14, supra note 76, at ¶ 8.

households"⁸⁰ and interprets the state's obligation in Article 12.2(d) to create "conditions which would assure to all medical service and medical attention in the event of sickness," including "provision of essential drugs."⁸¹ Comment 14 further requires states to observe an "immediate [rather than progressive]... obligation to take steps ... toward the full realization of Article 12. Such steps must be deliberate, concrete and targeted towards the full realization of the right to health."⁸² This interpretation would appear to oblige ICESCR signatories—in addition to trained medical and professional personnel⁸³—to make available lifesaving medications, such as those listed by the WHO Action Programme on Essential Drugs.⁸⁴

Comment 14's real utility in the realm of patents is its demand that states: (1) respect "the enjoyment of the right to health in other countries;" (2) prevent third parties over which they have legal or political authority from violating that right within the territory of other states; and (3) refuse to enter into international agreements that "adversely impact [their citizens'] right to health."⁸⁵ States owe a specific legal duty to "control the marketing of medical equipment and medicines by third parties" and to "ensure that third parties do not limit people's access to health-related... services."⁸⁶ Such an interpretation would require states to prevent third parties, such as pharmaceutical corporations, from using patent rights in a manner that impedes access to treatment for their citizens. Because ICESCR parties are states, and not individuals, only states and not their individual citizens would have a cause of action against another state that failed to regulate the policies of its own corporations, if those policies impeded the first state's ability to provide for its citizens' health.

The ICESCR's interpretation of the right to health would support a legal conclusion that developing states who sign TRIPS and TRIPS-like agreements, which objectively restrain their ability to provide affordable generic drugs to their people, might violate their citizens' right to health, as would wealthier states who draft and impose the terms of patent protection that keep life-saving medications out of reach.

Other international legal documents that address a right to health include the Convention on Rights of the Child, which obliges state parties to "recognize that every child has the inherent right to life" and to "ensure to the maximum

85. Comment 14, *supra* note 76, at ¶ 39.

86. Id. at ¶ 35.

^{80.} Id. at ¶ 12(b).

^{81.} Id. at ¶ 17.

^{82.} Id. at ¶ 30.

^{83.} Comment 14 asserts that "all members of society—individuals, including health professionals... as well as the private business sector—have responsibilities regarding the realization of the right to health." Id at ¶ 42.

^{84.} The WHO Action Programme on Essential Drugs included thirteen anti-retroviral medicines on its 2003 Essential Drugs List. See WHO Department of Essential Drugs and Medicine Policy, Essential Drugs in Brief, Mar. 19, 2003, at http://www.who.int/medicines/organization/par/edl/expcom13/eml13_en.pdf (last visited Apr. 11, 2005).

extent possible the survival and development of the child," which could be interpreted as creating a child's right to health.⁸⁷ Similar provisions exist in the International Convention on the Elimination of All Forms of Racial Discrimination⁸⁸ and the Convention on the Elimination of All Forms of Discrimination Against Women.⁸⁹ Regional agreements include the African Charter on Human and Peoples' Rights, ⁹⁰ the European Social Charter,⁹¹ and the American Declaration of Rights and Duties of Man.⁹² While these documents only bind signatories, the prevalence of multi-national legal agreements addressing health support a view of the right to health as emerging customary international law.⁹³ Numerous domestic constitutions establishing a right to health and the demonstrated commitment of high domestic courts to enforce this right against the state further bolster the assertion that an international consensus exists on a right to health and treatment.⁹⁴ In its Declaration of Commitment on HIV/AIDS, the General Assembly has also averred support for this interpretation of the binding nature of the right to health, vowing to use legal means to:

enact, strengthen or enforce as appropriate legislation, regulations and other measures... to ensure the full enjoyment of all human rights and fundamental freedoms by people living with HIV/AIDS and members of vulnerable groups; in particular to ensure their access to, inter alia[,] education, inheritance, employment, health care, social and health services, prevention, support, treatment, information and legal protection.⁹⁵

Although no international tribunal or adjudicative body has yet enforced such right-to-health measures against a state, widespread commitment to health as a universal right does exist.

90. African Charter on Human and Peoples' Rights, adopted by the OAU June 27, 1981, art. 16, OAU Doc. CAB/LEG/67/3/Rev. 5 (establishing the right of every individual to "the best attainable state of physical and mental health").

91. Revised European Social Charter, May 3, 1996, art. 11, E.T.S. No. 163, 36 I.L.M. 31 (establishing the right to the "highest possible standard of health attainable").

92. American Declaration of the Rights and Duties of Man, May 2, 1948, art. 11, O.A.S. Res. XXX (establishing the right of every person to medical care).

93. See, e.g., Hurst Hannum, The Status of the Universal Declaration of Human Rights in National and International Law, 25 GA. J. INT'L & COMP. L. 287, 290 (1995-96).

94. Yamin, *supra* note 69, at 334-35, n.37 (citing Glenda Lopez v. Instituto de Venezolano de Seguros Sociales, 487-060401 (Supreme Court of Venezuela, Constitutional Chamber 1997); Protection Writ, Judgement of Fabio Moron Diaz, Magistrado Ponente, T-328/98 (Corte Constitucional de Columbia 1998); Mullen v. Union Territory of Delhi, 2 S.C.R. 516 (1981)).

95. Declaration of Commitment on HIV/AIDS, June 27, 2001, ¶ 58, available at http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html (last visited Apr. 11, 2005).

^{87.} Convention on the Rights of the Child, Nov. 20, 1989, art. 6, 1577 U.N.T.S. 3, GAOR 44/25.

^{88.} International Convention on the Elimination of All Forms of Racial Discrimination, opened for signature Mar. 7, 1966, art. 5, U.N.T.S. 195, 5 I.L.M. 352.

^{89.} Convention on the Elimination of All Forms of Discrimination Against Women, adopted by the UN Dec. 18, 1979, arts. 11.1(f), 12, 1249 U.N.T.S. 13, 19 I.L.M. 33.

B. The Limited Justiciability of a Right to Life-Saving Medication as a Sub-Set of the More General Right to Health

While the agreements discussed above indicate broad acceptance of the right to health, reading into that right a right to medication is tenuous: the existing treaty language is vague, and most provisions call for progressive, rather than immediate, realization. Under these treaties and conventions, whether a right to health and treatment is enforceable against a domestic government becomes a question for that state's judiciary. Moreover, the absence of any universal international jurisdiction over civil-political or social rights that fall short of peremptory norms would hinder a citizen's ability to enforce her right to treatment against non-state actors.⁹⁶ That non-signatory states are probably not bound to the international covenants establishing the right to health poses another significant obstacle, as does the questionable authority of Comment 14: issued almost forty years after the ICESCR entered into force, Comment 14 may not be legally binding on earlier signatories.

Notwithstanding these challenges to enforceability, Yamin asserts that states violate their legal obligations to support their citizens' right to health when they agree to be bound to externally imposed patents, when that protection impedes their ability to provide anti-retroviral treatment to their people.⁹⁷ David Fidler acknowledges that whether non-signatories—and consequently third parties—are bound to such obligations is controversial but asserts that international trade law such as TRIPS has put illegal restraints on public health sovereignty.⁹⁸ In the globalized present, he argues that "[p]ublic health isolationism or rejection of international legal instruments on public health can [] be viewed as a dereliction of a state's duty to protect the health of its people."⁹⁹

The AIDS epidemic requires the kind of response Fidler suggests: an immediate, globally coordinated action focused on both prevention and treatment. Increasing access to life-prolonging medication would help to stabilize political, social, and economic structures in the global South. As discussed in Part II, relaxing patent protection would effect immediate and significant increase in access. Yet the limitations of using current international law to enforce a right to treatment against either states or third parties present

^{96.} Peremptory norms are enforceable by any individual against any individual or state. See Philippe Lieberman, Expropriation, Torture, and Jus Cogens Under the Foreign Sovereign Immunities Act: Siderman de Blake v. Republic of Argentina, 24 U. MIAMI INTER-AM. L. REV. 503, 514 (1993) ("A nation's practice, encouragement, or condonation of acts of genocide, slavery, murder or disappearance, torture, prolonged arbitrary detention, systematic racial discrimination, or consistent pattern of gross violations of international human rights have been recognized as peremptory norm violations.").

^{97.} Yamin, supra note 69, at 354-55.

^{98.} David P. Fidler, A Globalized Theory of Public Health Law, 30 J.L. MED. & ETHICS 150, 156 (2002) (asserting that the "international trade [legal regime] . . . restrict[s] the exercise of public health sovereignty by states").

^{99.} Id.

real obstacles to encouraging wealthy states to modify their problematic stance on pharmaceutical patents. The following Part explores strategic arguments for easing patent protection to increase access that might appeal to pro-patent states.

IV.

WHY INCREASE ACCESS TO TREATMENT AT THE EXPENSE OF PATENTS?

Because HIV/AIDS rates in the United States and other wealthy countries have largely plateaued, ¹⁰⁰ policy-makers in these administrations have relegated the crisis to a distinctly global-South problem. Adequate responses to the HIV/AIDS crisis thus require an appeal to the self-interest of these wealthier countries. Arguments in favor of increasing access even at the expense of patents include a cost-benefit analysis, an appeal to national security interests, and a human rights approach. Because each perspective has limitations and strengths in terms of the audiences to which they might appeal, healthcare and human rights advocates should employ them strategically, depending on the preferences and biases of a particular audience.

A. Cost-Benefit Argument

One might argue the expediency of improving access to anti-retrovirals from a cost-benefit analysis, along the lines of common-law nuisance doctrine.¹⁰¹ This approach stresses that the failure to increase access to treatment now will create externalities that will ultimately cost donor states more later, in the form of aid to counter the effects de Waal predicted, including the collapse of economic and social structures and a continuing increase in the number of AIDS orphans.¹⁰² Indeed, beyond the "spend now to save later" rationale, generalized private-sector gains might accompany these benefits to the public sector as investment interests attain increased access to African markets accompanying new political and socio-economic stability.¹⁰³

Aid dollars would also spread farther if the cost of anti-retroviral medication dropped. If generics were available at a cost of \$140 annually as opposed to the \$10,000 annual price tag for name-brand medication, making generic medications widely available would yield a 70% increase in the number of people every aid dollar reaches.¹⁰⁴ On the whole, both public and aggregate private gains flowing from increased life expectancy and quality of life in AIDS-

^{100.} See Alexandra Greeley, Concern about AIDS in Minority Communities, FDA CONSUMER MAG. (1995), at http://www.fda.gov/fdac/features/095_aids.html (last visited Apr. 11, 2005) (describing "rapid increases in HIV infection ... among minorities [in the United States], specifically in the African American and the Hispanic communities").

^{101.} See RESTATEMENT (SECOND) OF TORTS § 821B (1979).

^{102.} See supra note 29 and accompanying text.

^{103.} Because trade with sub-Saharan countries currently comprises a negligible percentage of U.S. international activity, this argument will not be as compelling as it would be in another region where U.S. trade interests were more significant, such as Asia.

^{104.} See supra notes 10, 33.

stricken regions would outweigh the private-sector costs to pharmaceutical corporations of relaxing patent protection. The societal benefit of increased length and quality of life for infected people—and the resulting decrease in future economic costs of dealing with the AIDS epidemic—should outweigh the profit loss some pharmaceutical corporations would suffer from patent relaxation.

History, however, offers little hope for the potential appeal of this argument to wealthier states. Despite the persuasiveness of a cost-benefit argument that preventative action now will save aid dollars later, the historic disinterest of the United States and other powerful states in humanitarian crises in Africa suggests that, based on the current small scale of economic interest in African markets, the possibility of bigger obligations in the future will not register concern. Aid to Africa has been fickle at best, leaving little reason to believe that the United States and other wealthy countries will consistently engage in any future humanitarian commitments out of concern for African citizens.

The private sector's demonstrated interest is also minimal. Sub-Saharan Africa ranks twelfth out of sixteen regions on the list of U.S. export partners, ahead of only non-EU Western Europe, republics of the former USSR, Eastern Europe, and Oceania and the Pacific.¹⁰⁵ Nigeria is the only sub-Saharan country to appear on the list of the top thirty-five export partners, and the dollar measures of exports to sub-Saharan Africa have dropped steadily since 1997.¹⁰⁶

The United States does have an economic interest in Africa's oil markets, which currently supply 15% of U.S. petroleum needs.¹⁰⁷ Yet in the context of oil enterprises, profit motives have rarely led to voluntary private-sector implementation of humanitarian assistance, at least in recent history. As one corporate official explained, the company's responsibility was not promoting social welfare but instead "efficiently develop[ing] resources in the country for our shareholders and our partners."¹⁰⁸ Recent cases alleging human rights abuses by multinational oil corporate profit motives do not tend to incorporate concern for human life into their cost-benefit analyses.¹⁰⁹ Even when companies do engage in humanitarian aid in local sites, vital continued

^{105.} U.S. BUREAU OF THE CENSUS, Trade Data: U.S. Exports of Bulk: 1997-2001 and Yearto-Date Comparisons, available at http://www.fas.usda.gov/ustrade/USTReports/BICOProd.htm (last visited Apr. 11, 2005).

^{106.} *Id*.

^{107.} John Murphy, A Businesslike View of Africa Policy, BALTIMORE SUN, Jan. 15, 2001, at 2A.

^{108.} Daphne Eviatar, Africa's Oil Tycoons, NATION, Apr. 12, 2004, at 4.

^{109.} See, e.g., Bowoto v. Chevron Texaco Corp., 312 F. Supp. 2d 1229 (N.D. Cal. 2004), 1233-34 (involving five Nigerian plaintiffs who alleged that Chevron Texaco, a Delaware corporation, participated in human rights abuses in cooperation with the Nigerian military and police); see also Doe v. Unocal, 248 F.3d 915, 920 (9th Cir. 2001) (involving a class action suit brought by a coalition of Burmese citizens against Unocal, a California corporation, and Total, S.A., a French corporation, alleging international human rights violations including supporting a military junta, forced relocations, rape, torture, and forced labor).

support is far from guaranteed. In Angola for example, Chevron Texaco and other international oil companies have spent \$24 million on development projects over a course of five years, but most of that money built schools and hospitals that the company has since failed to supply with staff or supplies.¹¹⁰ Hospitals stand empty, with no money for doctors, nurses, or medications; schools likewise lack books and teachers.¹¹¹

A broader shortcoming of the cost-benefit approach is the low value economic formulas assign to human life, especially the lives of the global poor. As Joseph argues:

The present weight given to the "profit" interest under national and international patent regimes prejudices the interests of sick people in gaining access to drugs that they need.... Reevaluation of the notion of profit and ownership in crucial areas such as access to health-restoring drugs is necessary.

Given the undervaluation of human lives, especially impoverished African lives, in these equations, a cost-benefit analysis is unlikely to lead to the conclusion that providing life-prolonging treatment at the expense of immediate profit is in the best interests of overall market gain.

B. National Security Argument

The value of human life does not fare much better within the framework of a national security approach to foreign policy. A political-realist view that conceives of the world in terms of state-actors in competition for survival and power would reject human suffering as an important foreign policy consideration unless it bore immediately on national security. This view accurately reflects the United States' historical approach to international relations. The political-realist approach of the current U.S. administration, which separates the political realm from the social-economic realm, ensures that human rights violations will not rise to the level of a national security priority.¹¹³

Susan Rice, Assistant Secretary of State for African Affairs from 1997 to 2001, has cited the spread of infectious diseases such as HIV/AIDS, malaria, and tuberculosis throughout Africa as threats to U.S. national security.¹¹⁴ The thrust of her appeal is based on a generalized vision of "enhancing the security, health, freedom, and economic well-being of others around the world" rather than a specific causal link between U.S. security interests and stability in sub-Saharan Africa.¹¹⁵ Yet U.S. policy-makers and politicians have largely failed to respond to repeated warnings about the threats the AIDS crisis in Africa poses to

^{110.} See Eviatar, supra note 108, at 3-4.

^{111.} Id.

^{112.} Joseph, supra note 36, at 152.

^{113.} Gathii, Structural Power, supra note 22, at 283-84.

^{114.} Susan E. Rice, U.S. National Security Post-9/11: Perils and Prospects, 28 FLETCHER F.

WORLD AFF. 133, 139-40 (2004).

^{115.} Id. at 139.

U.S. national security. Predictions of political, economic, and social collapse in regions perceived as geographically and culturally remote have thus far failed to rouse either politicians or the general public.

Without a more urgent perception of danger to U.S. interests, the level of attention given to Africa's AIDS crisis as a security threat is unlikely to shift. Geographic and cultural distance has relegated Africa to the bottom of U.S. security concerns. As is true for any region, Africa has historically enjoyed foreign policy prioritization only when U.S. security or economic concerns have been directly at risk, leading to an "incoherent and inchoate" application of foreign policy in the region.¹¹⁶ Indeed, President George W. Bush has admitted that "[Africa] doesn't fit into the national strategic interests, as far as I can see them."¹¹⁷

National security concerns are generally territorially focused. The human rights of non-U.S. nationals rarely merit substantial consideration in U.S. foreign policy decisions concerning national security, and the AIDS epidemic does not easily fit within current national security interests in the African continent: what U.S. security interest does exist in Africa currently focus instead on apprehending Islamic terrorist cells in east and north Africa.¹¹⁸ Employing national security rationales to inspire the United States to engage with Africa on the HIV/AIDS crisis will not succeed until both policymakers and the public perceive more tangible, even territorial, connections between AIDS and the United States' own stability. This more tangible perception may occur if and when de Waal's predictions materialize, but only after sub-Saharan Africa suffers an even greater toll and at a high financial cost to the United States. Until then, given these territoriality biases in U.S. foreign policy, the United States would arguably worry more about an AIDS pandemic in Canada or Mexico, where frequent trans-border migration would pose a more perceptible threat to U.S. health.¹¹⁹

Yet the havoc the AIDS epidemic in sub-Saharan Africa could wreak on U.S. national security is real.¹²⁰ Demographic projections support a frightening worst-case scenario of forty-four million AIDS orphans by 2010, widespread famine, and political turmoil.¹²¹ Many, including former Secretary of State Madeline Albright, have warned that such structural collapse will foreseeably

^{116.} Gathii, Structural Power, supra note 22, at 285.

^{117.} Murphy, supra note 107.

^{118.} Gathii, Structural Power, supra note 22, at 286.

^{119.} See Fidler, supra note 98, at 153-54 (discussing U.S. attempts to "[p]rotect against importation of public health threats"). One could also argue that U.S. interests in protecting its own citizens' health are best served by investing in prevention and treatment in other countries to prevent the spread of outbreaks to the United States. A "forward deployment of resources," as Fidler articulates, will not likely be persuasive to wealthier countries that have already checked the spread of HIV/AIDS within their own borders. Id. at 154.

^{120.} See supra notes 25-31 and accompanying text.

^{121.} Press Release, USAID, Children on the Brink: Updated Estimates & Recommendations for Intervention (2000), *available at* http://www.usaid.gov/press/releases/2000/childrenreport.pdf (last visited Apr. 11, 2005).

lead to political instability and violence.¹²² Alex de Waal forecasts that national governance systems will centralize power, leading to decreasing respect for human rights, the erosion of democratic institutions, the collapse of an early warning system in case of famine, and popular discontent leading to warlordism and civic and political violence.¹²³

The United States has not entirely ignored the possible erosion of national security the AIDS crisis poses. The Clinton administration, for example, declared the AIDS epidemic a "major threat to U.S. national security" in a May 2000 report that warned that the pandemic in sub-Saharan Africa could erode the administration's "policy of encouraging the emergence of free-market democratic governments throughout the world" and cited concerns of a "demographic catastrophe" that could lead to genocide and violent revolution.¹²⁴

But U.S. policy during the Clinton and George W. Bush administrations has not demonstrated a commitment to fighting AIDS as a national security priority.¹²⁵ During TRIPS negotiations, the United States objected to provisions that would have eased patent restrictions on countries suffering HIV/AIDS emergencies at the same time that the Central Intelligence Agency issued specific warnings connecting the AIDS crisis in Africa to heightened U.S. security risks. Decision makers did not consider the AIDS risk to outweigh the profit-based motives of major pharmaceutical corporations in maintaining patent protections at the expense of human lives, suggesting that national security concerns, no more than private-sector profit, will not on their own compel an effective response to sub-Saharan Africa's AIDS pandemic.¹²⁶

C. Human Rights Argument

The limited persuasiveness of cost-benefit rationales and national security justifications will not likely compel wealthy states, especially the United States, to commit immediately and consistently to increasing access to anti-retroviral

^{122.} The extent to which the United States believes the national security threat Madeline Albright and others have cited can be measured by the inadequacy of the steps the Clinton and Bush administrations have taken to ameliorate the burdens plaguing sub-Saharan countries. See Transcript: Albright Speaks Out on HIV/AIDS, Dec. 11, 2000, at http://www.usembassy.it/file2000 12/alia/a0121106.htm (last visited Apr. 11, 2005).

^{123.} See de Waal, supra note 29, at 18.

^{124.} Robert Tait, *HIV/AIDS Classified as Threat to U.S. Security*, THE SCOTSMAN, May 1, 2000, at 8.

^{125.} Gathii, Structural Power, supra note 22, at 312. President Bush's \$15 billion incentive bill, while welcome, is of questionable efficacy. It limits aid to twelve African and two Caribbean countries, enforces restrictions on condom use, and is not guaranteed against the cycles of Congressional appropriations. Id. at 311-12. See also Salih Booker, Bush's AIDS Plan: More Smoke and Mirrors, Economic Justice News (March/April 2003), available at http://www.africaaction.org/resources/docs/smokeandmirrors.pdf, at 2 (last visited Apr. 11, 2005) (explaining that in order to meet Bush's purported goals of treating two million people "with life-extending drugs" and preventing seven million new infections, the United states "would need to start spending at least \$3 billion a year immediately," not the current \$1 billion annual expenditure).

^{126.} Gathii, Structural Power, supra note 22, at 298.

treatments. Global enforcement of the human right to health-interpreted to include the right to life-saving medication as identified by the WHO Essential Drugs Monitor—is a more viable perspective from which to make an appeal for dramatically and instantaneously increasing access to affordable anti-retrovirals. Cost-benefit and national security perspectives assume the ability to rationally quantify and weigh all of the relevant factors. Yet quantifying the value of a given human life for the purpose of determining whether costs outweigh harms runs counter to the very core of every individual's right to life as established in the UDHR and embraced in every subsequent human-rights treaty. As Yamin asserts:

The fundamental premise underlying the notion of universal human rights is that people are not expendable; those people's avoidable deaths are not just a tragic shame. Thus, adopting a human rights view of access to medications changes how we think about this crucial issue, and therefore what we do about it.

From a human rights perspective, the rights to life and dignity supersede the private sector's right to profit, especially when that profit offers only dubious potential ever to benefit the people most in need.¹²⁸

Still, enforceability remains a problem. Human-rights law is often viewed as "soft" rather than "hard" international law, suggesting that current humanrights legal treaties and institutions may be inadequate to compel more flexible observance of patents. The numerous reservations with which states enter into human-rights treaties further destabilize those instruments' legal power. Enforcing a right to health against the United States, for example, would be particularly difficult given this country's numerous reservations to most major human-rights treaties to which it is a signatory.¹²⁹

In addition, an individual can traditionally only enforce her human rights against her own state, not against third-party states or non-state actors. Consequently, even if Comment 14 to the ICESCR were interpreted to require the government of state A to order its domestic companies to relax patent protection in state B, a citizen of B could probably not seek judicial enforcement of this right in state A's courts, and her own courts would lack jurisdiction over the culpable state A companies. And, as discussed above, whether a right to health is justiciable at all remains an open question. Given these limitations, it seems that those concerned with increasing access to affordable anti-retrovirals should focus on practical solutions to the present crisis, while concomitantly working towards the creation of transnational institutions with authoritative jurisdiction to interpret and enforce the right to health as embodied in existing

^{127.} Yamin, *supra* note 69, at 330.128. Intellectual property protection that restricts, rather than increases, access to life-saving medication belies the ultimate justification for patents as an end toward engendering net social good. See infra notes 147-52 and accompanying text.

^{129.} See Kenneth Roth, The Charade of U.S. Ratification of International Human Rights Treaties, 1 CHI. J. INT'L L. 347 (2000) (lamenting that, "on the few occasions when the U.S. government has ratified a human rights treaty, it has done so in a way designed to preclude the treaty from having any domestic effect").

human-rights treaties.

METHODS FOR EASING PATENT RESTRICTIONS

Resistance from the pharmaceutical industry and beholden politicians to easing patent protection is strong. Under a natural-law theory of intellectual property rights, ideas, as the fruits of one's intellectual labors, merit protection as personal property.¹³⁰ But the status of ideas as personal property is far from universal.¹³¹ An alternative view of patents that understands "ideas [as] incapable of ownership and . . . the dissemination of one person's ideas [as] a reflection of the collective wisdom of the society" would actually support the loosening of patent protection, especially if it spread the benefits of innovation more widely.¹³² The rationale underlying patent protection is to reward innovators with profits so as to encourage further net social good, and in this case further research and increased availability. This rationale is not a purely natural-law theory but rather an integration of Lockean property notions with twentieth-century understandings of collective good.

One might well question whether the profit incentive of patent-protection theory actually "foster[s] pharmaceutical and medical innovation" for the diseases impacting poor countries because users in the global South constitute a minimal percentage of the global pharmaceutical market.¹³³ Because pharmaceutical corporations do not currently cater to a sizable sub-Saharan market, they have little incentive to make future innovations accessible to these populations. The entire continent of Africa, for example, comprises only 1.3% of that market.¹³⁴ The contention that patent-based profits ensure further research is further belied by the fact that major pharmaceutical corporations typically spend two to three times more on marketing existing drugs than researching and developing new ones.¹³⁵

Given these market realities, patent protection in the context of international public health emergencies will necessarily undermine public welfare rather than promote it, in contravention of the very spirit of patent law, which favors private-sector profit only insofar as it leads to net social gain. Richard Posner articulates the necessity of balancing "the interest in encouraging the production of intellectual property and the interest in promoting its widespread use."¹³⁶ Yet applying the traditional patent rationale of

^{130.} Gathii, Structural Power, supra note 22, at 276.

^{131.} See Harrelson, supra note 7, at 176.

^{132.} Gathii, Structural Power, supra note 22, at 277.

^{133.} Exec. Order No. 13,155, supra note 62.

^{134.} Joseph, *supra* note 36, at 449 (stating that "the African continent constitutes only 1.3 percent of Big Pharma's market"). Joseph employs the term "Big Pharma" to refer to Merck, Glaxo-SmithKline, Pfizer, and Bristol Myers Squibb, the "world's major pharmaceutical corporations" that "essentially determine" the price of anti-retrovirals.

^{135.} Id. at 432.

^{136.} Richard A. Posner, The Law and Economics of Intellectual Property, 131 DAEDALUS 5,

rewarding an inventor for creating a benefit to society to the current crisis reveals a failure of patent protection to achieve its doctrinally mandated end.¹³⁷ When patent protection restricts rather than fosters use because of unequal resource distribution, it undoes the fundamental patent goal of providing for social good. Allowing private-sector profit motives based on patent protection to overpower the aim of creating net social good thus thwarts the underlying public policy goals of TRIPS.¹³⁸ Patent-holding corporations would likely suffer some financial losses from easing patent protection, but as the suggestions below indicate, those losses would be minor and could be mitigated by governmental action.

A. Honor the Doha Declaration and Read TRIPS Flexibly

The Doha Declaration calls for an interpretation of TRIPS that would allow member states suffering public health crises to balance patent protection with access to pharmaceutical products.¹³⁹ Specifically, the declaration asserts the autonomy of developing countries "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, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency, it for the circumstances of extreme urgency."¹⁴⁰

The Doha Declaration affirms the issue of compulsory-license rights as allowed by the plain text of TRIPS, with some restrictions. However, the Doha Declaration does not resolve the question of the permissibility of parallel imports, through which a country without manufacturing capabilities can solicit other countries with such capabilities to produce generics on its behalf.¹⁴¹ In response to the restriction on compulsory licensing rights in TRIPS to domestic markets,¹⁴² the Doha Declaration seeks an "expeditious solution" to the limited effect of compulsory license provisions for the poorest member states without manufacturing ability, though as of May 2003, no resolution had been reached despite the urging of the Africa Group.¹⁴³ Those who favor reading TRIPS in light of the Doha clarifications point to the coercive bargaining atmosphere of both the TRIPS negotiations generally and the final Uruguay round specifically.¹⁴⁴

- 140. Doha Declaration, supra note 55, at ¶ 5(c).
- 141. Sell, supra note 58, at 935-36.

- 143. Doha Declaration, supra note 55, at ¶ 6.
- 144. See Gathii, Intellectual Property, supra note 33, at 765; Gathii, Structural Power, supra

^{11 (2001).}

^{137.} The U.S. Supreme Court, for example, has interpreted the rationale for granting patent monopoly "contemplated by the Constitution and the Congress . . . [as] the benefit derived by the public from an invention with substantial utility." Brenner v. Manson, 383 U.S. 519, 534 (1966).

^{138.} See Gathii, Intellectual Property, supra note 33, at 770 (noting that, "clearly Article 7 of TRIPS provides for safeguard provisions, and Article 8 provides for public interest exceptions").

^{139.} See generally Mike Moore, Introduction, in DOHA AND BEYOND: THE FUTURE OF THE MULTILATERAL TRADING SYSTEM v-xx (Mike Moore ed., 2004).

^{142.} TRIPS, supra note 50, art. 31(f).

In light of the very real political, economic, and social devastation that an unchecked AIDS epidemic will continue to wreak on sub-Saharan states, those states should enjoy the unrestricted right to declare AIDS-related public health emergencies and issue compulsory licenses for the generic manufacture of anti-retrovirals. Countries that have not already signed away their rights to issue compulsory licenses for generic manufacture through TRIPS-plus bilateral agreements with the United States should assert this right. In some settings, this assertion alone has been enough to initiate negotiations for price reductions in name-brand medicines, suggesting that major pharmaceutical companies might be willing to compromise on price in the face of sufficient international legal pressure.¹⁴⁵

B. Allow Differential Pricing and Subsidize Pharmaceutical Companies' Losses

In keeping with the discussion above, countries should be able to negotiate differential pricing structures based on a formula that considers per capita income, government resources, and the severity of the need for immediate access to medication.¹⁴⁶ Astonishingly, differential pricing already exists, but in favor of wealthy states. Two leading anti-retrovirals, acyclovir and neverapine, cost twice as much in Kenya and 35% more in Tanzania than in Norway, a price differential that equates to 500 hours' worth of work for a Tanzanian worker compared to an hour's worth of wages for a Norwegian.¹⁴⁷

Rectifying this imbalance to enable poorer countries with greater need to provide their people with affordable anti-retrovirals could supplement or complement the easing of patent protections so as to increase access. Given the miniscule percentage of their market that sub-Saharan Africa comprises, major pharmaceutical companies would not likely experience any substantial profit loss under a tiered pricing system. Government subsidies could compensate the corporations for any slight losses. The International Intellectual Property Institute advocates this combination of tiered pricing and subsidies.¹⁴⁸ Some maintain that such a plan would provide affordable anti-retrovirals to developing states while also providing pharmaceutical companies with resources for new research.¹⁴⁹ Yet whether pharmaceutical companies would direct profits from subsidies toward research for treating developing-world diseases is far from

149. Id.

note 22, at 282; see also Health GAP, supra note 6, which cites U.S. coercion during the FTAA and CAFTA negations, in which the U.S. sought bilateral agreements with individual states to preclude the use of multi-state coalitional resistance. So far the United States has not agreed to a compromised interpretation of TRIPS in line with the Doha demands.

^{145.} Sell, supra note 58, at 951.

^{146.} See Harrelson, supra note 7, at 195-96 (discussing "tiered-pricing" options).

^{147.} Gathii, Structural Power, supra note 22, at 307.

^{148.} Harrelson, *supra* note 7, at 178 (stating that the IIPI plan "combines tiered pricing, national patent exhaustion, and pharmaceutical subsidies to provide a balance of the seemingly conflicting interests").

certain.¹⁵⁰ Strict governmental regulation would be necessary to ensure that both affordable anti-retroviral drug development and the search for a cure become top research priorities.

C. Publicly Fund Research

Publicly funded research might provide a better balance between humanitarian urgency and patent protection. Direct government subsidies already fund much medical research in the United States and other wealthy countries, for example through public university laboratories and tax deductions for private-sector pharmaceutical researchers.¹⁵¹ Public funding would require strict regulation and monitoring to ensure that the funds are utilized specifically for AIDS-related research. It would also require a brokered understanding that companies significantly reduce prices in developing-world markets or concede This solution, perhaps optimistically, relies on to generic manufacture. pharmaceutical companies' willingness to relinquish the ability to control their profits through market exploitation. Both the subsidy and public-funding approaches would require that companies trade their right to profit from their prior inventions for the reassurance that public funds would support future AIDS-specific research and that the United States increase investment in financial and human resources dedicated to fighting AIDS.

D. Implement a Policy of Global Health Governance

For human rights advocates seeking to enforce a universal right to health, patent relaxation is one tool for the transition towards a system of true international health governance. Fidler cites the emergence of globalization— which both entails and is driven by ever-increasing trans-border movement of resources, peoples, and capital—to argue for a globalized approach to public health.¹⁵² According to Fidler, public health is no longer governable solely within domestic borders and must therefore include the cooperation of international and non-state actors as well as domestic governments.¹⁵³ Fidler advocates a globalized system of health governance that emphasizes a cooperative response to public health crises over questions of legal responsibility.

The international response to the outbreak of Sudden Acute Respiratory Syndrome (SARS) in 2003 provides a successful example of a globalized

^{150.} See Gathii, Intellectual Property, supra note 33, at 785-87 (discussing bow research and development costs are artificially high in part due to the "cartelization" effects of patent protections on the pharmaceutical industry, as well as the industry's "misdirected" and "unnecessary" spending on marketing and advertising); see also Joseph, supra note 36, at 449 (noting that "it seems unlikely that... deep discounts per se in the developing world threaten pharmaceutical R&D").

^{151.} Joseph, *supra* note 36, at 433.

^{152.} See generally Fidler, supra note 98.

^{153.} Id. at 157.

response that effectively contained what could easily have become a widespread epidemic.¹⁵⁴ In countering the SARS outbreak, the WHO implemented a transnational, population-based strategy that represented a recognition that public health has become a global concern requiring multinational coordination. In March 2003, within days of the first diagnostic announcements from China, the WHO issued a global alert through the Global Alert and Response System, which tracks outbreaks of infectious diseases in order to initiate an international response when necessary. During the incipient stages of the outbreak, the WHO researchers, infectious disease experts. mobilized clinicians, data epidemiologists, laboratory experts, logistics experts, medical epidemiologists, microbiologists, media experts, pathologists, public health specialists, and virologists as part of the international effort to address this global public health emergency. As the WHO SARS website proclaimed, "It cannot be predicted when this outbreak will end but the world is on high alert, is better prepared and is acting in a true global alliance to protect the health of the world's population against a threat of as yet unknown dimensions."155

In contrast to this coordinated effort of doctors, public health officials, and world leaders, a globalized response to AIDS, first diagnosed in 1984, did not begin in earnest until the mid-1990s, when the UN and the WHO formed offshoot branches such as UNAIDS to begin implementing responses to what had already become a decimating epidemic. The respective success and failure of the international community to respond effectively to SARS and AIDS demonstrate the need for continued global cooperation that combines medical, legal, and political efforts to combat the AIDS crisis.

Beyond initiatives coordinated by international organizations such as the UN and the WHO, domestic governments must consider international law in their domestic health policy. In his model of globalized public health governance, Fidler posits "the growth in the power and reach of non-state actors, such as multinational corporations and non-governmental organizations [as evidence that] private actors also have a special responsibility for protecting public health."¹⁵⁶ Global public health decisions, according to Fidler, can no longer ignore international law.¹⁵⁷ Because power has been steadily shifting away from individual states and towards both multi-state and non-state organizations, a global analysis should incorporate non-state actors. Alex de Waal similarly advocates an international response through which multi-state

^{154.} The viral traits of the SARS virus differ significantly from those of the human immunodeficiency virus that causes AIDS, as do many socio-cultural implications associated with either virus and the more advanced technology existing at the time of the initial SARS outbreak. In making a comparison between the global responses to SARS and HIV/AIDS, I only wish to demonstrate how the former was met with a coordinated, global effort that effectively contained the virus' spread.

^{155.} WHO, Response to SARS, Apr. 16. 2003. at The Operational http://www.who.int/csr/sars/goarn2003_4_16/en/ (last visited Apr. 11, 2005).

^{156.} Fidler, supra note 98, at 151.
157. Id. at 152.

and non-state entities assume "treatment and care" for HIV/AIDS-infected individuals and their families, and an incorporation of the HIV/AIDS crisis in devising economic development plans.¹⁵⁸ The emergence of this global system of health governance requires the collaboration of international lawyers, world leaders, and public health experts to create policies that ensure all global citizens actually realize the rights to health and medication.

As the UN Declaration of Commitment on HIV/AIDS affirms, "realization of human rights and fundamental freedoms for all is an essential element . . . to reduc[ing] vulnerability to HIV/AIDS."¹⁵⁹ Respect for the rights of people living with HIV/AIDS drives an effective response. A coordinated effort to relax patents and increase the affordability of generic anti-retrovirals would be one step in this direction. Making anti-retroviral medication affordable to citizens in the global South through patent relaxation or public subsidies that lowers prices would significantly stabilize the decimating effects of the AIDS crisis while also providing HIV/AIDS patients with the right to live longer, more dignified, productive lives.

Because existing international law addressing rights to health and medication are not universally honored as justiciable, those minded towards change must turn to policy appeals to encourage wealthy states to increase their commitment to fighting HIV/AIDS by expanding access to treatment in addition to pursuing important prevention efforts. Affirming the rights of developing countries to issue compulsory licenses and to import generic anti-retrovirals will immediately increase access to treatment, while other measures such as pharmaceutical subsidies or public funding of research might help ensure that pharmaceutical corporations prioritize affordable AIDS-related innovation.

^{158.} Alex de Waal, supra note 29, at 22.

^{159.} Declaration of Commitment on HIV/AIDS, supra note 95, at ¶ 16.