ON THE RELATIONSHIP BETWEEN INTELLECTUAL PROPERTY RIGHTS AND THE NEED OF LESS-DEVELOPED COUNTRIES FOR ACCESS TO PHARMACEUTICALS: CREATING A LEGAL DUTY TO SUPPLY UNDER A THEORY OF PROGRESSIVE GLOBAL CONSTITUTIONALISM

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"Everyone has the right, individually and in association with others, to develop and discuss new human rights ideas and principles and to advocate their acceptance."

U.N. General Assembly¹

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1. INTRODUCTION

The HIV/AIDS\(^2\) epidemic is a fundamental human rights issue\(^3\) both in terms of the rights of those who have been infected and the absence of rights that serves as its fuel. Primarily targeting the poorest of nations and the most vulnerable of people,\(^4\) forty million adults and children are currently living with HIV/AIDS\(^5\) and more than twenty-seven million have died since 1981.\(^6\) Assuming the

\(^2\) Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS).


\(^5\) *AIDS Epidemic Update: December 2003*, supra note 4, at 5.

status quo, it is estimated that sixty-eight million people will die from HIV/AIDS-related causes in the most affected nations between 2000 and 2020. Adult infection rates have now reached 20.1% in South Africa and 37.5% in Botswana, and the epidemic continues to escalate in areas such as China, Indonesia, Central Asia, the Baltic States, and North Africa. While three million people died of AIDS in 2003 (including 500,000 children) and five million more people were newly infected with the virus, the vast majority of victims were left untreated, and only 1% of pregnant women had access to services that prevent mother-to-child transmission ("MTCT").

Despite these figures, the world's major research-oriented pharmaceutical companies are not (nor should they be) governmental or charitable institutions. Instead, they are business entities based upon traditional western notions of rational profit maximization, individualism, and risk-reward management. These entities make substantial investments where profits are expected. The profit incentive breeds inventiveness and innovation that will benefit society through the creation of new goods, new services, and the dissemination of knowledge.

As a result, the solution to this need for access/need for incentive dichotomy, as well as solutions to a variety of issues surrounding the distinction between the existence of a human right and the duty to protect and fulfill that right, will not be based on such arguments as morality, excessive profit margins, or the desirability of

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*AIDS Statistics* (stating that there have been 21.8 million AIDS deaths since 1981 until the end of 2001), at http://www.avert.org/worldstats.htm (last visited Oct. 12, 2004).

7 See *Report on Global HIV/AIDS*, supra note 3, at 45 ("In the 45 most affected countries, it is projected that, between 2000 and 2020, 68 million people will die earlier than they would have in the absence of AIDS."). In regard to infection rates, see Geoffrey Cowley, *Can He Find a Cure?*, *Newsweek*, June 11, 2001, at 39 ("[A] vaccine is our . . . best hope of ending the pandemic . . . we'll be lucky to have even a crude one on the market by 2007. At current rates, an additional 50 million to 100 million people will have contracted the virus by then . . . ").


10 Id. at 4. The 1% figure refers to women located in "heavily-affected countries." Id.

11 For a discussion of the duty to "respect, protect and fulfill" the right to health, see *Substantive Issues*, supra note 3, paras. 30-37 (discussing particular legal obligations of states to respect, protect and fulfill the right to health).
shifting costs to users of luxury drugs. Instead, such a solution will be found in a constitutional approach to international law that recognizes the interlocking relationships of enforceable contractual and normative duties that have developed between states and their citizens and between sovereigns and other sovereigns. Such an approach may draw, at least in part, from theories such as Immanuel Kant’s inevitable progression toward a federation of states, the ‘constitutive process’ of the New Haven School, and the ‘internalization’ of Harold Koh. It may also draw upon theories such as Christian Tomuschat’s legal framework of ‘common values,’ Alec Stone’s ‘regime continuum,’ and even Bruce Ackerman’s ‘higher lawmaking’ and ‘constitutional moments.’

Such a constitutional approach does not attempt to prove that the Charter of the United Nations represents a global constitution

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15 See Christian Tomuschat, Obligations Arising for States Without or Against Their Will, 241 RECUEIL DES COURS 195 (1993) (expanding the concept of an international constitution interdependent of the international community cited and discussed in Fassbender, supra note 13, at 548-51).

16 See Alec Stone, What is a Supranational Constitution? An Essay in International Relations Theory, 56 REV. POL. 441 (1994) (providing ways to assess forms of “institutionalized cooperation in the international system”).

or that truly autonomous legislative, executive, or judicial bodies function at the international level. It does not deny the relevance of sovereignty, the demands of domestic effect, the frailties of individual and collective enforcement, or the need to identify an international 'community.' Nor does it argue that the web of interlocking treaties, covenants, customary laws, peremptory norms, and domestic legislation represent any form of a complete international constitution or world government.

Instead, the theory of progressive global constitutionalism recognizes that international relationships are not completely anarchic. Sovereign states have exercised their right to surrender a degree of their sovereignty through a variety of enforceable contractual agreements. Additionally, all States have become bound to certain fundamental norms even without their agreement, as the expanding doctrine of humanitarian intervention clearly indicates, and the citizens of those non-agreeing States have similarly

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19 For a discussion of issues surrounding anarchy, see Stone, supra note 16, at 448-70 (discussing international relations theory and supranational constitutionalism).

20 See Military and Paramilitary Activities (Nicar. v. U.S.), 1986 I.C.J. 14, 131 (June 27) (indicating that "[a] State . . . is sovereign for the purpose of accepting a limitation of its sovereignty . . . ").

been placed (at least under certain circumstances) within the jurisdiction of a higher external authority.\textsuperscript{22}

As a result, the totality of a common set of enforceable values and a myriad of interlocking agreements represents a \textit{progression} with constitutive and rule of law dimensions. It is a progression that is expanding the scope of individuals as subjects of international law; broadening both the rights of those individuals and the duties of their States; recognizing that such concepts as ‘community,’ progressive realization,\textsuperscript{23} and ‘universal jurisdiction’\textsuperscript{24} are not illusional; and viewing self-determination and economic and social development as inalienable rights with which no other nation may interfere.\textsuperscript{25} As the overlap between international and domestic domains continues to increase, a theory of progressive global constitutionalism refutes the fact that a constitution must either be in a complete state of existence or a complete state of nonexistence.

It is within such a framework that this Article will examine the relationship between the Agreement on Trade-Related Aspects of


\textsuperscript{23} \textit{International Covenant on Economic, Social and Cultural Rights}, Dec. 16, 1966, art 2.1, 993 U.N.T.S. 4, 5 (entry into force on Jan. 3, 1976) [hereinafter \textit{ICESCR}] (stating that “[e]ach State Party . . . undertakes to take steps . . . to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means . . .”


Intellectual Property Rights ("TRIPS Agreement"), and the need of individuals in less-developed countries for treatment and prevention of HIV/AIDS. In doing so, however, there are two caveats to keep in mind. First, while this Article will primarily discuss the HIV/AIDS crisis, its arguments are equally applicable to other health issues, such as those surrounding malaria and tuberculosis, as well as to epidemics that are as yet unknown. Second, while this Article will address questions concerning such 'rights' as the right to the 'highest attainable standard of health,' the right to access, and the right to development, it is primarily directed at the other side of the 'rights equation'—namely, the duty of a sovereign to respond to the rights of its citizens and the duty of other nations not to interfere with those obligations. As a result, this Article will not concentrate on the right of a nation to exercise the flexibility inherent in the TRIPS Agreement but rather on a nation's duty to do so. It will argue that while the need for access may conflict with certain theories of intellectual property rights ("IPR"), it does not conflict with the TRIPS Agreement. It will also argue that a nation's unwillingness to exercise such flexibility constitutes a breach of a duty owed to its citizens, and a breach of a duty owed to other States that may be adversely affected by such a decision.

Section 2 of this Article will explore the HIV/AIDS crisis, the social and cultural factors that contribute to its spread, and the lack of infrastructure that frustrates treatment and prevention efforts. It will highlight the pandemic's destructive effect on the social fabric of a nation, including its impact on both social structure and future economic development. It will also address the HIV/AIDS crisis from a human rights perspective in light of a variety of declarations and covenants, and will touch upon such issues as discrimination, human dignity, equal protection, self-determination, and


27 See ICESCR, supra note 23, art. 12.1 ("The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."); see also Substantive Issues, supra note 3, para. 1 ("Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity.").
the rights of women and children.

Section 3 will examine some of the arguments advanced by pharmaceutical companies, including the position that the HIV/AIDS crisis is far more than an access-to-drugs issue. It will briefly discuss the philosophy of patents and the benefits provided by the protection of intellectual property, including the provision of incentives for innovation, the ability to recoup research and development ("R&D") and other costs inherent in bringing products to market, and the stimulation of foreign investment and technology transfer.

In Section 4, this Article will turn its attention to the flexibility provided in the TRIPS Agreement. It will examine the objectives and principles set forth in Articles 7 and 8, the issue of patentable subject matter under Article 27.2, the limited exceptions found in Article 30, the compulsory licensing provision of Article 31, the transition extensions established in the Doha Declaration on the TRIPS Agreement and Public Health ("Declaration on TRIPS"), and the somewhat ignored security exception of Article 73.28


Section 5 will examine the duty to exercise this flexibility in light of both contractual and customary international and domestic legal obligations. It will argue that a failure to take advantage of the flexibility provided in the TRIPS Agreement actually constitutes a breach of these legal obligations\(^{30}\) and that such a breach is

\(^{30}\) See, e.g., Substantive Issues, supra note 3, paras. 46-52.

Violations of the right to health can also occur through the omission or failure of States to take necessary measures arising from legal obligations. Violations through acts of omission include the failure to take ap-
actionable (under appropriate circumstances) by both nationals and other sovereign States.

Finally, Section 6 will place these obligations in the perspective of progressive global constitutionalism and will explore issues surrounding increasing hierarchy and intervention, the rebalancing of the concepts of sovereignty and individual interests, and the development of a totality of legal expressions that go far beyond the status of treaty law. By conceptualizing a constitution as a continuing process of expression establishing the rights and duties of individuals and States—and not as a document or body of institutions—this Article will conclude with a synthesis of constitutional public health concepts that are mandated by logical progression. In doing so, it is hoped that the tragedy surrounding the HIV/AIDS crisis will give rise to an additional sense of “human interdependence” and an acceptance of a new and critical axiom of international law.

2. THE HIV/AIDS CRISIS AS A HUMAN RIGHTS ISSUE

2.1. The Nature of the Crisis

Acquired immunodeficiency syndrome is now the most “lethal pandemic since the Black Death 650 years ago.” Nearly twenty-eight million people have died, including more than five million children. Of the forty million people now living with HIV/AIDS,

appropriate steps toward the full realization of everyone’s right to the enjoyment of the highest attainable standard of physical and mental health

Id. para. 49.


34 See AVERT, supra note 6 (noting that 4.3 million deaths occurred by 2001, another 500,000 in 2003); AIDS Epidemic Update: December 2002, supra note 6, at 3
two-thirds are located in Sub-Saharan Africa, and in the words of President Obasanjo of Nigeria, "the prospect of extinction of the entire continent looms larger and larger."

Unfortunately, the HIV/AIDS epidemic is still in its early stages of development, and nearly fourteen thousand people are still contracting the virus every day. The epidemic is no longer recognizing geographic boundaries. In the Caribbean, for example, approximately 2.5% of all adults have now been infected. Reported HIV infections in China rose more than 67% in one six-month period and the epidemic is expected to explode not only in that nation but in India, Russia, and the countries of Eastern Europe as well.

Despite the rapid spread of the virus, it has been estimated that only 2% of those needing antiretroviral treatment in Africa are actually receiving the life-saving drugs that can slow the effects of the virus on the body's immune system and significantly extend the lives of those infected. The World Health Organization's ("WHO") new "3 by 5 initiative" (designed to provide HIV/AIDS treatment to three million people by the end of 2005) and the new South African program (designed to provide drug regimens free of charge) are of course directed at alleviating this lack of access.

(finding another 610,000 deaths before age fifteen in 2002).

36 Wren, supra note 33, at A4.
37 Report on Global HIV/AIDS, supra note 3, at 6, 16, 44.
38 See AIDS Epidemic Update: December 2003, supra note 4, at 3 (citing five million as the number of people newly infected with HIV in 2003). For earlier statistics, see Cowley, supra note 7, at 41 (citing 15,000 as the number of people contracting HIV daily).
39 AIDS Epidemic Update: December 2003, supra note 4, at 5.
44 In regard to the "3 by 5 initiative," see WHO, The 3 by 5 Initiative, at
Yet even if these programs prove to be successful, they must continually adapt to a variety of different strains of the disease including those that mutate into drug-resistant forms. As a result, these drugs must be taken pursuant to a strict daily regimen without which the efficacy of the drugs will plummet, the patient’s health will be further damaged, and more powerful strains will be created. The ability to constantly monitor a patient’s regimen becomes critical, along with the ability to provide ongoing clinical care for the treatment of opportunistic infections and a variety of drug-related side effects. Unfortunately, poor countries lack both the financial resources and the medical and physical infrastructures that are necessary to carry out these distributional and monitoring functions.

Although the transmission of HIV occurs primarily through sexual intercourse, it may also occur through the use of unsterilized needles by intravenous drug users and by ‘collectors’ of blood bought off the street from impoverished donors. It also occurs by means of blood transfusions which have been prescribed as a form of “pick me up” and “dispensed like Tylenol” in some nations


45 Sharon Begley, AIDS at 20, NEWSWEEK, June 11, 2001, at 34, 36 (“Susceptible strains mutate into drug-resistant strains.”).

46 Mark Schoofs, African Gold Giant Finds History Impedes a Fight Against AIDS, WALL ST. J., June 26, 2001, at A1, A10 (citing a study “that suggested that the efficacy of AIDS drugs plummets in patients who miss more than five of every 100 doses”).


51 Rosenthal, Blood and Tears, supra note 49, at A25 (referring specifically to China).
using unscreened and contaminated blood collected in violation of acceptable medical standards.\(^{52}\)

The spread of the disease may also be vertical in nature in the form of MTCT. In 2003, an estimated 700,000 children became infected with HIV and over 90% of those were babies who acquired the virus at birth or through their mother's breast milk.\(^{53}\) At the beginning of the decade, 24% of pregnant women in South Africa were HIV positive,\(^{54}\) and the median HIV prevalence among pregnant women in urban areas in Botswana was nearly 45%.\(^{55}\) Most children who are infected at birth or through breastfeeding will die of AIDS before their fifth birthday,\(^{56}\) and the fact that interventional antiretroviral treatments can reduce MTCT by 50-90%\(^{57}\) shows these mortality figures to be truly unacceptable.

The transmission of the HIV virus must also be viewed in terms of the economic, social, and cultural factors that play a substantial role in its spread. The existence of poverty, for example, not only affects the ability to receive treatment; it also influences the type of behavior in which individuals engage. When more than a billion people live on less than one dollar a day,\(^{58}\) the sale of one's blood, the purchase of cheap but ultimately contaminated blood, and the existence of prostitution become more understandable.\(^{59}\) When costs place any hope of treatment beyond reach, the incentive for being tested for the disease is substantially reduced.\(^{60}\)

\(^{52}\) Id.

\(^{53}\) AVERT, supra note 6; see also Alan Berkman, Confronting Global AIDS: Prevention and Treatment, 91 AM. J. PUB. HEALTH, 1348, 1349 (2001) (discussing transmission of AIDS to nursing babies).

\(^{54}\) Treatment Action Campaign v. Minister of Health, 2002 (4) BCLR 356, 359 (T) (S. Afr.).


\(^{56}\) Id. at 46.

\(^{57}\) Berkman, supra note 53, at 1349.

\(^{58}\) Report on Global HIV/AIDS, supra note 3, at 19.

\(^{59}\) See Rachel Zimmerman & Mark Schoofs, World AIDS Experts Debate Treatment vs. Prevention, WALL ST. J., July 3, 2002, at B1 (explaining that as AIDS strikes rural families, less able-bodied people are around to work the land and this leads people to make drastic choices); Rosenthal, China Now Facing an AIDS Epidemic, A Top Aid Admits, supra note 49, at A10 (noting how poor farmers could give blood several times a month for a fee of about five dollars).

While the cost of antiretroviral cocktails has dropped substantially—dropping to 38 cents a day in some African and Caribbean countries—treatment, diagnostics, and monitoring are still beyond reach for many of those infected around the world. Such a realization often leads to despair, suspicion, resignation, and low expectations of survival, all of which increase the likelihood of risky behavior such as drug use and unprotected sexual promiscuity.

As a corollary to poverty, the subservience or powerlessness of women in many countries also substantially contributes to the spread of the HIV virus. As the Joint United Nations Programme on HIV/AIDS ("UNAIDS") has noted, the low economic and social status of women limits their power to refuse sex with an infected husband or other partner, to discuss issues of fidelity with these partners, to negotiate the use of a condom, or to leave risky relationships. Lack of education and employment opportunities, coupled with a variety of socio-cultural norms and practices, have resulted in an economic dependence on men that extinguishes the sexual and reproductive rights of women. Gender stereotypes, inequalities, lack of legal capacity, and harmful traditional practices often result in physical abuse, sexual violence, and the trafficking of women and girls. Where women are viewed as property of their family, where their rights are vested in male relatives, and where wife inheritance is permitted, it is not sur-

62 See Lynette Clemetson, Our House Is On Fire!, NEWSWEEK, June 11, 2001, at 50 (discussing the difficulty of solving the AIDS problem in impoverished communities); Epstein & Chen, supra note 43, at 31 (noting that what some countries seem to need even more than AIDS drugs is "the alleviation of the loneliness, poverty, and despair that are likely to motivate risky sexual behavior"); Douglas Frantz, Drug Use Begetting AIDS in Central Asia, N.Y. TIMES, Aug. 5, 2001, at A6 (connecting drugs and AIDS).
64 Id.; see also Declaration of Commitment, supra note 3, para. 62 (noting lack of gender equality in family matters).
65 See Declaration of Commitment, supra note 3, paras. 47, 61 (noting that women's rights are essential to fighting AIDS); A Human Rights Based Approach to HIV/AIDS, supra note 3, paras. 12-13 ("States should devote particular attention to the human rights of children and women. . . .").
66 Epstein, supra note 4, at 20.
prising that men determine the nature of sexual behavior. As a result of these social vulnerabilities, the prevalence of HIV/AIDS among teenage girls in some countries of Sub-Saharan Africa, for example, rose to five times higher than that of teenage boys. Sexual coercion, both inside and outside of marriage, has left an undeniable legacy.

Additionally, rape and other forms of sexual abuse are now being employed as fundamental "weapons of war." The Bosnian Ministry of the Interior, for example, has estimated that Serbian soldiers raped 50,000 women and girls. It was also estimated that "virtually every woman who survived the Rwandan genocide was raped" and that at least 250,000 rapes occurred during the 1971 war of independence in Bangladesh. The threat of HIV/AIDS transmission has made these crimes all the more horrific.

While poverty and the lack of empowerment of women are leading contributors to the spread of the HIV/AIDS epidemic, a variety of other social and historical factors play a role as well. For example, those infected with the virus are often stigmatized and ostracized by their society. Such a stigma may extend to their family, to their business, to their farm, and even to their village or region. Victims fear for their jobs, for their ability to generate income and support their dependents, and for sustained acceptance within the community. As a result, those who suspect that they are infected often refuse to be tested, and those who know that they are infected often refuse needed treatment. The discrimination that accompanies the disease actually shortens the lives of those infected and fuels its transmission to others.

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68 See Mark Schoofs & Rachel Zimmerman, Sexual Politics Drives AIDS Epidemic, WALL ST. J., July 9, 2002, at D4 (citing a report "from the London-based Panos Institute, which is working with [UNAIDS], on how to encourage men to change their behavior").


70 Id. at 66.

71 Eisner, supra note 21, at 218.

72 Epstein, supra note 4, at 19.

73 See A Human Right-Based Approach to HIV/AIDS, supra note 3, para. 2 (noting that the stigma decreases the likelihood of treatment); Declaration of Commitment, supra note 3, para. 13 (noting that the stigma undermines prevention); Report on Global HIV/AIDS, supra note 3, at 67 (noting problems associated with discrimination); Collie, supra note 47, at A7 (discussing the incidence of particular stigma in Haiti); Dafna Linzer, AIDS Forum Draws Thousands, HARTFORD COURANT, June 26, 2001, at A2 (describing complaints from AIDS activists); Rosenthal, Blood and Tears, supra note 49, at 27 (noting stigma in China); Rosenthal, China Now Fac-
Denial of the disease can also be found at the political level. The largest problem in Sub-Saharan Africa, according to a health commissioner in Nigeria, was that "people still refuse to believe the disease exists."\textsuperscript{74} South African President Thabo Mbeki, for example, received substantial criticism for his former stance on the AIDS epidemic in South Africa after he allegedly questioned the extent of the problem, the use of antiretrovirals in light of their cost and safety issues, and whether AIDS was actually caused by the HIV virus.\textsuperscript{75} Similarly, a member of the South African Parliament apparently argued that South Africans could not be used as "guinea pigs" for dangerous antiretrovirals that could be used to "exterminate" patients and could "lead to genocide."\textsuperscript{76} "HIV? It doesn't exist," he concluded.\textsuperscript{77} HIV was thought to be a fiction created by multinational pharmaceutical companies hoping to boost profits.\textsuperscript{78} In the fall of 2003, however, both President Mbeki and the South African cabinet dramatically shifted their AIDS policy and indicated that South Africa would undertake the world's largest AIDS treatment program.\textsuperscript{79}

Indefensible positions that some have taken on the HIV/AIDS crisis reflect historical suspicions on the part of the Third World toward the more industrialized powers. Colonialism, political and economic suppression, apartheid, and even medical experimentation\textsuperscript{80} have been unfortunate realities in human history. Unfortunately, healing such wounds and developing a trust between rich and poor nations will take additional time.

Finally, the risk of both exposure and transmission of the dis-

\textsuperscript{74} Linzer, supra note 73, at A2 (citing Dr. Ben Anyene, Health Commissioner in southeastern Nigeria's Anambra state).

\textsuperscript{75} John Aubuchon, South Africa's Millennium Recovery Program, Introductory Remarks at the National Press Club Luncheon with South African President Thabo Mbeki 3 (June 27, 2001) (transcript available from Federal News Service, Inc.); see also President Thabo Mbeki, id. at 12-14 (claiming alternative causes of AIDS).


\textsuperscript{77} Id.

\textsuperscript{78} Id.

\textsuperscript{79} Schoofs, supra note 44, at B1.

\textsuperscript{80} See Swarns, supra note 76 ("[T]he white government long abused science to oppress the black majority.").
ease is increased by the displacement of individuals, whether in the form of refugees destabilized by armed conflict, by natural disaster,\textsuperscript{81} or in the form of migrant workers detached from family structure. UNAIDS has noted, for example, that the likelihood that individuals will hire commercial sex workers clearly increases when large numbers of single migrant men live together.\textsuperscript{82} Mining communities, established as a result of a "complex interplay of economics and history,"\textsuperscript{83} provide unfortunate testimony to such a fact, as low-skilled workers live in company-owned barracks hundreds of miles from home.\textsuperscript{84} In 2001, for example, AngloGold estimated that of its forty-four thousand mineworkers, nearly one-third were infected with the virus.\textsuperscript{85} It has also been estimated that migrant workers as a whole are almost two and one half times as likely to have HIV as are non-migrant workers.\textsuperscript{86} These figures not only reflect the loneliness and despair of many of these individuals, but also a cultural resistance to sex education, discourse regarding sexual relations, and condom use.\textsuperscript{87}

Whatever the particular cause, there is no question that the HIV/AIDS epidemic is destroying the social, economic, and political fabric of many nations. Families are being broken apart as mothers and fathers succumb to the disease. By the end of 2001, for example, fourteen million children under the age of fourteen had already lost either one or both of their parents to AIDS,\textsuperscript{88} and it is estimated that by 2011 there will be forty million AIDS orphans in Africa.\textsuperscript{89} In its Report on the Global HIV/AIDS Epidemic 2002,

\begin{itemize}
\item \textsuperscript{81} See Declaration of Commitment, supra note 3, para. 75 (discussing problems of displaced persons).
\item \textsuperscript{82} Report on Global HIV/AIDS, supra note 3, para. 25.
\item \textsuperscript{83} Id.
\item \textsuperscript{84} Schoofs, supra note 46, at A1.
\item \textsuperscript{85} Id.
\item \textsuperscript{86} Id. at A10 (citing a study by Mark Lurie, an AIDS researcher with South Africa's Medical Research Council).
\item \textsuperscript{87} See Booker & Minter, supra note 43, at 74 (discussing Africans' aversion to sexual discourse and resistance to using condoms); Collie, supra note 47, at A7 (discussing difficulties in Haiti); Frantz, supra note 62 (discussing regional attitudes toward sex as a hindrance to open dialogue); Steinhauer, supra note 67 (discussing the United Nations' assessment of AIDS threat).
\item \textsuperscript{88} Report on Global HIV/AIDS, supra note 3, at 8. The term "children orphaned" is defined as "children aged 0-14, as of end of 2001, who have lost one or both parents to AIDS." Id.
\item \textsuperscript{89} Akukwe & Foote, supra note 44, at 1; Begley, supra note 45, at 36.
\end{itemize}
UNAIDS described how the epidemic dissolves the household, stripping the family of both its income earners and its productive assets. UNAIDS further reported that HIV/AIDS redirects energies from income producing activities to caretaking, which depletes savings and increases debt, driving extended families further into poverty. As a result, farms are abandoned, food production falls, and hunger escalates.90

From an economic growth and development perspective, the AIDS epidemic has had the effect of lowering GDP growth and increasing the risks for foreign investors.91 Productivity has continued to fall as absenteeism and turnover have continued to rise. The workforce has experienced a loss of valuable skills and know-how, and limited resources have been diverted to new recruitment, training, and higher health care costs.92 In South Africa, for example, it has been estimated that 23% of the skilled workforce will be HIV-positive by 2005.93 In light of such forecasts, foreign investments will be further inhibited, thereby compounding both the rise in individual and governmental debt and the fall in overall market demand.

As life expectancies are diminished and educational systems abridged,94 the effects on economic development, social cohesion and political stability may be felt for generations.95 Unfortunately, the destruction of a nation’s fabric also gives rise to immediate international security concerns. Poverty, hunger, and despair often serve to ignite internal strife and political vacuum. The result can be civil war, cross-border and regional conflicts, the suppression of human rights, and mass migration. Internal struggles quickly expand to international struggles with substantial peace and security consequences. As the United Nations Security Council recognized in Resolution 1308,96 the HIV/AIDS pandemic may have “a uniquely devastating impact on all sectors and levels of society… on social instability and emergency situations,” and if unchecked it

91 Id. at 56-57.
92 Id. at 54.
93 Id. at 58 (citing an ING Barings study).
94 See id. at 44-45 (discussing the demographic effect of the HIV/AIDS pandemic).
95 See id. at 23 (discussing the scale of AIDS crisis); Declaration of Commitment, supra note 3, para. 8 (noting that AIDS in Africa threatens development).
“may pose a risk to stability and security.”

In light of the above, the $7-$10 billion annual budget requested by Secretary-General Kofi Annan for the purpose of fighting this epidemic seems like a wise investment in both humanitarian and economic terms. As UNAIDS has pointed out, such an amount would represent only a fraction of the $300 billion that was spent on agriculture subsidies in 2001 alone by the world’s high-income nations.

2.2. HIV/AIDS as an Issue of Human Rights

The HIV/AIDS epidemic gives rise to a variety of human rights issues, including the right to gender equality, the right to equality of those infected, and—in light of the fact that the virus disproportionately affects both Africans and African-Americans—the right of racial equality as well. The epidemic also gives rise to issues regarding discrimination in the workplace, in education, and in receiving medical care. The right to be free from unlawful isolation or detention, the right to be free from cruel or degrading treatment, and the rights to privacy, information, association, movement, and even life itself are all involved in addressing the impact of the disease.

This Article, however, will focus on the fundamental right of every individual to the highest attainable standard of health, including the right of access to both treatment and prevention measures. In doing so, this Article will examine these rights not simply in terms of the International Covenant on Economic, Social and Cultural Rights (“ICESCR”) from which the “highest attainable

97 Id.

98 The $7-$10 billion figure for the Global Fund for AIDS and Health also includes the fight against malaria and tuberculosis.


100 See id. at 40 (“African-Americans . . . make up only 13% of the population of the United States, but accounted for an estimated 54% of new HIV infections in 2000.”).

standard" language is drawn, but in terms of both customary law and principles of *jus cogens* that are applicable to all States irrespective of whether they are parties to any particular covenant. It will also examine these rights in light of the rights of self-determination and development, the right to share in the benefits of scientific advancement, and the indivisibility of civil and political rights with economic, social, and cultural rights. Because these issues will be examined in more detail in Sections 5 and 6 of this Article—which will explore both the duties imposed by domestic and international law regarding the protection and fulfillment of these rights and the constitutionalization of these duties—this section will be limited to providing a background for that discussion.

### 2.2.1. The U.N. Special Session

"In a world of AIDS, the lack of human rights protection can become a matter of life and death." As a result, the sanctity of these rights must be universally established in order to curb the spread of this disease and to allow those infected not only to extend their lives but to live their lives in dignity as well.

In recognition of such a fact, the United Nations Special Session on HIV/AIDS, held during the summer of 2001, transformed a medical crisis into an issue of basic human rights. In "[r]ecognizing that the full realization of human rights and fundamental freedoms for all is an essential element in a global response to the HIV/AIDS pandemic," the Special Session’s Declaration of Commitment on HIV/AIDS ("Declaration of Commitment") stressed the need for equality and the empowerment of women in reducing vulnerability as well as the need for abolishing the myriad of discriminatory practices and stigma that undermine prevention and treatment efforts. It also linked both the epi-

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102 See ICESCR, *supra* note 23, art. 12.1 ("The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.").


104 *Declaration of Commitment, supra* note 3, para. 16; *see also id.* para. 20 (emphasizing the respect of all human rights and fundamental freedoms while fighting the HIV/AIDS pandemic).

105 *See id.* paras. 14, 47, 59-61 (stressing gender equality and female empowerment).

106 *See, e.g., id.* paras. 13 (stigma, silence, discrimination, denial, and lack of confidentiality), 58 (stigma and social exclusion).
demic and the enjoyment of human rights to a variety of other socio-economic issues including poverty, illiteracy, armed conflict, future social and economic development, and the need for technology transfer.107

The Declaration of Commitment also specifically addressed the fact that access to pharmaceuticals in the context of pandemics is one of the fundamental elements in progressively achieving the "right of everyone" to the highest attainable standard of health.108 It acknowledged the fact that the lack of affordable drugs and health infrastructure continued to hinder effective responses, and that non-discriminatory access (at reduced costs) must be provided.109

The Office of the High Commissioner for Human Rights echoed each of these sentiments. After noting the inseparability of the epidemic and the lack of respect for fundamental human rights,110 the High Commissioner for Human Rights recalled the obligations of States under international law to "respect, protect and fulfil the right to the highest attainable standard of health"111 and to ensure the accessibility and affordability of essential drugs.112 Since accessibility is "a fundamental element to achieving the full realization of the right to health,"113 no lesser obligation can be demanded of States. Additionally, "[t]he right to the highest attainable standard of health should inform the implementation of States' obligations under other relevant international agreements[,]"114 including the obligation to exercise the flexibility inherent in the TRIPS Agreement.115

107 See, e.g., id. paras. 2, 5, 8, 11, 62, 68, 69, 73, 78, 87 (discussing these and other issues).
108 Id. para. 15; see also id. para. 37 (listing means to combat these problems).
109 See id. paras. 23-25 (discussing problems in confronting HIV/AIDS related to medical care).
110 See A Human Rights-Based Approach to HIV/AIDS, supra note 3, paras. 1-3 ("Human rights are inextricably linked with the spread and impact of HIV/AIDS ....").
111 Id. para. 9.
112 See id. paras. 9-10 (discussing the right to the highest attainable standard of health).
113 Id. para. 10.
114 Id. para. 11.
115 See id. ("The High Commissioner . . . encourages States to implement the flexibility within the TRIPS Agreement in line with their concurrent obligations under the right to health.").
2.2.2. A Human Rights Foundation

The human right to health (or to the highest attainable standard of health) has been recognized in a substantial number of international instruments. Both the ICESCR\(^{116}\) and the Convention on the Rights of the Child ("CRC")\(^{117}\) specifically employ "the right . . . to the enjoyment of the highest attainable standard of health" language, while the Universal Declaration of Human Rights ("Universal Declaration"),\(^{118}\) the Convention on the Elimination of All Forms of Discrimination Against Women ("CEDAW"),\(^{119}\) and the International Convention on the Elimination of All Forms of Racial Discrimination ("ICERD")\(^{120}\) speak in such terms as the right to the protection of health, the right to health and well-being, the right to health care, and the right to security in the event of sickness. Additionally, the right to health has been incorporated in several regional agreements\(^{121}\) and consistently recognized by the U.N. Commission on Human Rights.\(^{122}\) As will be discussed in more detail later, there are also a wide variety of other international agreements that unquestionably support, although from different perspectives, the right to the highest attainable health.

It can certainly be argued that U.N. resolutions and declarations are not legally binding and that covenants and conventions are only binding on those states that are actually parties to those agreements. As a result, the United States, not being a party to any covenant embracing the 'right to health' or 'highest attainable standard of health' language, would arguably owe no legal duties

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\(^{116}\) ICESCR, supra note 23, art. 12.1.


\(^{121}\) For a listing in this regard, see Substantive Issues, supra note 3, para. 2.

in such a regard. As will be demonstrated in Sections 5 and 6, however, such a position is absolutely without merit in the context of epidemics such as HIV/AIDS.

All human rights are in fact derived from the inherent "dignity and worth" of the individual person. With such a recognition as a core value, the international community has long taken the position "that all human rights and fundamental freedoms are universal, indivisible, interdependent and interrelated." It is therefore not surprising that both the ICESCR (to which the United States is not a party) and the International Covenant on Civil and Political Rights ("ICCPR") (to which the United States is a party) link the enjoyment of economic, social and cultural rights to the enjoyment of civil and political rights. While the ICESCR indicates that "freedom from fear and want" can only be achieved when individuals enjoy not only economic, social, and cultural rights, but civil and political rights as well, the latter indicates that "civil and political freedom" can only be achieved when individuals enjoy not only civil and political rights, but also economic, social, and cultural rights. Additionally, both of these Covenants link their respective rights to the common bonds of inherent dignity and the requisites for international peace and security.

Perhaps in recognition of this indivisibility, U.N. Resolution 2001/33 reaffirmed that the "right of everyone to the enjoyment of the highest attainable standard" of health is indeed a "human right." The use of such language clearly implies that such a right is not contractual in nature and is not limited to those living in nations that are parties to the ICESCR. The resolution thereafter calls on all nations to pursue policies that will promote the availability

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123 Vienna Declaration, supra note 101, pmbl.; see also Universal Declaration, supra note 118, pmbl. (recognizing the inherent dignity of individuals).
124 Declaration on the Right and Responsibility of Individuals, supra note 1, pmbl.; see also Vienna Declaration, supra note 101, para. 5 ("All human rights are universal, indivisible, and interdependent and interrelated.").
125 See ICESCR, supra note 23, pmbl.; International Covenant on Civil and Political Rights, Dec. 16, 1966, pmbl., 999 U.N.T.S. 171, 173 (entry into force on March 23, 1976) [hereinafter ICCPR] ("Recognizing that, in accordance with the Universal Declaration, the ideal of free human beings enjoying freedom from fear and want can only be achieved if conditions are created whereby everyone may enjoy his economic, social and cultural rights as well as his civil and political rights.")
126 See ICESCR, supra note 23, pmbl. ("Recognizing that these rights derive from the inherent dignity of the human person.").
127 Access to Medication, supra note 122, pmbl.
and affordability of pharmaceuticals and will refrain from taking measures that would deny or limit access. 128 Similarly, the Committee on Economic, Social and Cultural Rights has taken the position that "[h]ealth is a fundamental human right indispensable for the exercise of other human rights" 129 and that the right to health must embrace a "wide range of socio-economic factors." 130

The interdependence of rights, as well as the interdependence of various covenants and customary norms, is further highlighted by the "inalienable" rights to development 131 and self-determination. 132 The right to development has been defined as "a comprehensive economic, social, cultural and political process" which is designed to continually improve the well-being of both individuals and entire populations. 133 The collateral right of self-determination, contrary to traditional (and limiting) notions of decolonialization, encompasses not only the freedom to determine political status, but the freedom to pursue economic, social, and cultural development as well. This broader definition of self-determination, which is incorporated into both the ICESCR and the ICCPR, 134 helps to bridge the theoretical gap between the negative obligations surrounding civil and political rights and the more positive obligations surrounding economic, social and cultural rights.

As noted earlier, 135 the HIV/AIDS epidemic continues to have a devastating effect on the social and cultural fabric of many nations. It inhibits economic growth and development, it creates social and political instability, and it threatens the actual existence of a number of nations. In such a context, it is not difficult to argue that a voluntary denial of access to either preventative measures or

128 See id. paras. 2-4.
129 Substantive Issues, supra note 3, para. 1.
130 Id. para. 4.
131 DRD, supra note 25, art. 1.1; see also Vienna Declaration, supra note 101, para. 10 (reaffirming the right to development as universal and inalienable).
132 Vienna Declaration, supra note 101, para. 2.
133 DRD, supra note 25, pmbl.; see also id. art. 1.1 ("The right to development is an inalienable human right.").
134 ICESCR, supra note 23, art. 1.1; ICCPR, supra note 125, art. 1.1; see also DRD, supra note 25, pmbl. (discussing various rights related to development); Vienna Declaration, supra note 101, para. 2 (declaring the right of self-determination).
135 See supra notes 88-97 and accompanying text (discussing the social and cultural effects of HIV/AIDS).
treatment would in fact constitute a denial of the rights to development and self-determination under a variety of circumstances. In advancing such an argument, it should be noted that it is the individual person, and not the State, that is in fact "the central subject of human rights and fundamental freedoms." As a result, the concepts of development and self-determination, while certainly applicable to the relationships among States, may be equally applicable to the relationships between a State and its own citizens. The Declaration on the Right to Development ("DRD"), for example, expressly recognizes the distinction between 'individuals' and 'peoples' by noting that the right to development is an "inalienable human right" by which "every human person," as well as all "peoples," are entitled to participate. Under such an approach, a policy of a nation that has the effect of denying prevention and treatment to the citizens of that nation (whether such a policy takes the form of domestic law or the ratification of an international agreement) would constitute a violation of this right. Additionally, a policy of a foreign nation that interfered with the domestic obligations of another State (or that breached a contractual duty to promote development or to aid in the progressive realization of that right) would similarly constitute a violation.

In such a light, it is becoming increasingly difficult for a nation to extol the values of one set of human rights while denying responsibility or recognition of another. It is impossible to achieve the benefits of 'freedoms' when the conditions necessary to realize those freedoms are lacking. As a result, the totality of international law must be used to impose complimentary duties on individual States. Certainly, the Covenants noted above impose substantial duties on States that are parties to those agreements and many nations have pledged to provide their citizens with a progressive realization of the highest attainable standard of health. Additionally, these agreements increasingly impose a variety of "immediate" legal obligations as the concept of progressive realization contin-

136 Vienna Declaration, supra note 101, pmbl.
137 DRD, supra note 25, art. 1.1 (emphasis added).
138 In regard to the ratification of international agreements that may inhibit access to prevention or treatment, see, e.g., Access to Medication, supra note 122, para. 4(b) and Substantive Issues, supra note 3, paras. 39, 50.
139 Such contractual duties, along with a variety of others, will be discussed in detail in Section 5 of this Article.
140 Substantive Issues, supra note 3, para. 30.
ues to develop an actual, substantive identity.\textsuperscript{141}

In the absence of binding covenants, a variety of international norms have developed that impose similar sets of duties. While this issue will be addressed in Section 6 of this Article, it may be briefly noted that the Universal Declaration, for example, has been consistently viewed as the "common standard of achievement for all peoples and all nations."\textsuperscript{142} It represents the "veritable Magna Carta" of human rights,\textsuperscript{143} "backed by the authority" of the United Nations,\textsuperscript{144} and accepted as authoritative not only by States that have become parties to the ICCPR or ICESCR, but by States that have not ratified or acceded to either of these Covenants.\textsuperscript{145} Its principles have been employed by the U.N. General Assembly and Security Council; they have served as the basis for a number of other human rights instruments and national constitutions; they have been invoked by the International Court of Justice ("ICJ") and national tribunals;\textsuperscript{146} and they have affirmed the rights of individuals "regardless of whether or not governments have formally . . . accepted" such principles.\textsuperscript{147} As a result, the Universal Declaration's recognition that economic, social, and cultural rights are indispensable for the dignity of humanity\textsuperscript{148}—and its recognition that all people have the right to medical care, to a standard of living adequate for their health and well-being,\textsuperscript{149} and to the benefits of scientific advancement\textsuperscript{150}—establishes a dimension far beyond contractual relationships.

This is not to imply that developed countries have the duty to

\textsuperscript{141} See, e.g., \textit{id.} paras. 30-52 (describing the States parties' legal obligations and illustrating violations of those obligations); Treatment Action Campaign \textit{v.} Minister of Health, 2002 (4) BCLR 356 (T) (S. Afr.) (holding that the Ministry must extend its plan to dispense Nevirapine and provide other services for the prevention of mother-to-child transmission of HIV from the original eighteen designated sites to a comprehensive national program).

\textsuperscript{142} \textit{Universal Declaration}, supra note 118, pmbl.


\textsuperscript{144} \textit{id.} at 3.

\textsuperscript{145} \textit{id.} at 10.

\textsuperscript{146} \textit{id.} at 11.

\textsuperscript{147} \textit{id.} at 10.

\textsuperscript{148} \textit{Universal Declaration}, supra note 118, art. 22.

\textsuperscript{149} \textit{id.} art. 25.1.

\textsuperscript{150} \textit{id.} art. 27.1.
provide free health care or pharmaceuticals to their less fortunate neighbors. If such an argument was to prevail, it could be logically argued that developed countries have the duty to provide housing, education, and clothing as well. Such a scenario, of course, is simply not realistic. What is being argued, on the contrary, is that all nations have the duty to their own citizens to protect and fulfill the right to health, and that a failure to take all conceivable actions to achieve that goal (within the bounds of legality and available resources) would be a violation of that right. Such an obligation goes far beyond the Declaration on TRIPS which reaffirms the right of nations to exercise the flexibility of the TRIPS Agreement, but does not require those nations to do so.

The actual recognition and imposition of such a duty, however, will result in an inherent conflict between the fulfillment of human rights and the benefits derived from the protection of the Western notion of intellectual property. Such a conflict can only be resolved by an admission of its absolute inevitability. Only then can practical steps be taken, in the context of a progressive global constitutionalism, to protect both the creators of intellectual property and those in need of its benefits.

3. THE INTELLECTUAL PROPERTY RIGHTS DEBATE

3.1. The Lack of Historical Consensus

The term "intellectual property rights" is often accepted as a given among much of the Westernized world. It is a phrase that is often authoritatively (and perhaps cavalierly) used to define a whole set of creative endeavors that deserve protection under the laws of patents, copyrights, and trade secrets. Such a phrase, however, is far from innocuous. The use of the words "property" and "rights" carries substantial, ideological flavor that may or may not be shared by other nations of the world.

The concept of property, for example, implies the ability to 'own' and thus the ability to exclude others from interfering with or usurping that ownership. As Ronald Corbett has noted, individual ownership in intangibles such as intellectual property, while recognized in Western nations, may not be recognized in de-

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151 Declaration on TRIPS, supra note 28.
veloping countries. Cultural norms may conflict with notions of individual ownership, societies may be based on the value of collectivism rather than individualism, and nations may assume positions that simply reflect the needs of their own citizenry. These factors, and the fact that the developing world is a net consumer of products protected by theories of intellectual property, serve to reinforce a continued resistance to Western claims of ownership and exclusivity.

Similarly, the protection afforded to intellectual property has somehow become a natural right. Under such an umbrella, protection is no longer granted as a reward for creative productivity or as an inducement to invent, but as a recognition of a fundamental human entitlement. Intellectual property rights are no longer viewed as a mere reflection of positive law or as a reflection of the economic, social, and political interactions that give rise to that positive law. Instead, they have been elevated to a higher realm and attached to man as a human being much like equal protection, equality, and self-determination. In this process, these rights have been placed on a moral plane and removed from political and ideological challenge. After all, a fundamental right of man cannot be limited by territorial boundaries, and all nations (irrespective of wealth, history, culture, or need) must award universal acceptance. Despite its suspicious origin and questionable rationale, this notion of the rights of creators and disseminators of knowledge had a substantial impact on the development of the TRIPS Agreement.

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153 Chiappetta, supra note 29, at 376.
154 See id. at 377-78 (describing the conflicts that may occur when "national norms place unselfish contribution to overall social welfare above individual self-interest").
155 Id. at 344.
156 See Oddi, supra note 29, at 418-20, 426, 433 (discussing the history of patent justifications).
157 Id. at 426-27.
158 See id. at 426-27 (discussing the natural rights aspects of intellectual property).
159 Weissman, supra note 29, at 1087; see also Oddi, supra note 29, at 432-33 ("[The natural rights theory] of intellectual property has had great rhetorical power.").
160 Professor Oddi has argued that "the patent portion of TRIPS implements,
It can be argued that the protection of intellectual property is not borne from a natural right but merely represents a conscious governmental decision regarding the means for maximizing social welfare. Much like the right to create a separate business entity or the right to drive an automobile, the protection of intellectual property may represent nothing more than a "product of government" or a "creation of the state." As Weissman has noted, the entire intellectual property debate (and presumably its outcome) would be altered if intellectual property were to be viewed in terms of governmental "grants," "licenses," or "privileges," which could then be conditioned or even refused. Such a positive law perspective would certainly undercut the basic universality approach of the TRIPS Agreement.

Recognizing this fact, some have argued that the owners of intellectual property have tried "to stretch their qualified grants into a more absolute form of control" and have "skewed the original legal and cultural meaning" of intellectual property even when the result is somewhat puzzling. As Oddi has observed, if protection was truly a natural right, why would it be subject to governmental approval or be limited in duration, by territory, and to the first inventor to file (thus depriving other independent creators of the same invention of their natural rights)? Despite these logical inconsistencies, the proponents of a natural rights theory apparently gained control during the Uruguay Round and prevailed in the privilege/entitlement debate.

The fact that the entitlement approach has prevailed should not lead to the conclusion that some form of theoretical truism has fu-

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in significant provisions, a natural property rights theory of patents." Oddi, supra note 29, at 425. For a discussion in this regard, see id. at 426-40 (discussing the foundations of a natural rights based patent system).

161 Abbott, The WTO TRIPS Agreement and Global Economic Development, supra note 29, at 386 ("To some, IPRs are a right of nature . . . . To others, IPRs are purely the product of government.").

162 Weissman, supra note 29, at 1087.

163 Id. at 1087 n.107.

164 Amy Harmon, In the 'Idea Wars,' a Fight to Control a New World Currency, N.Y. TIMES, Nov. 11, 2001, § 3, at 1.

165 See Oddi, supra note 29, at 420-23, 429-31 (describing how legal developments of the 19th century do not indicate a trend toward the natural rights theory of intellectual property law and the inherent failures in the current entitlement system).

166 Id. at 423, 433.
nally been discovered. Whether rightly or wrongly, it is undeniable that this approach was adopted because it represented the position of more powerful nations. Issues regarding the proper balance between private property and public domain, between market efficiency and guaranteed access to medical care, between individualism and collectivism, and between personal and societal ownership of knowledge were all preempted by the elevation of intellectual property in the hierarchy of rights. Such a preemption should not disguise the fact that there are a wide variety of other conceivable patent regimes that could be employed, and that intellectual property protection has historically been left to the national policymaking of individual countries precisely because substantial cultural, normative, and economic differences exist among nations.

Confucianism, for example, emphasizes the importance of maintaining social order and of exhibiting obedience to the family, whether that family be defined in terms of the natural family, the corporate family, or the nation itself. While both the influence and application of Confucian thought may vary from nation to nation—and may be shaped by both domestic needs and external forces over time—a desire for social order may produce a more group-oriented identity that values harmony and loyalty, encourages national views knowledge as an improper subject

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167 See Ackermann, supra note 29, at 497-98 ("One view is that certain kinds of idea-based property are, or should be, pure public goods . . . . [and resultingly,] that knowledge, and its products should be used for the 'benefit of all mankind,'") (citation omitted); Chiappetta, supra note 29, at 337 (noting that disagreement remains as to "whether economic market efficiency and wealth maximization should yield to other conflicting values, such as guaranteed access to basic needs, natural rights of IP creators or even the inappropriateness of individual incentives within a communitarian perspective of the human enterprise."); Harmon, supra note 164, at BU1 ("[Critics of 'intellectual capitalism'] complain . . . that property rights are regularly trumping social values like . . . public health.").

168 See Weissman, supra note 29, at 1071-75 (discussing various patent policy options available for balancing competing interests).

169 Chiappetta, supra note 29, at 343.


171 See Linowes, supra note 170, at 27 (noting the interpersonal network of professional relationships essential to Japanese management success).

172 See WHITEHILL, supra note 170, at 99 (describing Japanese pride since the
of ownership or control, or views the creation of ideas as contributions to a "common heritage" and therefore "freely accessible to all." Similarly, nations may occupy different points along an individualism/groupism continuum, and some States may actually measure the success of an individual by the success of the group. Likewise, some societies may allow communal development concerns to preempt individual intellectual property rights or choose to deemphasize the concept of self-interest and find the incentive to invent in the desire to improve the "common good."

Despite these normative differences, the proponents of stronger intellectual property protection have been quite successful in framing the debate in terms favorable to their position. Unlike many of the rights contained in the Universal Declaration or the ICESCR, intellectual property protection has been considered a trade issue. As a result, the debate was placed within the negotiating arena of the Uruguay Round, where substantial economic and political power was employed to reach the result desired by the most powerful nations. One might rightly question why certain natural rights are in fact trade-related while others are not. Additionally, the use of such metaphors as 'property,' 'right,' 'ownership,' 'propriety,' 'theft,' and 'infringement' has had the effect of transforming a discussion regarding cultural and historical perspective into an overly simplistic moral dichotomy.

post-war era).


174 Chiappetta, supra note 29, at 376 (citing WILLIAM P. ALFORD, TO STEAL A BOOK IS AN ELEGANT OFFENSE 8-29 (1995)).


177 Chiappetta, supra note 29, at 377.

178 See Elizabeth Henderson, TRIPS and the Third World: The Example of Pharmaceutical Patents in India, 11 EUR. INTELL. PROP. REV. 651, 651-52 (1997) (discussing the inclusion of IPR in the General Agreement on Tariffs and Trade ("GATT") negotiations); Oddi, supra note 29, at 426 (writing intellectual property's fundamental acquisition of trade-related aspects); Weissman, supra note 29, at 1075-85 (describing intellectual property's evolution into a trade issue as a pharmaceutical industry offensive).

179 Oddi, supra note 29, at 432; Weissman, supra note 29, at 1070, 1086-91; see
conduct tends to engender more universal condemnation, otherwise legitimate arguments have become substantially less viable.

The issue of morality, of course, is an elusive concept. As will be discussed in the next Section of this Article, there are a number of very credible arguments that support the protection of intellectual property. Any attempt to summarily dismiss such arguments would not only be intellectually inept, but would reflect nothing more than the advancement of utopian liberalism. While arguing the absolute or definitive correctness of any given theory is a rewarding academic experience, the realities of self-interest and confrontation demand more compromising and concrete solutions.

For example, legitimate arguments in favor of intellectual property protection must be viewed in light of the millions of people who have died of AIDS, the millions of people currently living with AIDS, and the millions of people who will be infected with AIDS in the future. Western notions regarding the rights of creators should also be viewed in light of 'Western' responses to their own recent emergencies. Both the United States and Canada, for example, appeared quite ready to bypass Bayer's patent on Cipro (and purchase millions of generic doses) when confronted by the threat of anthrax.¹⁸⁰ Such actions were averted only when Bayer agreed to slash its prices by nearly 50%.¹⁸¹ While such a stance may have been totally justified in light of national security concerns, the threat to the security of nations facing the HIV/AIDS pandemic is certainly no less dramatic.

Additionally, the desire to impose a set of minimum intellectual property standards on the developing world must be viewed in light of the fact that the protection of pharmaceuticals in industrialized nations is a relatively recent phenomenon.¹⁸² For exam-

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¹⁸⁰ See Keith Bradsher, Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine, N.Y. TIMES, Oct. 25, 2001, at B8 (linking Bayer's price reduction to threats to generic brand Cipro); Harmon, supra note 164, at 1 (noting hypocritical behavior by the United States); Joseph Kahn, Trade Deal Near for Broad Access to Cut-Rate Drugs, N.Y. TIMES, Nov. 13, 2001, at A3 (citing the United States' actions regarding Cipro as an example of a possible public health exception to IPR); Andrew Pollack, Drug Makers Wrestle With World's New Rules, N.Y. TIMES, Oct. 21, 2001, at B3 (discussing the Cipro care in terms of national security).

¹⁸¹ Bradsher, supra note 180, at B8.

¹⁸² See Henderson, supra note 178, at 660 ("[M]any Western nations only be-
ple, it has been argued that "many industrialized countries developed pharmaceutical industries in the absence of patent protection." Moreover, "virtually every industrialized country adopted strong patent laws after developing their technological infrastructure, in significant part through copying strategies." If we are to mandate a different pattern of historical development for less-developed nations, some compromises are necessary.

The TRIPS Agreement’s mandate to broaden the scope of patentable subject matter to include any invention, whether a product or process, in all fields of technology should be compared to the lack of protection afforded ‘traditional knowledge’ under the Agreement. Traditional knowledge, developed by indigenous populations over the course of generations, often serves as the basis for the discovery of patentable pharmaceutical products. Nevertheless, this knowledge may remain outside the scope of the TRIPS Agreement’s protection since it is not “new,” does not involve an “inventive step,” and lacks an identifiable connection with one person or small group of persons. The result is that the TRIPS framework does not ordain compensation for the substantial contributions to scientific advancement by poorer nations. This lack of compensation for the use of traditional knowledge and the appropriation of genetic resources has led to credible claims of biopiracy.


\[ 183 \text{ Weissman, supra note 29, at 1123.} \\
\[ 184 \text{ Id. at } 1119 \text{ (citations omitted).} \\
\[ 185 \text{ Provided it is new, involves an inventive step, and is capable of industrial } \\
\[ \text{application. TRIPS Agreement, supra note 26, art. 27.1.} \\
\[ 186 \text{ See Gana, supra note 173, at } 751-52 \text{ (“The use of cultural knowledge to } \\
\[ \text{facilitate the innovative process has recently been documented.”).} \\
\[ 187 \text{ For a substantial discussion regarding traditional knowledge, biopiracy, } \\
\[ \text{misappropriation, etc., see Carlos M. Correa, Traditional Knowledge and Intellectual } \\
\[ \text{Property: Issues and Options Surrounding the Protection of Traditional Knowledge } \\
\[ (2001) \text{ (discussion paper) (describing the development of pharmaceutical } \\
\[ \text{patenting in the industrial world), available at } \text{http://www.geneva.quno.info/} \\
\[ \text{pdf/tkcol3.pdf} \text{ (last visited Sept. 16, 2004). See also Gana, supra note 173, at } 749-52 \\
\[ (discussing the impact of the TRIPS Agreement’s “new” requirement on traditional } \\
\[ \text{knowledge); S.K. Verma, TRIPS and Plant Variety Protection in Developing } \\
\[ \text{Countries, 6 EUR. INT’L PROP. REV. 281, 287-88 (1995) (highlighting cases where} \\
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The requirements of the TRIPS Agreement, however, cannot be isolated from other international obligations. For example, a fundamental tenet of international law is that nations have complete sovereignty over all of their natural wealth and resources. Such a right has been recognized in a variety of international agreements including both the ICCPR and the ICESCR. More particularly, the 1992 Convention on Biological Diversity ("CBD"), to which 183 nations are parties, reaffirmed the fact that States have sovereign rights over their biological resources (including their genetic resources) and that the governments of those states retain the authority to grant access to those resources. Additionally, the CBD recognizes the need to promote a "fair and equitable sharing of the benefits arising out of the utilization of genetic resources" and indigenous knowledge. In doing so, the CBD aims to stimulate access on behalf of countries that are in a position to utilize and commercialize these resources. In return, the CBD is also designed to promote the "sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources." Countries supplying resources should also be given "access to and transfer of [the] technology which makes use of those resources" and should be given the opportunity to participate in the biotechnological re-

dveloped countries patent new forms of indigenous materials from developing countries while pointing out that the indigenous people receive no reward for their knowledge and work that preserved the properties of these now coveted materials; Weissman, supra note 29, at 1089-93 (discussing the industrialized nations' manipulative patenting of Third World biological resources).

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188 See, e.g., ICCPR, supra note 125, art. 47; ICESCR, supra note 23, art. 25; DRD, supra note 25, pmbl., art. 1, para. 2 (recalling sovereignty over natural resources); Declaration on the Right and Responsibility of Individuals, supra note 1, pmbl. (stressing that prime responsibility of protecting human rights are on the states).


190 Id. pmbl., art. 15, para. 1.

191 Id. art. 1.

192 Id. art. 8(j).

193 See id. art. 15 (explaining the utilization of power in relation to the access to genetic resources).

194 Id. art. 15, para. 7.

195 Id. art. 16, para. 3; see also id. art. 1 (articulating the "fair and equitable sharing" philosophy).
search activities undertaken in their regard.\textsuperscript{196} By recognizing that the authority to grant access may reside in one country while the technological capacity for commercialization may reside in another, the CBD attempts to balance the rights and obligations of each country, subject to mutually agreeable terms.\textsuperscript{197} It would therefore be inconsistent to argue that access to traditional knowledge and genetic material should be free, while access to the resulting scientific advancement should be subject to royalty payments.

Finally, the protection of intellectual property cannot be isolated from the fact that the transfer of technology and the sharing of the benefits of scientific advancement are principle mechanisms for accelerating the economic development of poorer nations and for stimulating the protection of human rights.\textsuperscript{198} As the United Nations has observed, scientific and technological developments should be used for "the welfare of man,"\textsuperscript{199} for the purpose of "strengthening international peace and security,"\textsuperscript{200} and for "the realization of human rights and freedoms."\textsuperscript{201} As will be discussed shortly, it can be argued that stronger intellectual property protection ultimately encourages the transfer of technology, thus economic and social development, by reducing the risks of information sharing. Despite this argument, it is beyond a doubt that the AIDS epidemic imposes an immediate threat both to individuals and to international security, and that the most affected of nations lack the capacity to take advantage of technology transfer. As a result, any debate surrounding the need for intellectual property protection (as well as any attempt to interpret the law of the TRIPS Agreement) cannot escape the complexities of immediacy, international security, self-determination, and the property rights-human rights distinction. While denying such a perspective may serve a useful political purpose, it has no place in the environment of the HIV/AIDS crisis.

\textsuperscript{196} Id. art. 19, para. 1.

\textsuperscript{197} See generally, id. art. 19.


\textsuperscript{199} Id.

\textsuperscript{200} Id. para. 1.

\textsuperscript{201} Id.; see also id. paras. 5, 7 (describing what the states must do to advance the social and economic rights).
3.2. The Need for Patent Protection

The patent system, at least according to traditional thought, represents a balancing of interests that is designed to maximize social welfare. A patentee receives exclusive rights over his or her creation for a limited period of time in exchange for a complete, public disclosure of the knowledge upon which the invention is based. Not only may the public use this knowledge upon the patent term's expiration, but also the knowledge may serve (even during the patent term itself) as the foundation for further advancement of science and technology in a variety of fields. In addition to this general dissemination, the monopoly that is granted serves to encourage the patentee to license the discovery so that the invention can be commercialized, technology can be transferred, and other products can be developed for the benefit of society. By ensuring protection for creative efforts, the patent system also provides the necessary incentive for inventiveness since creators will be able to profit from their R&D investments. Each of these dimensions are reflected in Article 7 of the TRIPS Agreement, which notes that the protection of intellectual property rights will promote both technological innovation and the transfer and dissemination of technology "to the mutual advantage of producers and users . . . in a manner conducive to social and economic welfare."202

3.2.1. **Providing Incentives for Innovation**

According to the Pharmaceutical Research and Manufacturers of America ("PhRMA"), R&D is "the key to pharmaceutical innovation."\(^{203}\) The pharmaceutical industry is the most research-intensive major industry in the United States, and PhRMA member companies invested an estimated $33.2 billion in R&D in 2003 as compared to slightly less than $2 billion in 1980.\(^{204}\) This $33.2 billion figure represented a 7.1% increase in R&D expenditures over the previous year\(^ {205}\) and an estimated 15.6% of total sales.\(^ {206}\)

In the pharmaceutical industry, R&D is a "long, risky and expensive" process, with the average cost of developing a new drug now exceeding $800 million compared to only $231 million in 1987.\(^ {207}\) It is also estimated that it takes ten to fifteen years to develop a drug from the laboratory to Food and Drug Administration ("FDA") approval, with an average time period of 14.2 years during the 1990s.\(^ {208}\) Researching more complex, chronic, and degenerative diseases, complying with more demanding developmental requirements, and handling longer clinical trials with more participating patients all increase the cost of both capital and R&D.\(^ {209}\)

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HIV-infected populations), at http://www.who.int/medicines/library/par/hivrelatedocs/patentshivdrugs.pdf (last visited Oct. 14, 2004); Chiappetta, supra note 29, at 362 (contrasting U.S. intellectual property law exhaustion outcomes to copyright and patent exhaustion conclusions); Henderson, supra note 178, at 654-57 (contending that patent protection in developing countries, unlike Western countries, will not be beneficial); Weissman, supra note 29, at 1071-72 (describing the rationale underlying patent policy).

\(^ {203}\) **PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PHARMACEUTICAL INDUSTRY PROFILE 2002**, at 12 (2002) [hereinafter PhRMA PROFILE].


\(^ {205}\) *Id.*

\(^ {206}\) *Id.* at 40 tbl.2.

\(^ {207}\) PhRMA PROFILE, supra note 203, at 12, 20-21 fig.2-11 (citing DiMasi et al., J. HEALTH ECON., 10: 107-42 (1991) and Tufts Center for the Study of Drug Development (2001)); see also PhRMA PROFILE 2004, supra note 204, at 2 ("On average it . . . costs more than $800 million to advance a potential new medicine . . .").

\(^ {208}\) PhRMA PROFILE, supra note 203, at 18-19, fig.2-7 (citing JOSEPH A. DIMASI, *New Drug Development in U.S. 1963-1999*, CLINICAL PHARMACOLOGY & THERAPY, May 2001); see also *Id.* at 69-70 ("On average, it takes more than 14 years and costs $802 million to develop a new medicine."). In 2001, FDA approval alone took an average of 16.4 months. *Id.* at 18-19, fig.2-8.

\(^ {209}\) PhRMA PROFILE, supra note 203, at 12, 22-23.

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Nevertheless, the average period of effective patent life in the pharmaceutical industry has been substantially shorter than that of other industries. For example, new medicines introduced in the early to mid-1990s have had an effective patent life (even with patent term restoration) of eleven to twelve years compared to the 18.5 year patent life in industries that do not receive regulatory approval before bringing a product to market.\footnote{Id. at 30-31, fig.3-1 (citing Henry Grabowski & John Vernon, Longer Patents for Increased Generic Competition in the U.S.: The Waxman-Hatch Act After One Decade, 10 PHARMACOECON., Supp. 2, at 110-23 (1996); Hearing on H.R. 673 and H.R. 400 Before the House Subcomm. on Courts and Intellectual Property (1997) (statement of Michael K. Kirk, Executive Director, The American Intellectual Property Law Association)); see also PHRMA PROFILE 2004, supra note 204, at 31, fig.4.2 (charting the effective patent life of Rx drugs and non-Rx products).}

These substantial investments of both time and money must also be viewed in light of the high failure rates that are involved in pharmaceutical R&D. For example, only 250 of 5,000 - 10,000 screened compounds actually enter preclinical testing and only five of those go on to clinical testing.\footnote{Id.} Only one of these is ultimately approved by the FDA as a new medicine\footnote{Making Contact: 24-01 “Cost of Living: AIDS and Pharmaceutical Companies” (National Radio Project radio broadcast, June 13, 2001) [hereinafter Making Contact] (comment by Jeff Truitt, available at http://www.radioproject.org (last visited Oct. 14, 2004).} and it is often seven to nine years into the process before a company knows whether a drug will prove successful.\footnote{See PHRMA PROFILE, supra note 203, at 22-23 (discussing chronic and degenerative diseases).} In light of these failure rates which are highest when researching complex diseases about which little is known,\footnote{Id. at 20; see also PHRMA PROFILE 2004, supra note 204, at 31 fig.4.1 (comparing marketed drugs' revenue with average R&D costs).} pharmaceutical companies “must rely on a limited number of highly successful products to finance their continuing R&D.”\footnote{Id. at 30-31, fig.3-1 (citing Henry Grabowski & John Vernon, Longer Patents for Increased Generic Competition in the U.S.: The Waxman-Hatch Act After One Decade, 10 PHARMACOECON., Supp. 2, at 110-23 (1996); Hearing on H.R. 673 and H.R. 400 Before the House Subcomm. on Courts and Intellectual Property (1997) (statement of Michael K. Kirk, Executive Director, The American Intellectual Property Law Association)); see also PHRMA PROFILE 2004, supra note 204, at 31, fig.4.2 (charting the effective patent life of Rx drugs and non-Rx products).}

Accordingly, it can be strongly argued that intellectual property protection must be granted for those research efforts that ultimately prove successful. Such protection diminishes some of the risks associated with R&D and thereby encourages private investment in innovative activities. Without potential reward, incentives
for investing private capital would be substantially lacking.\textsuperscript{216} Additionally, a credible argument can be made that in light of the disproportionately high level of both investment and risk—as well as the tremendous social benefits resulting from the introduction of an important new medicine—society should err on the side of "over-incenting" R&D in the pharmaceutical industry.\textsuperscript{217}

The need to preserve incentive has given rise to a number of allegations regarding the "rampant" and often "unfettered" piracy of intellectual property in many developing countries\textsuperscript{218} that result in billions of dollars in losses to a variety of American industries.\textsuperscript{219} In specific regard to the pharmaceutical industry, Corbett has indicated that patented drugs are "particularly vulnerable" to piracy since generic versions can be produced by using methods disclosed "in the patent itself or . . . [through] the development of alternative synthetic routes" by reverse engineering.\textsuperscript{220} As a result, while patented pharmaceuticals are extremely costly and time-consuming to create, they are relatively easy and inexpensive to copy.\textsuperscript{221} In addition to billions of dollars in lost sales, however, global piracy has also reduced pharmaceutical R&D investment by hundreds of millions of dollars each year.\textsuperscript{222} At least in theory, it could be argued that if all pirating producers were made to share in the burdens of R&D (by means of royalty payments), not only could the level of R&D be enhanced, but global prices could be reduced.

As of 2002, more than one thousand new medicines were under

\textsuperscript{216} See Robert M. Sherwood, The TRIPS Agreement: Implications for Developing Countries, 37 IDEA 491, 492-93 (1997) (explaining how legal tools can encourage investment by reducing the risk).

\textsuperscript{217} Chiappetta, supra note 29, at 363.

\textsuperscript{218} Corbett, supra note 152, at 1084.

\textsuperscript{219} See id. at 1084-85 (discussing piracy rates in several world regions and countries). For additional discussion in this regard, see Weissman, supra note 29, at 1085-86 (discussing an industry study finding high costs for the United States resulting from inadequate intellectual property protection).

\textsuperscript{220} Corbett, supra note 152, at 1085.

\textsuperscript{221} See Henderson, supra note 178, at 660 (discussing the high cost of pharmaceuticals development and the low cost of copying existing pharmaceutical products); Int'l Fed'n of Pharm. Mfrs. Ass'n ("IFPMA"), GATT TRIPS and the Pharmaceutical Industry: A Review, PAT. WORLD, Sept. 1995, at 29 ("The medically innovative products are increasingly difficult to invent, but frequently straighthforward and inexpensive to copy.").

\textsuperscript{222} See PhRMA PROFILE, supra note 203, at 36 ("[T]he U.S. International Trade Commission found that global patent piracy reduces pharmaceutical R&D investment by $720-$900 million annually.").
development, either in human clinical trials or awaiting FDA approval, including thirty-eight AIDS antivirals, fifteen drugs aimed at AIDS-related cancers, and fourteen AIDS vaccines. The potential benefits of these drugs for suffering individuals around the world cannot be overstated. Nevertheless, companies simply cannot make these types of investments when their successes can be copied and sold at reduced prices by competitors who need not recover R&D expenses. PhRMA maintains that without intellectual property protection, there would be no research-based pharmaceutical industry (at least as we know it), no generic pharmaceutical industry (since there would be no new drugs to copy), and a greatly diminished flow of life-saving medicines. Additionally, any reduction in protection would first be felt by those with diseases that afflict smaller numbers of individuals or those with diseases that primarily afflict the poor.

There are a number of arguments that have been advanced to counter, although only in part, the positions taken by the pharmaceutical industry. It has been argued, for example, that the level of R&D expenditure and the level of income resulting from a patented drug are not necessarily directly correlated. It has been noted, for example, that the AIDS drug Norvir was developed with a $3.2 million grant and generated $41 million in sales during the first half of 1997. Similarly, the pharmaceutical company that ultimately acquired exclusive control over AZT, which had in fact been developed in federal government laboratories, actually contributed little in the way of funding for the development of the drug. It has also been argued that the figures cited by the industry regarding the costs of R&D are "inflated" and do not reflect

223 Id. at 2, 3 fig.1-1.
224 Id. at 30.
225 Id. at 30, 36, 70.
226 See Kahn, supra note 180, at A3 (articulating the debate surrounding the public health exception to patent rules).
227 See ACCESS TO MEDICINES, supra note 29, at 40-41 ("[T]here is no direct correlation between the income that is obtained on the basis of a patent and the amount of R&D undertaken.").
228 Making Contact, supra note 213, at 6 (comment by Babich) (citing the Boston Globe).
230 Making Contact, supra note 213, at 6 (comment by Babich) (citing Jamie
the fact that the industry receives substantial subsidies from the federal government to aid in the development process. In addition to large subsidies, the industry is also the beneficiary of substantial tax credits for the development of drugs that treat "orphan diseases" affecting fewer than 200,000 people.

In response to such allegations, PhRMA has taken the position that any contention that the government pays for most of the research for top-selling prescription drugs is simply false and that only a small portion of those drugs have been developed through technologies created with NIH funding. Additionally, the benefits accruing to the U.S. economy have far exceeded any subsidies borne by the nation's taxpayers. In particular regard to orphan drugs, it is argued that ten to twenty million Americans suffer from thousands of orphan diseases and that tax credits (making R&D more "commercially feasible") have helped to develop more than 220 drugs and biological products aimed at these diseases over the last two decades.

Some critics also believe that the patent system, and particularly the granting of patents in the pharmaceutical sector, can actually frustrate both innovation and the competition upon which it is based. In 2000, for example, approximately 6800 biotechnology patents were granted in the U.S. alone, representing a 400% increase over the last decade. When thousands of ideas, products,
and processes are being monopolized each year, building on the ideas of others becomes substantially more difficult when "a license must be negotiated to use any existing sliver of innovation."\(^{237}\) As a result, potential competition is held at bay and both the incentive and the ability to pursue incremental scientific advancement are considerably reduced. The fact that many patents lie unexploited by their owners and exist solely for the purpose of guarding against competitive imports, or protecting the commercial viability of older products, provides support for those questioning the current regime.\(^{238}\) Additionally, any benefits of the patent system must also be viewed in light of a number of expenses that include the resources wasted in attempting to 'invent around' the patent rights of others,\(^{239}\) the market inefficiencies caused by monopoly abuse,\(^{240}\) the innovation that would have occurred even in the absence of patent protection,\(^{241}\) and the losses incurred when multiple inventors, only one of whom will be rewarded, are pursuing identical creations.\(^{242}\)

Finally, the need for incentive argument loses some of its credibility when applied to pharmaceutical patent protection in poor countries. Patent-driven research is primarily supported by profits derived from the lucrative Western markets and not by any anticipated profits in impoverished nations.\(^{243}\) Enforcing patent protection in those nations or engaging in futile attempts to exact substantial rewards are not prerequisites for the creation of incentive. A decision to undertake a particular R&D project, for example, is

\(^{237}\) Harmon, supra note 164, at 1. Bristol-Myers Squibb, for example, has indicated that "its researchers cannot pursue at least 50 promising approaches to fighting cancer because of patents accumulated by others." Id. at 7; see also Oddi, supra note 29, at 448-49 (discussing how broad patent protection may retard the improvement and evolution of a particular technology).

\(^{238}\) See Henderson, supra note 178, at 656 ("[M]ost foreign owned patents are unexploited, which preserves a protected import market and obstructs potential competition."); see also Anand, supra note 236, at A1, A6 (discussing patent-holder’s refusal to license a patent in order to protect existing products).

\(^{239}\) Henderson, supra note 178, at 655.

\(^{240}\) See id. (discussing how royalties must be paid to foreign companies in order to legally use the patent).

\(^{241}\) Oddi, supra note 29, at 441-45 (explaining that competitive market pressures would also lead to the creation of inventions).

\(^{242}\) Id. at 446 (discussing rent dissipation theory).

\(^{243}\) Attaran & Gillespie-White, supra note 32, at 1890 (stating that "the entire African pharmaceutical market, at 1.1% of the global whole, is commercially negligible").
not dependent upon anticipated African sales. In all fairness, however, proponents of such an argument should also recognize that competition from the legitimate generic drug industry has already increased substantially and that proposals for price differentiation must be accompanied by an ability to successfully engage in geographic market segmentation.244

3.2.2. Providing Incentive for Development

In mandating minimum intellectual property standards, the TRIPS Agreement reflects the traditional arguments that IPR protection will spur technology transfer, increase the level of foreign investment, and stimulate economic and social development within the Third World.245

In regard to technology transfer, it would appear logical that knowledge-holders would be reluctant to license their technology in a jurisdiction where IPR protection was inadequate. Where protection and/or enforcement is lacking, a licensee would be free to breach the licensing agreement without consequence, misappropriate the knowledge without compensation, and even sell that knowledge to other potential pirates. Under such a circumstance, all knowledge becomes (in a sense) nothing more than a set of trade secrets that must be scrupulously guarded. As IPR protection gains acceptance, however, these risks are correspondingly reduced and technology transfer becomes a more rational business decision making option as potential benefits begin to outweigh po-

244 Since 1984, “the generic industry’s share of the prescription drug market has jumped from less than 20% to almost 50% today.” PHRMA PROFILE, supra note 203, at 31-33.

245 For a discussion regarding various aspects of these traditional arguments see, e.g., PHRMA PROFILE, supra note 203, at 34 (foreign investment, economic and social development); Abbott, The WTO TRIPS Agreement and Global Economic Development, supra note 29, at 390-93 (technology transfer and economic development); Chiappetta, supra note 29, at 344, 358 (technology transfer and economic development); Corbett, supra note 152, at 1093 (economic development); Jamie Eisenfeld & François Serres, African Legal Developments in the United States and Sub-Saharan Africa, 35 INT’L LAW. 869, 871 (social and economic development); Harmon, supra note 164 (economic development); Henderson, supra note 178, at 656-57 (technology transfer, foreign investment, and economic development); IFPMA, supra note 221, at 33 (foreign investment and economic development); Oddi, supra note 29, at 459-60, 467-69 (technology transfer and industrialization); Sherwood, supra note 216, at 502-11 (technology transfer, foreign investment, and economic and social development); Weissman, supra note 29, at 1086, 1121-24 (foreign investment and economic and social development).
tential costs. Similarly, foreign investment rises as licenses are granted, production facilities are financed, joint ventures are created, and workers are hired and trained.

In addition to spurring an infusion of foreign-based technology and capital, IPR protection would theoretically encourage more domestic innovation and internal development. Potential innovators, as well as those capable of commercializing those innovations, would tend to increase their domestic activities if their government provided an adequate reward system. Domestic risk capital would be enhanced, facilities would be constructed, skilled workers and scientists would be domestically retained (and could build upon protected technology transfer), and more products would be produced that were aimed specifically at local needs. Wealth creation and the provision of new or improved products would accrue to the benefit of society as a whole.

Unfortunately, many poor nations lack the financial, educational, physical, and human infrastructure that is necessary to transform these theories into reality. A substantial amount of domestic risk capital, for example, will not be forthcoming when it simply does not exist. As a result, the benefits envisioned by the TRIPS Agreement will vary dramatically from country to country. These variations will reflect different levels of domestic education and expertise, available natural and capital resources, and administrative and judicial capabilities. They will also reflect historical relationships with industrialized nations, the general attractiveness of the domestic market, the immediacy of societal needs, and the cultural propensity to employ creative mechanisms for interpreting the mandates of the TRIPS Agreement in terms of domestic a

246 See Abbott, The WTO TRIPS Agreement and Global Economic Development, supra note 29, at 390 ("[I]f developing countries do not adopt high levels of [intellectual property rights protection], their scientists and other innovators will leave because they will not be adequately rewarded for their innovation . . . ."); Sherwood, supra note 216, at 504 (discussing how better IPR protection can lead companies to invest in employee skills improvements).

247 See Chiappetta, supra note 29, at 344 (describing how low protection arguably leads to an under-supply of goods and services tailored to local needs).

248 See Henderson, supra note 178, at 654 (discussing the different circumstances between developing countries and developed countries while still in development); Oddi, supra note 29, at 459 (arguing that developing countries need technology transfer to benefit from the TRIPS Agreement); Weissman, supra note 29, at 1122-24 (supporting the notion that developing countries may not have the domestic capability to undertake research and development to solve local problems).
With such variations in mind, it has been argued that there is in fact no dispositive evidence that the Agreement will result in increased economic development, increased domestic R&D and innovation, or increased foreign investment in poorer nations. As a result, any attempt to apply universal truths in such a diverse global environment must be subject to considerable scrutiny.

3.2.3. Placing Patent Protection in Perspective

The need to preserve a viable and increasingly innovative pharmaceutical industry and the need to effectively respond to the growing HIV/AIDS epidemic and other global public health concerns are in the process of colliding. In light of the duties that nations owe to their citizens and to other nations, however, such a collision serves as an opportunity to pursue a new approach to international relations based upon an inevitable progression toward a global constitutionalization of human rights.

The existence of such a collision should not be interpreted as an allegation that the HIV/AIDS crisis is a consequence of intellectual property protection. The fact that AIDS drugs are proprietary should not be equated (as a truism) with their lack of accessibility. In a controversial study conducted by Attaran and Gillespie-White, for example, the patent status of fifteen antiretroviral drugs in fifty-three African nations (yielding 795 data points) was examined. With the exception of South Africa (where a comparatively large number of antiretrovirals were patented), the authors found that these drugs were patented in few African countries and that in countries where patents did exist only a small subset of antiretrovi-

249 See, e.g., Abbott, The WTO TRIPS Agreement and Global Economic Development, supra note 29, at 391-93 (explaining that while there are economic advantages to the TRIPS Agreement, there remains considerable uncertainty as to the extent of those advantages); Sherwood, supra note 216, at 493-511 (discussing the benefits and costs of TRIPS Agreement compliance for developing countries at the macroeconomic level).

250 See Abbott, The WTO TRIPS Agreement and Global Economic Development, supra note 29, at 390-91 (citing a U.N. study that found no correlation between high levels of IPR protection and foreign investment); Corbett, supra note 152, at 1093 (discussing the theory that IPR protection spurs development); Harmon, supra note 164, at 7 (discussing IPR protection taking priorities over social issues); Weissman, supra note 29, at 1122-23 (citing a study by J. Davidson Frame which found that countries with low IPR protection have larger scientific and technological capacities than other developing countries).

251 Attaran & Gillespie-White, supra note 32.
rals were protected.\textsuperscript{252} Of 795 possible instances of patent protection, only 172 (21.6\%) actually existed.\textsuperscript{253} Additionally, geographic patent coverage did not appear to correlate with access to antiretroviral treatment and no evidence was identified that treatment was more accessible in countries with few or no antiretroviral patents.\textsuperscript{254} Both brand name and generic sources of drugs were available at substantially reduced prices—generally 90\% less than those sold in the United States.\textsuperscript{255} As a result, it was suggested that patent protection for antiretroviral drugs in Africa was not extensive and was not a major barrier to access.\textsuperscript{256} Instead, such a barrier may be found in the “extreme dearth of international aid finance.”\textsuperscript{257}

Critics have argued that the study ignores the basic fact that prices have been reduced as a result of the three-year battle over the costs of antiretrovirals, that the drugs most aggressively patented are those made by generic manufacturers in India, and that most patents have been taken out in the richer African countries or those in which Indian companies have offices.\textsuperscript{258} Additionally, the authors of the study recognize that their results should not be interpreted to mean that patents never affect access to medicines in general, nor should the results be used to reach any conclusions regarding the patenting of future antiretroviral drugs.\textsuperscript{259}

More importantly, the ability to acquire access to new life-

\textsuperscript{252} Id. at 1886-88.
\textsuperscript{253} Id. at 1887.
\textsuperscript{254} Id. at 1889-90.
\textsuperscript{255} Id. at 1891. Additionally, “[w]hile patents do limit the use of some highly active antiretroviral therapy regimens . . . the U.S. Department of Health and Human Services (“DHHS”) clinical guidelines list several ‘strongly recommended’ regimens for which there are encouraging clinical trials and which are unpatented in up to 52 of 53 African countries.” Id. at 1887. For a listing of antireinf ective and antiretroviral drugs, their patent owner, expiration dates, etc., see BOULET, supra note 202, at 11-16.
\textsuperscript{256} Attaran & Gillespie-White, supra note 32, at 1886-87; see also Attaran & Gillespie-White, supra note 32, at 1890 (“[I]t is doubtful that patents are to blame for the lack of access to antiretroviral drug treatment in most African countries.”).
\textsuperscript{257} Id. at 1891.
\textsuperscript{259} Attaran & Gillespie-White, supra note 32, at 1890 (discussing access to medicines); id. at 1889 (stating that “current antiretroviral drugs will remain largely unpatented in Africa,” but that future antiretroviral drugs “may be another matter”).
saving drugs may be altered dramatically in 2005. While the Declaration on TRIPS granted least-developed countries an extended transition period for pharmaceutical products (until January 1, 2016), such an extension may prove to be of questionable value since the major generic suppliers must comply with the TRIPS Agreement a decade earlier. Perhaps the new TRIPS Council Decision regarding the Implementation of Paragraph 6 of the Declaration on TRIPS—which is designed to make it easier for poor countries lacking domestic capacity to import cheaper generic drugs by means of allowing producing countries to export generic copies to eligible nations under compulsory licenses—will partially alleviate the problem of future access. As will be discussed in Section 4, this decision is not without problems of its own.

It is undeniable that the HIV/AIDS crisis is linked to a wide variety of economic, social, cultural, and political factors that have developed, at least in some cases, over the course of centuries. As discussed earlier, the existence of poverty, the lack of empowerment of women, and the imposition of stigma have, among other factors, all contributed to the spread of the disease. Attempts at treatment are not only hampered by the cost of antiretrovirals (even when sold at substantially discounted prices), but by the lack of a medical and physical infrastructure, unfavorable regulatory environments, inadequate capacity for monitoring and regime-setting, nonexistent distribution and delivery systems, an absence of political will, and a scarcity of international funding. Adding to these difficulties is the fact that a substantial portion of the drugs in developing countries may be counterfeit. The fact that these drugs may be contaminated, mislabeled, or lacking in essential ac-

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261 See supra notes 32-99 and accompanying text (discussing a variety of factors that have impeded HIV/AIDS prevention efforts).

262 See Attaran & Gillespie-White, supra note 32, at 1886, 1890 (analyzing the theory that patents are to blame for keeping drugs inaccessible); see also PhRMA Profile, supra note 203, at 36 (disputing patent theory by pointing to poverty and other conditions within impoverished nations).

263 PhRMA Profile, supra note 203, at 38 (citing World Health Organization, Counterfeit Drugs: Fact Sheet (Geneva: WHO, May 2000)).
tive ingredients not only undermines patient confidence in the integrity of medicines, but also encourages the development of drug-resistant strains.\textsuperscript{264}

As a result, rational solutions to the HIV/AIDS crisis cannot be based on attempts to blame pharmaceutical companies. Not only would such an approach be simplistic, it would fail to encourage a progressive global constitutionalism in the area of public health that can be spawned by the HIV/AIDS crisis. An accurate understanding of the crisis should include a recognition that the pharmaceutical industry has in fact taken steps to make their medicines more available in poor countries. Whether based on altruism or substantial public pressure, companies have provided AIDS drugs to these nations at severely discounted prices and, at least in a number of instances, at prices that are at or below their costs.\textsuperscript{265} Merck, Bristol-Myers Squibb, and Abbot, for example, have lowered their prices for antiretrovirals to levels that are at their stated costs of production and distribution,\textsuperscript{266} and Videx and Zerit have been offered to African countries at 93\% below their North American price.\textsuperscript{267} GlaxoSmithKline and Boeringer Ingelheim have agreed to allow more generic versions of their patented AIDS drugs to be produced in South Africa and other Sub-Saharan nations, and Glaxo has agreed not only to cap its royalty fees, but to allow generic licensees to export these drugs to forty-seven other poor nations.\textsuperscript{268} Similarly, Merck has indicated that it would cut the price of its once-a-day AIDS pill, Stocrin, in the most severely affected nations, resulting in a price that is actually lower than a number of generics.\textsuperscript{269} Boeringer Ingelheim has also offered to supply Nevirapine (which significantly reduces MTCT) free of charge to the public health authorities in South Africa for five years.\textsuperscript{270} Additionally, the industry as a whole has been involved

\begin{thebibliography}{99}
\bibitem{264} \textit{Id.} at 37-39.
\bibitem{265} \textit{Id.} at 7, 36.
\bibitem{266} Attaran \& Gillespie-White, supra note 32, at 1891.
\bibitem{269} Zimmerman \& Schoofs, supra note 268, at A2.
\bibitem{270} See Treatment Action Campaign v. Minister of Health, 2002 (4) BCLR 356, 360 (T) (S. Afr.) (ruling that respondents were to make Nevirapine available).
\end{thebibliography}
in such undertakings as the Academic Alliance for AIDS Care and Prevention in Africa, as well as a variety of programs designed to enhance community outreach, education, and research. It has also donated antiretroviral medicines (as well as millions of dollars) for work with the Bill and Melinda Gates Foundation in Botswana.  

Despite these efforts, and irrespective of the motives upon which they may be based, the economic, social, political, and infrastructural problems surrounding the HIV/AIDS crisis will remain. Even if patented or generic drugs were to be made consistently available at slightly over cost (and then added to the costs of medical personnel, distribution, monitoring, testing, and education), effective prevention and treatment would still be beyond reach in many nations. In some African countries, for example, annual health budgets have been as meager as $8 or less per person. Additionally, while differential pricing will certainly play an important role in combating the AIDS epidemic, it is a mechanism that is burdened with its own set of complexities. Questions will persist regarding the most effective means for market segmentation, the manner in which differential prices should be determined, the role to be played by competition law and the effects of constraints imposed by international agreements. Questions will also remain regarding the political ramifications resulting from substantial price differentials between poor and more affluent nations and the manner in which middle-income developing countries (as well as wealthy citizens within poor countries) will be treated. Further, if higher prices in one set of nations are used to subsidize lower prices in others, the need to ensure the rights of the poor living in wealthier nations will become even more critical.

Issues will also persist regarding the effect of intellectual prop-

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271 PhRMA Profile, supra note 203, at 7. Additionally, former President Bill Clinton’s foundation recently reached an agreement with five leading medical companies to cut the price of two critical HIV diagnostic tests. Mark Schoofs, HIV Test Makers Agree to Discounts for Poorer Nations, WALL ST. J., Jan. 14, 2004, at B1.

272 Attaran & Gillespie-White, supra note 32, at 1891 ("Countries such as Ghana, Nigeria, and Tanzania have annual national health budgets of $8 or less per capita.") (referring to Amir Attaran & Jeffrey Sachs, Defining and Refining International Donor Support for Combating the AIDS Pandemic, 357 LANCET 57, 57-61 (2001)).

erty protection on pharmaceutical prices in general, whether those pharmaceuticals are directed at HIV/AIDS or other diseases that will infect the poor in years to come. While acknowledging the importance of intellectual property protection, the Declaration on TRIPS specifically recognized substantial concerns regarding its effects on prices, and simple logic supports the proposition that monopoly power tends to raise pharmaceutical prices while competition from generics produces the opposite effect. As a result, while this Article will not attempt to decipher the motives behind current price reductions, it should be noted that generic drugs are in fact available from suppliers in India and Brazil at similar price levels. If the charitable actions taken by the pharmaceutical companies reflect nothing more than the realities of generic competition, substantial concern must be expressed regarding the industry’s stance in the event of a dramatic erosion in generic supply. As developing countries exhaust their transition periods and begin to implement patent protection for pharmaceutical products (including those in the mailbox pipeline), the incentive to lower prices on patented drugs, at least from a business perspective, will be correspondingly reduced.

The position of this Article is that even when the TRIPS Agreement is fully implemented, substantial downward pressure on prices can continue to exist if nations actually fulfill their domestic and international obligations. As will be argued, all consuming nations have the duty (and all producing nations have the right) to exercise the substantial flexibility of the TRIPS Agreement to ensure the progressive realization of the right to the highest attainable standard of health. Anything less would represent a violation of both domestic and international law. Such a model, whether directed at the current AIDS crisis or at future public health concerns, will therefore view the conflict between intellectual property protection and the right to health not as an obstacle, but as a mechanism for stimulating a new international relations

274 Declaration on TRIPS, supra note 28, para. 3.
275 See COMPULSORY LICENSING, supra note 29, at 9, 16-17 (describing how compulsory licensing can reduce the adverse effects that patents have on price and availability).
276 See id. at 9 ("The decrease will accelerate when on January 1, 2005, developing countries are required to implement pharmaceutical product patent protection, and grant patents as appropriate to pharmaceuticals in the mailbox pipeline.").
paradigm.

4. THE FLEXIBILITY OF THE TRIPS AGREEMENT

4.1. Objectives and Principles

Subject to a variety of transition periods, members of the World Trade Organization ("WTO") have the duty to implement the TRIPS Agreement and adhere to its mandates. Such a duty is in no way synonymous with a guarantee to protect all intellectual property or to honor all notions of patent-holder rights. Because the Agreement contains a number of both limited and broad-based exceptions, as well as a variety of subjective provisions that are open to differing interpretations, a nation's promise to be bound by the Agreement cannot be equated with a promise to enforce Western approaches to intellectual property rights. As a result, it can be argued that intellectual property protection (at least the form expressed in the TRIPS Agreement) and the provision of greater access to pharmaceuticals need not conflict as a matter of law. Individuals affected by the HIV/AIDS epidemic, for example, need not ask their governments to 'breach' the TRIPS Agreement. Such individuals must merely demand that their governments exercise the flexibility contained therein.

The TRIPS Agreement specifically recognizes the "special needs" of less developed countries in regard to maximum flexibility in the domestic implementation of laws and regulations.277 As will be argued shortly, the Agreement provides substantial flexibility in such areas as compulsory licensing, exhaustion, public health, patentability, the use of limited exceptions, the protection of essential security interests, and the interpretation of such terms as 'abuse' and 'unreasonable.' It is within such a light that developing countries have argued that Members must have the right to formulate and implement their own public health policies and to implement the TRIPS Agreement "in ways that best accommodate" those policies.278 The Agreement should not be used to undermine this discretion and patent protection should not be viewed as paramount to fundamental public health needs.279 After all, the in-

277 TRIPS Agreement, supra note 26, pmbl.
278 Developing Country Group's Paper, supra note 29, para. 38.
279 Id. paras. 2, 3, 15.
corporation of this "room to manoeuvre" served to accommodate
the different positions of the WTO Membership at the time of the
original negotiations.280

Such an approach was apparently endorsed at the WTO Minis-
terial Conference in Doha and later reaffirmed by the TRIPS Coun-
cil Decision regarding the Implementation of Paragraph 6 of the
Declaration on TRIPS. The Ministerial Declaration stressed
the importance of implementing and interpreting the TRIPS Agree-
ment "in a manner supportive of public health"281 and reiterated
the fact that "special and differential treatment" for developing
and least-developed countries is "an integral part of the WTO
Agreements."282 More particularly, in the accompanying Decla-
ration on TRIPS, the Members specifically recognized the gravity
of the current HIV/AIDS epidemic.283 In doing so, the Members reaff-
firmed the fact that the Agreement "does not and should not pre-
vent Members from taking measures to protect public health" and
that the Agreement "should be interpreted and implemented in a
manner supportive of WTO Members' right . . . to promote access
to medicines for all."284 The Declaration also reaffirmed the right of
each Member "to use, to the full, the provisions in the TRIPS
Agreement, which provide flexibility for this purpose,"285 includ-
ing the right to grant compulsory licenses and to determine the
grounds upon which they are granted, the right to determine what
constitutes a national emergency or other circumstance of extreme
urgency (with the understanding that public health crises such as
the HIV/AIDS epidemic have achieved such a status), and the
right to establish individual regimes for the exhaustion of intellec-
tual property rights without challenge.286

The Declaration on TRIPS also recognized that each provision
of the TRIPS Agreement must be interpreted in light of the Agree-
ment's objectives and principles287 as is mandated by Article 31 of

280 Id. para. 5.
281 Ministerial Declaration, supra note 202, para. 17.
282 Id. para. 44; see also id. para. 50 (noting several WTO provisions that offer
special treatment for developing and less-developed countries).
283 Declaration on TRIPS, supra note 28, para. 1.
284 Id. para. 4.
285 Id.
286 Id. para. 5.
287 Id. para. 5(a).
the Vienna Convention on the Law of Treaties. The objectives of the TRIPS Agreement, as outlined in Article 7, reflect far more than merely the protection of intellectual property rights. Instead, Article 7 speaks in terms of protecting intellectual property in a way that creates a "mutual advantage" for producers and consumers, that establishes a "balance of rights and obligations" and that is applied "in a manner conducive to social and economic welfare." As a result, developing countries have taken the position that intellectual property rights "do not exist in a vacuum," and when pharmaceutical patents "are not exercised in a way that meets the objectives of Article 7," nations may take measures (such as the granting of compulsory licenses) to ensure that those objectives are achieved.

In light of the fact that many nations are not in a position to develop their own patented products or even take advantage of potential technology transfer, it can be argued that only one side of the TRIPS bargain (namely the protection of intellectual property for patent producers) is being met. If the objectives of balancing rights and obligations and of creating mutual advantages among nations are not being fulfilled, one may question whether developing countries actually remain bound by the terms of the Agreement. Similarly, the economic and social destruction resulting from the HIV/AIDS epidemic should also be placed within the context of the TRIPS Agreement's objectives. Setting aside non-patent variables such as distributional and infrastructural problems, it can be argued that any patent-induced price increase or any patent-induced impediment to access would run contrary to

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289 Article 7 reads:

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.

TRIPS Agreement, supra note 26, art. 7.

290 Developing Country Group's Paper, supra note 29, para. 18.

291 Id. para. 19.

292 See ACCESS TO MEDICINES, supra note 29, at 24 ("Developing Members might choose to challenge the continued enforcement of the TRIPS Agreement or specific provisions on grounds that it is not meeting its stated objectives.").
the economic and social welfare objective of Article 7. As a result, all provisions of the TRIPS Agreement must be viewed in terms of a bargained-for exchange, and the protection of intellectual property must be seen not merely as a static set of rules, but as a mandated "process" ultimately leading to a series of mandated benefits.

The principles of the TRIPS Agreement are established in Article 8, which states that "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." Several brief comments can be made in regard to the selection of this language.

First, this provision actually provides two separate grounds upon which measures may be taken to combat the HIV/AIDS crisis. In addition to condoning measures that are adopted for the protection of "public health," Article 8 again recognizes the fact that the TRIPS Agreement has a strong socio-economic/developmental component. The effects of the AIDS crisis on the labor market, the training and retention of employees, the cost of doing business, the level of both productivity and consumer demand, the production and availability of adequate food supplies, and the international competitiveness of domestic industries could easily support the imposition of measures designed to promote the public interest in a variety of vital industrial and farming sectors.

Second, the use of the term "necessary," as opposed to the language "it considers necessary" employed in the Article 73 security exception, would seem to indicate that the imposition of these measures are not within the absolute discretion of the invoking Member, but are instead subject to potential WTO review in regard to their validity. In light of both the Declaration on TRIPS and the TRIPS Council Decision it would appear that substantial latitude would be granted to a Member in the midst of a health crisis.

Finally, it can be argued that the phrase "provided that such measures are consistent with the provisions of the Agreement" is substantially more restrictive than the General Exceptions found in Article XX of the General Agreement on Tariffs and Trade ("GATT") 1994, which allows measures that would otherwise be

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293 TRIPS Agreement, supra note 26, art. 8.1.
inconsistent with the GATT Agreement.\textsuperscript{294} It should be remembered, however, that Article 8 was not meant to be an exception but rather a guiding principle upon which all other provisions of the Agreement must be read. Additionally, it is the position of this Article that the flexibility provided by Articles 27, 30, 31, and 73 allow nations to take public health and developmental measures pursuant to Article 8 that are in fact absolutely consistent with the Agreement.

Article 8 also allows nations to take measures, provided they are consistent with the Agreement, to prevent the “abuse” of intellectual property rights or to prevent practices that “unreasonably restrain trade or adversely affect the international transfer of technology.”\textsuperscript{295} It would be pretentious to assume that such terms as “abuse,” “unreasonable restraints on trade,” and “adversely affect” have acquired some sort of universal definition or that some global truism has been discovered in their regard. Instead, these terms reflect a substantial subjectivity that can easily accommodate a variety of differing cultural and economic approaches to their interpretation. The developing countries, for example, have indicated that an “abuse” of intellectual property rights could include the charging of excessively high prices for patented pharmaceuticals, the selling of pharmaceuticals at prices beyond “reasonable” profit margins, or the failure to offer products in quantities sufficient to meet market demand.\textsuperscript{296}

Similarly, the interpretation and enforcement of antitrust law in general will continue to be dynamic. While these laws adapt to changes in economic thinking, they also respond to changes in the needs of society and they traditionally reflect particular stages of economic development. Concepts such as market power, the rule of reason, the importance of efficiencies, the relative unimportance of vertical activity, and the existence and effect of strategic behavior have been dramatically altered over the years as antitrust enforcers changed their focus from producer to consumer welfare. In the absence of a global antitrust code, poorer nations will therefore be free to develop their own views toward the “abuse” of intellec-

\textsuperscript{294} For a discussion in this regard, see COMPULSORY LICENSING, \textit{supra} note 29, at 51 (discussing changes to Article 8.1 to enhance the consistency of safeguard clauses); ACCESS TO MEDICINES, \textit{supra} note 29, at 24-25 (calling for changes in the context of a longer term review of the TRIPS Agreement).

\textsuperscript{295} TRIPS Agreement, \textit{supra} note 26, art. 8.2.

\textsuperscript{296} Developing Country Group’s Paper, \textit{supra} note 29, para. 23.
tual property rights, the "abuse" of market power, the "unreasonableness" of particular trade restraints, and the relationship between the use of traditional knowledge and the duty of technology transfer.

4.2. Patentable Subject Matter

Article 27 provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application." While this article substantially broadens the scope of patentable subject matter—and arguably reflects both a "natural rights" approach and a "western standard" of patentability—considerable room for flexibility nevertheless remains. As Frederick M. Abbott has noted, Article 27 only establishes general rules regarding the criteria to be applied when judging patentability, and these criteria can be interpreted flexibly in order to limit the number of pharmaceutical patents that must be granted. As a result, developing nations can administer their patent systems "in a manner suited to their specific interests" and could, for example, require that patents be granted only for new drugs that represent "breakthrough" developments rather than mere lower level improvements.

Similarly, Professor Ruth L. Gana has highlighted the fact that developing countries have no body of jurisprudence and no administrative or judicial history that provides actual content to terms such as 'new,' 'inventive step,' or 'industrial application.' The lack of a universal rule regarding 'novelty,' as well as the existence of issues surrounding the relationship between 'new' and 'traditional knowledge' and between 'non-obviousness' and more 'trivial' inventions provide the opportunity for developing countries to define the content of the standards imposed by Article 27.

297 TRIPS Agreement, supra note 26, art. 27.1.
298 Oddi, supra note 29, at 434-37, 440 (discussing natural rights philosophy); Id. at 465 ("Article 27 . . . imposes a Western standard for patentability.").
299 ACCESS TO MEDICINES, supra note 29, at 25.
300 Id. at 26.
301 Id.
302 Gana, supra note 173, at 748.
303 Id. at 749-50.
and to develop a jurisprudence that benefits their own societies.\textsuperscript{304} In short, the TRIPS Agreement imposes a set of minimum intellectual property standards, but it does not impose the judicial history of the western world.

While not without limitation, Article 27 also provides for a public health exclusion. Nations are allowed to exclude from patentability "inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect \textit{ordre public} or morality, including to protect human, animal, or plant life or health . . . ."\textsuperscript{305} The use of such language, at least according to S. K. Verma, transforms health-related concerns into "moral and public order issues" (to be judged by local patent officials) and thus incorporates "overriding social, ethical, and moral considerations" into the "patent regime."\textsuperscript{306} Additionally, \textit{ordre public} and morality are imprecise terms to say the least, and neither the TRIPS Agreement nor international usage provide adequate definitions in regard to their application.\textsuperscript{307} As a result, Article 27.2 arguably permits a nation to deny patent protection to one or more pharmaceutical products if there is a legitimate health reason to prevent their commercial exploitation within that nation.\textsuperscript{308}

As both Weissman and Ackermann correctly point out, the denial of patentability must be accompanied by the denial of any commercial exploitation of the invention within that country.\textsuperscript{309} Domestic corporations would not be allowed to produce generic drugs for profit or to engage in profit making compulsory licensing schemes since both of those strategies would represent commercial exploitation.\textsuperscript{310} On the other hand, a credible argument can be

\begin{itemize}
  \item \textsuperscript{304} Id. at 757.
  \item \textsuperscript{305} TRIPS Agreement, supra note 26, art. 27.2.
  \item \textsuperscript{306} Verma, supra note 187, at 281.
  \item \textsuperscript{307} See Ackerman, supra note 29, at 491, 494, 497 (noting the lack of specificity of the terms used in the TRIPS Agreement).
  \item \textsuperscript{308} See Weissman, supra note 29, at 1099-1100 (noting that the term "commercial" usually refers to a for-profit sale).
  \item \textsuperscript{309} Id. at 1100 ("[Article 27.2] requires the denial of patentability to be linked to a denial of commercial exploitation of the invention."); Ackermann, supra note 29, at 496 (explaining that if a "state must exclude the invention from patentability in order to prevent commercial exploitation, then the state may do so" to protect the \textit{ordre public} or morality).
  \item \textsuperscript{310} Weissmann, supra note 29, at 1100; see also Ackermann, supra note 29, at 508-09 (noting that if a country excludes an area of technology from patentability then domestic for-profit operations in that area amount to commercial exploitation).
\end{itemize}
made that a country, after denying patentability, could nevertheless produce and distribute the product non-commercially through either a state-owned enterprise or private non-profit manufacturer. Such an action, while certainly constituting an exploitation, would not constitute a ‘commercial’ exploitation of the invention. As a result, if a nation takes the position that the prevention and treatment of the HIV/AIDS epidemic is necessary to protect the ordre public, the TRIPS Agreement would apparently allow that nation to deny patent protection to relevant pharmaceuticals and then distribute those products, assuming they are attainable, on a non-profit, non-commercial basis. Since there could be no discrimination between the rights of foreign and domestic producers, as neither would be allowed to engage in commercial exploitation, such a strategy would appear consistent with the terms of the TRIPS Agreement.

Finally, it can be queried whether the ‘necessary’ and ‘least-trade restrictive’ tests would be applied to Article 27. In addressing this issue, Weissman correctly observes that the jurisprudence surrounding Article XX of GATT 1994 would arguably not apply to Article 27 of the TRIPS Agreement since the latter is one of the “core provisions” of the Agreement and “part of the very definition of patentable subject matter.” Article XX, in contrast, provides a series of limited and conditional exceptions to the Agreement Establishing the World Trade Organization (“WTO Agreement”) (allowing measures that would otherwise be inconsistent with that Agreement) and should therefore be viewed – along with the criteria employed for its application – in an entirely different context. Additionally, the mere reviewability of an ex-

311 Weissmann, supra note 29, at 1100-01.
312 Ackermann, supra note 29, at 509 (defining non-profit sales as not constituting commercial exploitation); see also Weissman, supra note 29, at 1101 (explaining that a nation may adopt a policy of domestic, non-commercial exploitation).
313 See Ackermann, supra note 29, at 509 (describing how non-profit sales do not constitute commercial exploitation).
314 For a discussion of this matter, see id. at 507-08 (discussing the GATT interpretation of the term “necessary”). See also Weissman, supra note 29, at 1101-07 (discussing the “necessary” and “least-trade-restrictive” tests).
315 Weissman, supra note 29, at 1107.
316 See id. Weissman notes that “the term ‘necessary’ in Article 27 should not be given the intrusive interpretation it has been in Article XX GATT Panel decisions. A less stringent reading of ‘necessary’—something closer to important, and with little or no attention to available alternatives—is more appropriate in this
exercise of Article 27.2 rights should never be equated with the invalidity of a measure. In light of the national emergencies being created by the HIV/AIDS epidemic, and in light of the lack of funds available to purchase patented pharmaceuticals, GATT Panels would be hard pressed to deny any concept of necessity. Unless pharmaceuticals are supplied at the lowest conceivable price, any measure designed to acquire those products more cheaply would appear to be justified.

4.3. Exceptions

In addition to the flexibility inherent in the subjective language of Articles 7, 8, and 27, the TRIPS Agreement also provides more formal exceptions under Articles 30, 31, and 73. In light of the fact that other authors have addressed the limited exceptions found in Article 30 and the compulsory licensing exception found in Article 31, this Section will only briefly outline those provisions. After doing so, attention will be turned to the security exception, which, although fundamentally universal in nature, has been substantially overlooked.

4.3.1. The Limited Exceptions

Article 30 allows members to "provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." This Article does not restrict the purposes for which a nation may establish such an exception and it may reflect the compromise that resulted from the inability of negotiators to agree on a more specific list of exceptions. It provides absolutely no guidance regarding the meaning of limited exceptions, unreasonable conflict or prejudice, normal exploitation, legitimate interests, or even the nature or scope of third parties. It also fails to address either the procedures to be employed when granting an exception or the issue of remuneration.

context." Id.
317 Id. at 1108.
318 COMPULSORY LICENSING, supra note 29, at 41.
319 Id. at 36.
As a result, Weissman has argued that Article 30 represents a balancing process between the rights of patent holders and third parties, including those citizens of the Third World, that specifically allows for the prejudicing, although not the unreasonable prejudicing, of patent holder rights.\textsuperscript{320} Such a balancing process, of course, is inherently subjective and incapable of precise boundary. In the Canadian Pharmaceuticals case,\textsuperscript{321} for example, the WTO Panel refused to equate the "legitimate interests" of third parties with their mere "legal interests."\textsuperscript{322} Instead, "legitimate interests" would be defined as "a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms."\textsuperscript{323} By clearly differentiating between "legal" and "legitimate" interests, the Panel provided substantial room for the consideration of economic, social, political, and security concerns. As a result, as the HIV/AIDS crisis continues to reach pandemic proportions, it is certainly arguable that a limited exception has become considerably more justifiable.

The use of the term "normal exploitation" also provides substantial flexibility for the development of responsive health policies. This language generally refers to the commercial activity by which patent holders "extract economic value from their patent."\textsuperscript{324} If poor nations are not in a position to be consumers of high-priced patented pharmaceutical products, one may question the economic value that such markets possess. If sales in these markets are indeed negligible, minimal economic value would be lost (assuming there was no diversion of these products to wealthier nations) if generic producers were to supply low-cost alternatives.\textsuperscript{325}

Similarly, the relationship between the non-discrimination clause of Article 27.1 and the ability to grant limited exceptions under Article 30 is far from transparent. While recognizing that

\textsuperscript{320} Weissman, supra note 29, at 1110-11 (arguing that the third limitation in Article 30 calls for a balancing process).


\textsuperscript{322} Id. paras. 7.68-7.73.

\textsuperscript{323} Id. para. 7.69.

\textsuperscript{324} Id. para. 7.54.

\textsuperscript{325} See COMPULSORY LICENSING, supra note 29, at 38, 45 (questioning the logic of wealthy nations wanting to preserve their patents while not profiting globally).
Article 30's very existence indicates that patent rights "would need certain adjustments,"326 the Panel in Canadian Pharmaceuticals noted that Article 30 was not designed to bring about a renegotiation of the basic balance of the TRIPS Agreement.327 As a result, the Panel held that the "limited" exception should be more narrowly defined, that it should not be used as a substantial curtailment of exclusionary rights, and that it should be subject to the "field of technology" anti-discrimination requirement of Article 27.1.328 More particularly, an Article 30 exception cannot be made 'limited' by simply 'limiting' it to one field of technology since Article 30 exceptions must not discriminate as to the field of technology.329

The Panel went on to note that "it is not true that Article 27 requires all Article 30 exceptions to be applied to all products" and "does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas."330 Even if Article 30 would not allow a limited exception to be directed at the entire pharmaceutical industry (a position that is still open to substantial doubt),331 it can be argued that an exception could be made for those particular pharmaceuticals aimed at the prevention and treatment of HIV/AIDS. The apparent distinction between a 'field of technology' and a 'certain product area' would justify the imposition of such an exception.

Whether based upon its subjectivity or the mere confusion to which it gives rise, Article 30 may provide a substantial means for delivering low-cost generic pharmaceuticals. Medicines Sans Frontieres (along with a variety of other organizations) have suggested, for example, that Article 30 be interpreted to allow Members to provide an exception to the exclusive rights conferred by a patent

327 Id.
328 Id. paras. 7.30-7.36, 7.44, 7.91, 7.93.
329 Id. paras. 7.92-7.93.
330 Id. para. 7.92.
331 See, e.g., ACCESS TO MEDICINES, supra note 29, at 23 ("A developing Member might therefore adopt regulatory measures affecting pharmaceutical patents that do not also affect software patents if there is a sound basis for the differential treatment . . . . [T]he express text of Article 30 does not indicate that it is limited by Article 27:1 . . . . [T]he panel's decision . . . is not entirely persuasive . . . . Developing Members might consider proposing an interpretation of Article 30 of the TRIPS Agreement establishing that it is not subject to Article 27:1, since exceptions allowed by Article 30 are defined to be limited, and limited exceptions may be addressed to particular fields of technology.").
that would permit a nation to produce and export patented products to another nation when the product is either not patented, or a compulsory license has been granted in the importing nation. If such an activity was deemed to be protected by the Article 30 exception, there would be no patent infringement by the exporting country and thus no need for that country to acquire patent-holder permission or render compensation. The patent owner would receive compensation in the country where the products were consumed, but only if patent protection had been acquired in that jurisdiction. Such a strategy would allow poor nations that lack the resources to engage in local production and have not yet exhausted their transition periods to import necessary medicines at the lowest possible cost.

Abbott has similarly argued that Article 30 allows Members to authorize the production and export of patented pharmaceuticals (without the consent of the patent owners) to address the neglected health needs of nations that lack the resources to provide access to their citizens. He suggests that such actions would indeed constitute a limited exception, and that they would not conflict with normal exploitation if limited to financially constrained nations. Abbott further suggests that they would not prejudice the legitimate interests of patent holders if not directed at developed markets and if systematic diversion could be prevented. In support of his argument, Abbott believes that the Ministers, in light of the Declaration on TRIPS, have "clearly acknowledged that the pharmaceutical sector may be treated differently than other sectors regarding the enjoyment of patent protection."

4.3.2. Compulsory Licensing and the Implementation of the Declaration on TRIPS

Since the adoption of the TRIPS Agreement, one of the most

332 Joint Letter, supra note 29 (presenting the author organizations' views on the exportation of medical technologies under the WTO TRIPS rules for patents).

333 Id.

334 Id.

335 See id. (listing the advantages of the Article 30 approach).

336 COMPULSORY LICENSING, supra note 29, at 5-6.

337 Id. at 5-6; see also id. at 33-45 (analyzing the meaning of "limited exceptions").

338 Id. at 50.
contentious issues regarding its interpretation has been the right of compulsory licensing. Subject to the requirements found in Article 31 of the Agreement, governments have the right to issue compulsory licenses to allow companies to produce a patented product, or to use a patented process, without the permission of the patent owner. Unfortunately, Article 31(f) provides that such a license shall be authorized "predominantly for the supply of the domestic market of the Member authorizing such use," thus limiting the amount of the product that can be exported under the license. As a result, less-developed countries that lacked the actual capacity to manufacture pharmaceuticals domestically were substantially restricted in their ability to import cheaper generics from drug-producing nations where pharmaceuticals were under patent.

In response to Paragraph 6 of the Declaration on TRIPS, the General Council approved a decision immediately prior to the Ministerial Conference in Cancun that was designed to make it easier for poor countries that lack domestic capacity to import cheaper generics produced under compulsory licenses. The decision takes the form of an interim waiver of Article 31(f), to be applicable until the TRIPS Agreement is formally amended, that allows any Member country that produces generic copies of patented pharmaceuticals under a compulsory license to export these products to eligible importing countries. According to the accompanying Statement by the General Council's Chairperson ("Chairperson's Statement"), such a waiver system should be used "in good faith to

339 For articles dealing with the issue of compulsory licensing, see supra note 29 (dealing with the issue of compulsory licensing).
340 TRIPS Agreement, supra note 26, art. 31(f).
341 Declaration on TRIPS, supra note 28, para. 6 ("We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem . . . .").
343 Id.; see also Implementation of Paragraph 6 of the Declaration on TRIPS, supra note 260, para. 2 ("The obligations of an exporting Member under Article 31(f) shall be waived . . . ."); id. para. 1(b) (defining an eligible importing Member as "any least-developed country Member and any other Member that has made a notification . . . of its intention to use the [waiver] system as an importer" (footnote omitted)).
protect public health" and not as an "instrument to pursue industrial or commercial policy objectives." 344

The Decision requires an eligible importing Member to make a notification to the Council for TRIPS that specifies the names and expected quantities of the products to be imported and confirms (if not a "least-developed" country) that the importing Member “has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector” for those products. 345 The compulsory license issued by the exporting Member must indicate that only the amount necessary to meet the needs of the importing country will be manufactured under the license and that the entirety of this production will be exported to the eligible Member. 346 Additionally, “adequate remuneration” shall be paid in the exporting Member to the patent holder taking into account the "economic value to the importing Member of the use that has been authorized." 347 All Members are directed to take reasonable measures to prevent the re-exportation of the products produced under these licenses, 348 and to ensure effective legal means for the prevention of diversion. 349

In characterizing the decision to waive Article 31(f) and to allow compulsory licenses to be issued for the purpose of exporting pharmaceuticals, Director-General Supachai Panitchpakdi indicated that “[t]his is a historic agreement for the WTO” that allows poorer nations “to make full use of the flexibilities in the WTO’s intellectual property rules in order to deal with the diseases that ravage their people.” 350 Unfortunately, a variety of constituencies have expressed substantially more skepticism toward this Decision and have questioned the prospects of its practical application as well as its ability to spur the provision of low cost generic drugs to nations in need. 351


345 Implementation of Paragraph 6 of the Declaration on TRIPS, supra note 260, para. 2(a).

346 Id. para. 2(b)(i).

347 Id. para. 3.

348 Id. para. 4.

349 Id. para. 5.


351 For comments in such regards, see, e.g., Economics Section, Brazilian Em-
Such a skepticism is based upon a variety of related concerns. First, there are doubts regarding whether the Decision will actually alter current conduct. It is feared that importing nations, despite the health problems being experienced, will come under external political pressure to refrain from exercising the system that is provided in the Decision.\(^{352}\) Similarly, exporting nations will have to be persuaded to suspend the relevant patent protection and issue a license to a local company to produce and export the product. Few exporting governments may be willing to do so if they face the possibility of retaliation by powerful nations with powerful lobbies.\(^{353}\)

Second, concerns have been raised regarding the Decision’s creation of complicated procedures and bureaucratic obstacles that may actually frustrate the trade of generic drugs.\(^{354}\) For example,


\(^{352}\) See Brazilian Embassy in London, supra note 351 (addressing concerns expressed at Doha regarding the Decision’s overall effect).

\(^{353}\) See Oxfam, supra note 351 (providing further reasons for the difficulties poor nations will face in spite of the Decision).

\(^{354}\) See Brazilian Embassy in London, supra note 351 (discussing the opposition to breaking down patents in other countries); Africa Action, supra note 351 (discussing the financial resources needed from wealthy nations); Oxfam, supra
some have argued that the government of the exporting country will be obligated to issue compulsory licenses for each individual product and will need to provide information to the Council in order to establish the good faith of their transactions.\textsuperscript{355} Such procedures "could weigh heavily" on potential importers and exporters and could effectively constitute "hidden barriers to trade."\textsuperscript{356} Additionally, the total costs of producing generic pharmaceuticals will be raised not only by these "hidden barriers," but by the use of such "overly stringent" anti-diversion mechanisms as distinguishing size, shape, color, and packaging.\textsuperscript{357}

Third, the costs, or the risks, to exporting nations are also arguably increased by some of the uncertainties that surround the implementation of the Decision. The Decision states that an importer's notification to use the system does not need to be approved by any WTO body,\textsuperscript{358} and that Members shall not challenge any measures taken in conformity with the Decision's waiver provisions under §§ 1(b) or 1(c) of Article XXIII of GATT 1994.\textsuperscript{359} On the other hand, the Decision does not define such terms as "insufficient" capacity or "good faith," and the Chairperson's Statement (regarding the understanding of the Members) indicates that "[a]ny Member may bring any matter related to the interpretation or implementation of the Decision . . . to the TRIPS Council for expeditious review, with a view to taking appropriate action."\textsuperscript{360} As a result, while the Decision appears to place the initial use of the system into the discretionary hands of importing nations, the Chairperson's Statement appears to provide legal recourse to Members that wish to challenge the legitimacy of that use.\textsuperscript{361} Such uncertainty may serve to dampen the willingness of nations to take

\textsuperscript{351} ("But thanks to the intransigence of the [United States] and pharmaceutical giants, poor countries would still not have the same legal rights to affordable medicines as industrialized countries.").
\textsuperscript{355} Brazilian Embassy in London, supra note 351.
\textsuperscript{356} Id.
\textsuperscript{357} Baker, supra note 351.
\textsuperscript{358} Implementation of Paragraph 6 of the Declaration on TRIPS, supra note 260, at 2 n.2.
\textsuperscript{359} Id. para. 10.
\textsuperscript{360} Chairperson's Statement, supra note 344.
\textsuperscript{361} See Oh, supra note 351 (discussing the hindering effect of the Chairperson's Statement).
advantage of the waivers being provided.  

Perhaps the most fundamental issue, however, involves the questionable economic impetus for private companies to produce and export pharmaceuticals under such a license, given these risks and uncertainties. As Baker has argued, such an impetus has been diminished by the Decision and the Chairperson’s Statement from both a "demand" and a "supply" perspective. From the demand side, twenty-three developed nations have already agreed not to use the system as importers, ten Eastern European nations have agreed that they will opt out of the waiver system upon accession to the European Union, and a number of other nations have agreed to use the system only in situations of national emergency or other circumstances of extreme urgency. The result, of course, is to substantially reduce the potential market for generic drugs and to exclude markets “with meaningful and stable purchasing power.” From the supply side, Baker notes that increased risks, uncertainties and costs, as well as both shrinking markets and the possibility of WTO review, all combine to reduce the incentive of would-be suppliers. As the potential for profit declines, the willingness to produce tends to evaporate as well. Additionally, Oh has posited that as a worse case scenario, the Chairperson’s indication that the system cannot be used for “industrial or commercial policy objectives” could conceivably prevent the use of waivers if they were “to result in a [sic] expansion of the generic drugs industry or if the generic manufacturers were to make any profit.”

The implementation of the Decision over time will ultimately determine whether these concerns are justified. In any event, the global community will have to address the resource issues that would accompany the use of this system. Such issues would involve the ability of stricken nations to purchase these generic drugs, even at discounted prices, the capacity to strictly monitor

362 See id. ("Whilst it is not clear what the legal implications are, it is feared that these elements would have a ‘chill effect’ on countries in their use of the Decision.")

363 Baker, supra note 351.

364 Id.; Chairperson’s Statement, supra note 344; Implementation of Paragraph 6 of the Declaration on TRIPS, supra note 260, para. 1(b) n.3 (discussing nations that have agreed to limit their use of the system).

365 Baker, supra note 351.

366 Id.

367 Oh, supra note 351.
their use, and the creation of an infrastructure that could effectively administer both prevention and treatment programs.

4.3.3. The Security Exception

Article 73 states that nothing in the TRIPS Agreement shall prevent a Member from taking any action "which it considers necessary for the protection of its essential security interests . . . taken in time of war or other emergency in international relations." It also provides that no party shall be prevented from "taking any action in pursuance of its obligations under the U.N. Charter for the maintenance of international peace and security." These exceptions, which are basically identical to those found in Article XXI of the GATT Agreement, are 'universal' in nature and thus serve, when exercised, to relieve a party from virtually all of its substantive obligations under the TRIPS Agreement.

368 TRIPS Agreement, supra note 26, art. 73(b)(iii).
369 Id. art. 73(c). Article 73 states that:

Nothing in this Agreement shall be construed:

(a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or

(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

(i) relating to fissionable materials or the materials from which they are derived;

(ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;

(iii) taken in time of war or other emergency in international relations; or

(c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.

4.3.3.1. *The Breadth of the Exception*

In order to appreciate the potential breadth of the Article 73 exception, it is useful to examine the position that has been taken by intellectual property–generating nations regarding the identical security exception found in Article XXI of GATT. Article XXI has, in fact, served as an implicit basis—although generally unspoken and uncited—for the unilateral imposition of restrictive trade measures for non-economic purposes. These measures, which have often been imposed without identifiable standards and without any accountability or effective retaliatory remedy, have reflected nothing more than a power-based approach to international relations. Actions allegedly taken for security purposes have often been only tangentially aimed at protecting essential security interests. They have been primarily directed at the subordination of sovereign rights and at the coercion of nations in regard to their foreign policies, their domestic policies, or their established trading relationships. Additionally, such actions have often reflected an intentional 'blurring' of a nation's essential security interests with its foreign/domestic policy agenda.

While the "General Exceptions" found in Article XX of GATT are limited by prohibitions against both arbitrary or unjustifiable discrimination and disguised restrictions on trade (and are often further limited by an additional 'necessary' requirement), many nations believe that the Article XXI security exception is indeed quite boundless. Sweden, for example, invoked Article XXI in order to establish a global import system designed to protect its inefficient footwear industry and to give that industry time to remedy its difficulties. In citing increased imports and high domestic production costs, Sweden indicated that the decrease in domestic footwear production had become a "critical threat" and that the maintenance of such a vital industry was indispensable "in case of

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373 *Id.* at 440; *see also id.* at 439-42 (explaining that international actors are obligated not to interfere in the free decisions of sovereign states, but that "there is no clear prohibition against the use of economic sanctions for political and ideological purposes").
374 *See id.* at 420, 432-35 (explaining the concept of "security-based" economic coercion and "exploring the blurring of the line"). Also, for a list of citations regarding various aspects of Article XXI, see *id.* at 416 n.10.
war or other emergency in international relations."³⁷⁶ Additionally, nations have invoked Article XXI in response to "risks of political instability" in a region and its "potentially destabilizing consequences elsewhere,"³⁷⁷ in response to "potential" danger arising out of a threat to the peace,³²⁸ and as a show of support to the foreign policies of another nation.³⁷⁹

The United States, based upon the argument of protecting its essential security interests, has chosen to intervene in the affairs of another State for reasons involving "the domestic policies of that country, its ideology . . . or the direction of its foreign policy."³⁸⁰ It has also exercised the security interest rationale for the purpose of encouraging the ouster of one regime and the establishment of another; for the purpose of requiring a transition to a particular political or economic system or for affecting political realignment; and for the purpose of coercing other nations into supporting various U.S. policies.³⁸¹ In passing the Cuban Liberty and Democratic Solidarity (LIBERTAD) Act of 1996 ("Helms-Burton Act"),³⁸² the protection of essential security interests was used to create a civil cause of action against European and Canadian defendants, to exclude corporate spouses and children from the United States, and to designate the operation of an unsafe nuclear power plant as an act of aggression.³⁸³ Additionally, the U.S. Trade Expansion Act³⁸⁴

³⁷⁶ Id. para. 4.
³⁷⁹ For a discussion in these regards, see Cann, supra note 14, at 424-25. See, e.g., Trade Restrictions Affecting Argentina Applied for Non-economic Reasons, May 18, 1982, GATT Doc. L/5319/Rev. 1 (stating that the European community, Australia, and Canada, in light of the invasion of the Falkland Islands, have taken certain measures against Argentina on the basis of "their inherent rights" in Article XXI).
³⁸¹ Cann, supra note 14, at 440 n.188.
³⁸³ See Cann, supra note 14, at notes 127-35 and accompanying text (describing the Helms-Burton Act as a means of economic manipulation rather than national security).
³⁸⁴ Trade Expansion Act of 1962, Pub. L. No. 87-794, 76 Stat. 872 (codified in

https://scholarship.law.upenn.edu/jil/vol25/iss3/1
specifically linked the concept of national security to a variety of 'vital industry' concerns such as the levels of domestic production, capacity, and growth.\textsuperscript{385} It also linked security to levels of unemployment and foreign competition, to losses in government revenues, and to the general "economic welfare of the Nation."\textsuperscript{386}

Finally, Article XXI encompasses substantially more than actual threats to a nation's security interests. It can also include 'potential' threats to those interests and, in light of the fact that a nation's security is dependent (at least in part) upon the security of its allies, both actual and potential threats to the security interests of another nation.\textsuperscript{387}

4.3.3.2. The Issue of a Self-Defining Nature

This Author has argued elsewhere\textsuperscript{388} that the security exception is not self-defining, that its exercise should be subject to external review, and that its scope is not without boundaries. Nevertheless, it is beyond question that most economically powerful nations have taken the position that security interests are indeed self-defining and that the 'validity' of an action taken for security reasons is solely within the discretion of the party taking that action. As a result, motivation becomes irrelevant, justification and approval become unnecessary, and any foreign interference becomes absolutely unacceptable. In effect, it is simply "impossible for a nation to violate Article XXI."\textsuperscript{389}

In defending this position, most industrialized countries have adopted the view that because the GATT Agreement is a 'trade' agreement (and the World Trade Organization is a 'trade' organization), matters concerning national security and foreign policy should not be placed within their reach. Such nations as the United States, Canada, Japan, New Zealand, Australia, and the European Union have been unified in their belief that the WTO has no power, competence, or experience to resolve such issues.\textsuperscript{390} As a

\textsuperscript{385} 19 U.S.C. § 1862(d) (1994).
\textsuperscript{386} Id.
\textsuperscript{387} Cann, supra note 14, at 425, 463-65.
\textsuperscript{388} See id. at 413-85 (concerning the creation of standards and accountability for the security exception).
\textsuperscript{389} Id. at 415-16. For citations to international perspectives on the self-defining nature of Article XXI, see id. at 416 nn.9, 10.
\textsuperscript{390} Id. at 417, 430.
result, it has often been stated that every nation "must have the last resort" or must be the "sole judge" in regard to questions involving its essential security interests. Additionally, the distinction between the "necessary" language often employed in Article XX exceptions and the "it considers necessary" language used in Article XXI (and in Article 73 of the TRIPS Agreement) has certainly not been ignored. By employing the term "necessary"—and by prohibiting arbitrary or unjustifiable discrimination and disguised restrictions on trade—Article XX implies that an objective, measurable, and reviewable standard should be applied to measures taken thereunder. In contrast, Articles XXI of GATT and 73 of the TRIPS Agreement allow a nation to take any action that "it considers necessary" to protect its essential security interests. By doing so, at least according to the industrialized world, the decision to invoke the security exception is both subjective in nature and within the total discretion of the nation exercising the exception. As a result, invoking nations have simply concluded that they are, by definition, 'always right' and economically powerful States have been allowed to proceed with impunity.

4.3.3.3. A Time for Role Reversal

If Article XXI of GATT and Article 73 of the TRIPS Agreement are indeed self-defining, HIV/AIDS-inflicted nations are free to exercise the security exception with impunity. Even if these articles were to develop boundaries—and were therefore subject to some

391 Summary Record of the Twenty-Second Meeting 7, GATT Doc. CP.3/SR.22 (June 8, 1949).
392 Summary Record of the Twelfth Session 196, GATT Doc. SR.19/12 (Dec. 21, 1961).
393 GATT, supra note 370, art. XX(a), (b), (d), (i).
394 Cann, supra note 14, at 416. Despite the very vocal positions expressed by various nations, the contracting parties have never decided whether Article XXI is self-defining. See GATT Secretariat, Panel Report on United States - Trade Measures Affecting Nicaragua, paras. 5.3, 5.17, L/6053 (Oct. 13, 1986), 1986 WL 363154 (un-adopted) (questioning how the Contracting Parties can ensure that the general exception is not "invoked excessively or for purposes other than those set out" if the contracting party has an exclusive right to interpret Article XXI); Michael J. Hahn, Vital Interests and the Law of GATT: an Analysis of GATT's Security Exception, 12 Mich. J. Int'l L. 558, 595 (1991) (stating that the contracting parties have "expressed neither tacit nor express consent" for the proposition that Article XXI(b)(iii) "leaves it completely to" the contracting party decide when to act).
form of external review—their exercise in light of the HIV/AIDS crisis would be beyond reproach. There is absolutely no question that this crisis has created a national emergency in a substantial number of nations. There is also no question that this crisis has given rise to an “emergency in international relations” under Article 73(b)(iii), that it constitutes an ‘external’ threat to the security of all nations, and that it threatens “the maintenance of international peace and security” under Article 73(c). Of equal importance, however, is the fact that the Article 73 security exception can be invoked under these criteria by both HIV/AIDS-infected consuming nations and by non-infected pharmaceutical-producing nations.

As indicated earlier, the HIV/AIDS epidemic is destroying the social, economic, and political structures of many nations. The family unit is being torn apart, farming and industrial productivity is being curtailed, the medical and educational communities are being attacked, and refugee populations are being created. When governments cannot provide adequate social services, the legitimacy of those governments is questioned, fledgling democracies are jeopardized, state institutions and the rule of law are weakened, and civil unrest and regional instability result. Each of these, in turn, threatens economic growth and development, life expectancy, food security, military defense capabilities, governmental revenues and resources, and the provision of essential services. In such a light, the ‘security’ concerns expressed by the United States in its Trade Expansion Act—regarding the need to protect its vital industries and the general economic welfare of the nation—seem absolutely dwarfed by the very real possibility that entire nations, as well as entire regions, may indeed collapse.

The Declaration on TRIPS stated that every Member “has the right to determine what constitutes a national emergency or other circumstances of extreme urgency” and it specifically recognized that public health crises (including the HIV/AIDS epidemic) can,

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395 See supra notes 32-48, 88-99 and accompanying text (detailing the devastating effects of HIV/AIDS and the lack of access to medicine that would help mitigate those effects).


397 Declaration of Commitment, supra note 3, paras. 8, 68.

398 See supra notes 384-86 and accompanying text (expressing the purpose of strengthening free international trade and of preventing “communist economic penetration”).
in fact, constitute such an emergency or circumstance. Nevertheless, the exercise of the security exception has been traditionally linked not merely to the existence of a national emergency, but to the existence of an ‘external’ threat. As indicated by the discussion above, the ambiguity surrounding the security exception has resulted in the use of a boundless potpourri of actual and potential external threats. In light of the fact that the U.N. Security Council has now formally recognized that the HIV/AIDS epidemic can pose a threat to both global stability and international security, there should be no difficulty—on the part of either a pharmaceutical-consuming or a pharmaceutical-producing nation—in establishing the existence of a credible external threat.

A consuming nation that is experiencing a high incidence of HIV/AIDS infection, for example, could argue that a variety of factors are either constituting an external threat or are giving rise to a potential external threat. Certainly the destruction of the social, economic, political, and military structure of a nation substantially increases its vulnerability to outside influence. Most dramatic of these influences, of course, would be a military invasion by a hostile neighbor which could result in a loss of sovereignty or, at a minimum, an exacerbation of the HIV/AIDS crisis, which generally accompanies an armed conflict. Internal weakness may attract foreign subversives into the country for the purpose of igniting civil unrest or advocating the overthrow of the government. Foreign buyers may refuse to enter into purchasing relationships in light of the uncertainties surrounding production capabilities and foreign sellers may cut essential supplies in light of an inability to pay. As foreign investment is withheld and diverted to more stable markets, a nation’s vulnerability is further increased.

Additionally, it can be argued that the HIV/AIDS crisis generally breeds regional, rather than merely national, instability. External threats from neighboring States are therefore heightened as

399 Declaration on TRIPS, supra note 28, para. 5(c).
400 See S.C. Res. 1308, U.N. SCOR, 4172d mtg., U.N. Doc. S/RES/1308 (2000) (stressing that the HIV/AIDS pandemic, given its possible growing impact on social instability and emergency situations, may pose a risk to stability and security if unchecked); see also Report on Global HIV/AIDS, supra note 3, at 58 (stating that “the U.N. Security Council made history in January 2000, when, for the first time, it debated a health issue” and “by subsequently adopting Resolution 1308 (2000), it highlighted the potential threat the epidemic poses for international security”).
401 See, e.g., Declaration of Commitment, supra note 3, paras. 75-78 (addressing concerns over the spread of HIV/AIDS in conflict and disaster affected regions).
those States experience similar breakdowns in their social, economic, and political systems. It can also be argued that diseases "are easily transmissible beyond the frontiers of a State," and that the incidence of an HIV/AIDS crisis in one nation may be viewed as an external threat to another. Further, the potential for mass migration of refugees from one crisis-country to another—perhaps because the later is experiencing a slightly less degree of incidence or possesses more resources with which to cope—can similarly constitute a recognizable external threat to a nation’s security.

In light of the increased vulnerability of HIV/AIDS-stricken States, it is simply impossible to deny either the existence of an external threat or the availability of the security exception. To compare the severity of these threats to a potential increase in foreign competition or to a decrease in the domestic production of footwear in Sweden would be ludicrous.

In addition to the availability of the Article 73 security exception, many States currently facing an HIV/AIDS crisis are not obligated, at least with respect to pharmaceutical products, to implement the TRIPS Agreement until January 1, 2016. Many of these States, however, lack the capacity to domestically produce the pharmaceuticals that they need. As a result, it is absolutely critical that pharmaceutical-producing nations, even though they are not experiencing an HIV/AIDS crisis within their own borders, be similarly entitled to exercise the security exception. By invoking Article 73, these nations would then be free to both produce generic pharmaceuticals and export those products to stricken nations. Without such a source of supply, the availability of the security exception to consuming nations would be of little value.

In establishing the existence of an external threat to their essential security interests, producing nations may argue many of the same concerns expressed above. From a broad perspective, producing nations may note that the HIV/AIDS epidemic has indeed

402 Substantive Issues, supra note 3, para. 40.
404 See Swedish Footwear, supra note 375 (instituting trade restrictions designed to bolster Swedish footwear production).
405 See Declaration on TRIPS, supra note 28, para. 7 (regarding the proper relationship between the TRIPS Agreement and public health concerns).
been found to constitute "a global emergency" and a potential "risk to stability and security." As members of the international community, producers should be allowed to help alleviate these concerns. Producers may similarly argue that the HIV/AIDS virus may be imported into their country from foreign sources, that a mass migration of refugees into their country would drain economic resources, that regional instability endangers the global peace, and that the loss of critical consumers and suppliers can threaten their own economic viability. Additionally, it can be argued that a nation's security is dependent, at least in part, upon the security of its allies and other friendly nations. As a result, the exception must encompass not only threats to the invoking nation itself, but threats to other (consuming) nations as well.

In weighing the credibility of these arguments, it is interesting to note that the National Intelligence Council on AIDS, which advises the U.S. Central Intelligence Agency, has indicated that the HIV/AIDS epidemic in five nations (Russia, Ethiopia, China, Nigeria, and India) poses a potential security threat not only to their respective regions, but to the United States as well. In coming to such a conclusion, the report cited the fact that the HIV/AIDS epidemic is likely to shape how Russia emerges in the post-Soviet era and that the political tensions generated by the epidemic in Nigeria could affect its status as a major oil producer and U.N. peacekeeper in Africa. According to the New York Times, the United States has, in fact "declared the global epidemic of AIDS a national security threat." Applying a similar rationale, such nations as India and Brazil could exercise their right to invoke Article 73 (to meet such external threats) and continue to produce and export generic pharmaceuticals even after their transition periods have elapsed.

It has also been held that "massive and systematic violations of human rights may constitute a 'threat to peace' under Article 39" of the U.N. Charter. Not only did the United States advance such an argument in support of its Helms-Burton Act, a variety

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406 Declaration of Commitment, supra note 3, para. 2.
407 S.C. Res. 1308, supra note 400, pmbl.
409 Id.
410 Id.
412 Id.
of fundamental international instruments have consistently linked the enjoyment of human rights (as well as the creation of a social and international order in which those rights may be realized) with the achievement of international peace and the promotion of friendly relations among nations.\textsuperscript{413} Since the HIV/AIDS crisis is often a symptom of human rights violations,\textsuperscript{414} the invocation of Article 73 may indeed represent a legitimate response. The absence of human rights often gives rise to the epidemic, the denial of human rights often accompanies infection, and the achievement of human rights could certainly aid in its cure. Under such circumstances, pharmaceutical-producing States could credibly argue that the human rights condition in many stricken nations represents a threat to the peace and therefore a threat to their essential security interests.

Finally, Article 73(c) recognizes the right of a Member to take "any action in pursuance of its obligations under the U.N. Charter for the maintenance of international peace and security." In such a regard, it is worth noting that the basic purposes of the U.N. Charter are to affirm our faith in fundamental human rights and the dignity of the person,\textsuperscript{415} to maintain international peace and security (and to take collective measures for the prevention and removal of threats to that peace and security),\textsuperscript{416} and to cooperate in solving global problems of an economic, social, cultural, or humanitarian character.\textsuperscript{417} It is also worth noting that Article 55 of the U.N. Charter recognizes that one of the primary goals of the United Nations is to create the "conditions of stability and well-being" that are "necessary" for securing international peace.\textsuperscript{418} The "conditions" specifically enumerated in Article 55 include higher

\textsuperscript{413} See, e.g., \textit{Universal Declaration}, \textit{supra} note 118, pmbl., art. 28 (providing that everyone has the right to a "social and international" which protects the rights and freedoms of individuals); \textit{ICESCR}, \textit{supra} note 23, pmbl. (asserting that the "equal and inalienable" human rights of individuals is the "foundation of freedom, justice and peace in the world"); \textit{ICCPR}, \textit{supra} note 125, pmbl. (guaranteeing all citizens basic human and political rights).

\textsuperscript{414} See \textit{supra} notes 100-151 and accompanying text (regarding the relationship between social rights and the HIV/AIDS pandemic).

\textsuperscript{415} See, e.g., \textit{U.N. Charter}, pmbl., art. 1.3 (stating that the purpose of the U.N. is international problem solving).

\textsuperscript{416} See \textit{id.}, pmbl., arts. 1.1, 1.2, 24.1, 33-51 (identifying that the development of friendly relations and peaceful dispute resolution as purposes of the U.N.).

\textsuperscript{417} \textit{Id.} art. 1.3.

\textsuperscript{418} \textit{Id.} art. 55.
standards of living, economic and social development, universal respect for human rights, and the solution of health-related problems.\textsuperscript{419} As a result, it can be argued that the deplorable standards of living in HIV/AIDS-stricken countries—as well as the abridgement of human rights and the total breakdown of economic, social, and political systems—pose a substantial threat to the peace by endangering the stability and well-being that are necessary to maintain that peace. Since all Members have the duty to promote the purposes of the U.N. Charter (and to fulfill their obligations under that Charter),\textsuperscript{420} it would seem logical that pharmaceutical-producing nations would have the right to exercise Article 73(c) of the TRIPS Agreement in such a regard. By exporting generic medicines to stricken States, producing countries would be meeting their responsibility to promote the necessary conditions for international peace and security.

4.4. Miscellaneous Sources of Flexibility

In addition to the substantial flexibility provided by the Articles examined above, there are a number of other mechanisms that may prove helpful in addressing the issue of high-priced patented pharmaceuticals. Some of these mechanisms are found within the body of the TRIPS Agreement, while others are based upon the fact that the Agreement is silent in their regard.

Weissman has noted, for example, that a nation can seek to limit pharmaceutical prices by instituting a system of price controls.\textsuperscript{421} As long as that system is nondiscriminatory between foreign and domestic producers, price controls are not precluded by the terms of the TRIPS Agreement.\textsuperscript{422} While such controls are certainly no panacea—since they are difficult to administer, are often more costly to consumers than alternative schemes, and do not accrue to the benefit of domestic producers—they may in fact be used to encourage the licensing of technology.\textsuperscript{423} By providing

\textsuperscript{419} Id. art. 55(a)-(c).
\textsuperscript{420} See, e.g., id. art. 2.2 (stating that “all Members ... shall fulfill in good faith the obligations assumed by them in accordance with the present Charter”); id. art. 56 (stating that “all Members pledge themselves to take joint and separate action in cooperation with the Organization for the achievement of the purposes set forth in Article 55”).
\textsuperscript{421} Weissman, \textit{supra} note 29, at 1074, 1098, 1099, 1114-16.
\textsuperscript{422} Id. at 1098-99, 1114-15.
\textsuperscript{423} Id. at 1099, 1115.
waiver incentives, patent holders could be given the choice of either submitting their products and processes to a price control regime or granting non-exclusive licenses to all domestic producers.424

Similarly, Abbott has indicated that the TRIPS Agreement does not require that intellectual property protection be granted on a tax-free basis.425 While of course subject to the requirement of national treatment, taxes are "an ordinary incidence of property ownership" and are not precluded by the terms of the Agreement.426 Since a preponderance of intellectual property is owned by firms in industrialized nations (and thus any taxation of that property would fall disproportionately on those firms), some transfer of wealth to consuming States may result.427 Additionally, since different products may be subject to different tax rates,428 an optimal tax regime could conceivably be created by taking into consideration the hierarchy of consumer needs and the ability (or lack thereof) to pass taxation on to the consuming public. The revenues generated by such a regime could be used to spur domestic investment in pharmaceutical production or to offset, at least in part, the cost of importation and distribution of HIV/AIDS-related products.

It can also be argued that the TRIPS Agreement imposes limitations on the ability of a nation (on behalf of its intellectual property owners) to seek relief through the WTO dispute settlement process. 'Non-violation' complaints, for example, are designed to provide relief to a complaining party despite the fact that the measure being challenged is absolutely consistent with the terms of the TRIPS Agreement.429 In effect, these complaints recognize the fact that even lawful activity may nullify or impair the benefits accruing to

424 Id. at 1115.
426 Id. at 401 n.41.
427 See id. at 401-02.
428 Id. at 402; see also Weissman, supra note 29, at 1074, 1098-99 (regarding the ability to impose a tax regime).
429 GATT, supra note 370, art. XXIII, para. 1(b); see also Understanding Regarding Notification, Consultation, Dispute Settlement and Surveillance, Nov. 28, 1979, GATT B.I.S.D. (26th Supp.) at 216 (1980) (describing procedures for a party to file a complaint against a measure which does not conflict with the provisions of GATT).

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a Member\textsuperscript{430} and that some form of adjustment may therefore be mandated. As a result, a bona fide exercise of the security exception (or any other legitimate exception found in the Agreement) may nevertheless give rise to a variety of adverse consequences based upon the nullification and impairment rationale. Article 64 of the TRIPS Agreement, however, specifically prohibited Members from instituting non-violation complaints for a period of five years from the date of its entry into force\textsuperscript{431} and this prohibition has now been extended by a ministerial decision at Doha.\textsuperscript{432}

Article 6 of the TRIPS Agreement is also of particular importance to developing countries. For the purposes of dispute settlement, this Article provides that nothing in the Agreement shall be used to address the issue of ‘exhaustion’ of intellectual property rights.\textsuperscript{433} The effect of this provision is to grant each nation the absolute right to choose its own exhaustion policy without external interference. If a nation chooses to adopt a ‘national exhaustion’ policy, the exclusive rights of patent holders will be enhanced and parallel importing will be foreclosed. On the other hand, the adoption of an ‘international exhaustion’ policy will quite arguably encourage the practice of parallel importing and thus lower domestic pharmaceutical prices. Additionally, the mere existence of this right to choose may exert considerable pressure on international pricing regimes.\textsuperscript{434}

Finally, it must be emphasized that the TRIPS Agreement represents only one of a number of legal obligations undertaken by Member States. As a result, the Agreement must always be placed within the context of other treaties, customary law, and domestic responsibilities. Article 62 of the Vienna Convention on the Law of Treaties, for example, recognizes that “a fundamental change of circumstances” not foreseen by the parties at the time of the conclusion of a treaty, may constitute grounds for terminating that treaty, withdrawing from that treaty, or suspending the operation.

\textsuperscript{430} See JACKSON, supra note 371, at 181-82 (discussing the necessity of injury to a Contracting Party if Article XXIII is invoked).

\textsuperscript{431} TRIPS Agreement, supra note 26, art. 64.2.

\textsuperscript{432} Decision, Implementation-Related Issues and Concerns, art. 11.1, WT/MIN(01)/17 (Nov. 20, 2001).

\textsuperscript{433} TRIPS Agreement, supra note 26, art. 6. This article, of course, is subject to the requirements of both national and most-favored-nation treatment.

\textsuperscript{434} For a discussion of exhaustion and parallel importing, see ACCESS TO MEDICINES, supra note 29, at 17-22 and Chiappetta, supra note 29, at 340-92.
of that treaty.\textsuperscript{435} Certainly the \textit{absence} of a crippling pandemic, the \textit{absence} of severely destructive social, political, and economic forces and the \textit{absence} of a threat to the actual sovereignty of a nation all served as an "essential basis of the consent of the parties to be bound" by the TRIPS Agreement.\textsuperscript{436} As a result, it can be argued that the effect of the subsequent evolution of these circumstances "is radically to transform the extent of obligations still to be performed."\textsuperscript{437} While the obligations under the Agreement may have remained constant over time, the effect of fulfilling those obligations certainly has not. Article 62 could therefore serve as a basis for the renegotiation of the TRIPS Agreement by HIV/AIDS-stricken countries. For without some adjustment in obligation—whether in the form of a formal recognition of the flexibility of the Agreement or a massive infusion of pharmaceutical products irrespective of the terms of the Agreement—some signatory nations may simply cease to exist.

Such interplay of international instruments, as well as the creation of obligations under both customary and domestic law, substantially detract from the importance that Western nations have placed on the protection of intellectual property. When one examines these duties in their totality, IPR's protection acquires a perspective quite different than that proposed in the TRIPS Agreement. Conflicts are created, hierarchies are developed, and compromise becomes both essential and constitutive.

\textbf{5. THE DUTY TO EXERCISE THE FLEXIBILITY OF THE TRIPS AGREEMENT}

\textbf{5.1. Introduction}

Every nation has the duty to exercise the flexibility of the TRIPS Agreement in meeting its public health needs. Such a duty exists despite traditional arguments regarding the non-justiciability of social issues, the non-self-executing nature of most international agreements, the difficulty of enforcing positive rights, and the 'available resources' limitation to the progressive realization doctrine. Those arguments find credence only when viewed in isol-  

\textsuperscript{435} Vienna Convention on the Law of Treaties, \textit{supra} note 288, art. 62.  
\textsuperscript{436} \textit{Id.}  
\textsuperscript{437} \textit{Id.} For a discussion of "changed circumstances" and a possible "waiver approach," see ACCESS TO MEDICINES, \textit{supra} note 29, at 30-32.
tion—when simplistic norms of sovereignty, non-intervention, and internal supremacy are advanced in an attempt to retard the inevitable evolution of international relations.

In contrast, the duty to provide the highest attainable standard of health—and thus the duty to exercise the flexibility of the TRIPS Agreement in a continuous progression toward that goal—is a result of a complex web of global treaties and conventions, regional charters, domestic constitutional and statutory mandates, and customary norms that have altered the responsibilities of governments to both their citizens and other States. This duty is also the result of the recognition that individuals are subjects of international law, that the welfare of a State's citizens is no longer a purely domestic matter, and that international agreements may be directed toward the conditions of persons rather than merely the relationships between nations. Such a perspective has served to solidify the basic premise that a State, if it is to be viewed as legitimate, must "protect, promote and implement all human rights and fundamental freedoms" and must ensure not only the territorial integrity of the State, but the security of its people as well. As both a recognized human right and a substantial determinant of national and international security, the right to enjoy the highest attainable standard of health can no longer be assigned a secondary status.

The duty of a State to protect this human right to health is further enhanced by an increasing recognition of the interdependence of economic, social, and cultural rights, civil and political rights, and the inalienable rights to development and self-determination. As a result, the substantial body of international

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438 For various discussions of humanitarian intervention into the domestic affairs of a nation, see supra note 21.


440 Declaration on the Right and Responsibility of Individuals, supra note 1, art. 2.1.


442 See, e.g., S.C. Res. 1308, supra note 400, at 2 (stressing how the HIV/AIDS pandemic may pose a risk to security).

443 See, e.g., DRD, supra note 25, art. 1 (explaining the universally recognized right to development).
law regarding each of these rights—and the accompanying legal obligations that have been imposed on all States—must be incorporated in the analysis of the right to health, particularly in the context of pandemics such as HIV/AIDS. It is often impossible to segregate, for example, the right to health from the concepts of equality, non-discrimination, equal protection, due process, and human dignity. Similarly, the progressive realization of the right to health is a fundamental determinant of the rights to life, social order and security, development, and self-determination. These rights impose universal duties on States irrespective of international treaty. Additionally, agreements regarding education, the sharing of the benefits of scientific advancement, the raising of standards of living, and the eradication of poverty provide further dimension to the duties placed on States regarding the right to health.

As a result, the right to the highest attainable standard of health cannot be reduced to the provisions found in such agreements as the ICESCR,\(^\text{444}\) the CRC,\(^\text{445}\) and the CEDAW.\(^\text{446}\) While these agreements are extremely important, they form only a part of an elaborate patchwork of global, regional, and normative relationships that encompass a wide variety of interlocking rights. When viewed in such a light, these rights become substantially more enforceable by means of a similar patchwork of individual claims, interstate complaints, and monitoring mechanisms. With such a premise in mind, this Section will first examine the international and domestic settings of the right to the highest attainable standard of health. It will then explore a variety of issues surrounding the scope of this right, the nature of progressive realization, and the relationship between the right to health and civil and political rights. It will then conclude with a look at some of the potential means for enforcing a State’s duty in this regard.

5.2. The International Setting

The ICESCR, to which 147 nations have now become legally bound, states that all Parties “recognize the right of everyone to the enjoyment of the highest attainable standard of physical and men-

\(^{444}\) ICESCR, supra note 23, art. 12.
\(^{445}\) CRC, supra note 117, art. 24.
\(^{446}\) CEDAW, supra note 119, arts. 11.1(f), 12.
tal health." The Covenant goes on to state that the steps to be taken by the Parties to achieve the full realization of this right shall include those necessary "for the healthy development of the child," for the creation of conditions that would assure to everyone "medical service and medical attention in the event of sickness," and for the "prevention, treatment and control of epidemic ... and other diseases." Unlike the rights guaranteed in the ICCPR, these rights are qualified by the concept of progressive realization found in Article 2.1. In addressing the duties of States under the Covenant, this article indicates that each Party "undertakes to take steps . . . to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means."

While the broad socio-economic nature of the right to health will be discussed later in this Section, some preliminary observations should be made regarding the basic definitional approach to the duties of States under the ICESCR. First, both the Commission on Human Rights and the Committee on Economic, Social, and Cultural Rights—having taken the position that the right to health is a fundamental human right—have adopted a framework by which States have the obligation to "respect, protect and fulfil" the right to the highest attainable standard of health. Under such a framework, parties to the Covenant must refrain from interfering with the enjoyment of the right to health; they must take measures to prevent third parties from interfering with the right to health; and they must take positive action to "facilitate," "provide," and "promote" the full realization of the right to health for all individuals and communities.

This framework also imposes on States the obligation to ensure—subject to progressive realization—that health-care facilities, goods, and services are "available in sufficient quantity," are of "good quality," and are both "accessible" and "affordable" to all.

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447 ICESCR, supra note 23, art. 12.1.
448 Id. art. 12.2(a), (d), (c).
449 Id. art. 2.1.
450 Substantive Issues, supra note 3, para. 33; see also A Human Rights-Based Approach to HIV/AIDS, supra note 3, para. 9 (recalling this tripartite obligation).
451 Substantive Issues, supra note 3, paras. 33-37.
452 Id. para. 12; see A Human Rights-Based Approach to HIV/AIDS, supra note 3, paras. 9, 10 (restating certain of these obligations).
More particularly, "affordable access to essential medicines"\footnote{A Human Rights-Based Approach to HIV/AIDS, supra note 3, para. 10 (emphasis deleted); see Substantive Issues, supra note 3, paras. 12(a), 12(b)(iii), 43(d) (establishing a duty to affordably provide essential drugs and referring to WHO authority to define "essential drugs").} and "access to medication in the context of pandemics such as HIV/AIDS"\footnote{Access to Medication, supra note 122, para. 1.} are viewed as fundamental elements for achieving progressive realization. Similarly, the provision of "equal and timely access to preventive, curative, [and] rehabilitative health services"\footnote{Substantive Issues, supra note 3, para. 17.} and the taking of measures "to prevent, treat and control epidemic and endemic diseases"\footnote{Id. para. 44(c).} are seen as essential obligations on the part of the State.

Second, it should be recognized that while the ICESCR provides for progressive realization and acknowledges limitations based on available resources, it does impose on States a variety of obligations "which are of immediate effect."\footnote{Id. para. 44(c).} In specific regard to the right to health, States are obligated, for example, to take "deliberate, concrete, and targeted" steps toward the full realization of Article 12.\footnote{Id. para. 30.} As a result, progressive realization is viewed not as a defense, but as a continuum on which each State must "use all the means at its disposal to give effect to the rights recognized in the Covenant."\footnote{Id.} Additionally, the norms reflected in the ICESCR must be recognized within the "domestic legal order" of each State and, when necessary, a State’s legal order must be modified to give effect to (and become compliant with) the State’s treaty obligations.\footnote{Id. paras. 2, 3.}

Third, the ICESCR (including its provisions regarding the right to health) not only creates rights and duties between a State and its citizens, but also establishes rights, duties, and relationships among nations as well. For example, all Parties are under the obligation to respect and protect the right to health in other countries.\footnote{Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights, U.N. ESCOR Comm. on Econ., Soc., and Cultural Rights, 19th Sess., 51st mtg. para. 2, U.N. Doc. E/C.12/1998/24 (1998) [hereinafter Substantive Issues (1998)].}
and to refrain from limiting or interfering with that right. Subject to available resources, States are also "called upon" to "facilitate access" in other nations to health facilities, services, and medicines and to provide financial aid whenever possible.\textsuperscript{462} Collaterally, all nations are directed to consider the right to health when implementing or negotiating international agreements and to ensure that such agreements do not adversely impact the right to health in any nation.\textsuperscript{463} The recognition of these interstate relationships can be of particular import in light of the fact that pharmaceutical-producing nations such as Germany, France, India, and Brazil are all parties to the ICESCR.

Finally, it should be reiterated that States are in fact sovereign for the purpose of entering into international agreements that limit their sovereignty.\textsuperscript{464} As a result, all of the parties to the ICESCR have chosen to internationalize a variety of issues (including the right to health) that have been traditionally viewed as matters of domestic policy. Having done so, the relationships between a Party and its citizens—and the duty of a Party to engage in the level of progressive realization suitable to its circumstance—are no longer beyond international scrutiny.

While the ICESCR has been traditionally viewed as the core of the right to the highest attainable standard of health, a variety of other international instruments clearly acknowledge this right as well. In the CRC,\textsuperscript{465} for example, the Parties recognize "the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness."\textsuperscript{466} Although subject to the "maximum extent of their available resources" language,\textsuperscript{467} 192 Parties agreed that they "shall pursue full implementation of this right" and "shall take appropriate measures" to reduce infant and child mortality, ensure necessary medical assistance and health care, combat disease through readily avail-

\textsuperscript{462} Id.
\textsuperscript{463} See id. (discussing the obligation of States to the promotion and facilitation of the right to health in other countries); see also Access to Medication, supra note 122, para. 4(b) (stating that international agreements should support broad access to "the highest attainable standard of physical and mental health").
\textsuperscript{464} Military and Paramilitary Activities (Nicar. v. U.S.), 1986 I.C.J. 14, 131 (June 27).
\textsuperscript{465} CRC, supra note 117.
\textsuperscript{466} Id. art. 24.1.
\textsuperscript{467} Id. art. 4.
able technology, and ensure appropriate pre-natal and post-natal health care for mothers.\textsuperscript{468} Additionally, the 192 Member States of WHO have formally recognized that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being”\textsuperscript{469} and 174 nations have recognized the particular right of women to health care under the CEDAW.\textsuperscript{470}

These global conventions are supplemented by a variety of regional agreements recognizing the right to health. The Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (the Protocol of San Salvador),\textsuperscript{471} for example, indicates that “[e]veryone shall have the right to health, understood to mean the enjoyment of the highest level of physical, mental and social well-being.”\textsuperscript{472} In order to ensure this right, the Parties further agreed to adopt measures to provide primary health care and services to all individuals, to prevent and treat endemic and other diseases, and to satisfy the health needs of those in the “highest risk groups” and those “whose poverty makes them the most vulnerable.”\textsuperscript{473} Similarly, the African Charter on Human and People’s Rights,\textsuperscript{474} which is of particular import to the HIV/AIDS crisis, states that “[e]very individual shall have the right to enjoy the best attainable state of physical and mental health” and that the Parties shall take the necessary measures “to protect the health of their people” and to ensure medical attention for the sick.\textsuperscript{475} Fifty-two African nations have ratified this Charter and have agreed “to adopt legislative or other measures to give effect” to the rights contained therein.\textsuperscript{476} It is interesting to note (and

\textsuperscript{468} Id. art. 24.2(a)-(d) (emphasis added).


\textsuperscript{470} CEDAW, supra note 119, art. 12.


\textsuperscript{472} Id. art. 10.1.

\textsuperscript{473} Id. art. 10.2(f).


quite reflective of the patchwork of international instruments giving rise to the right to health) that South Africa, while not a Party to the ICESCR, is in fact a Party to the African Charter as well as to both the CRC and WHO.

The international setting becomes substantially more intricate if one accepts the proposition that the right to health is a fundamental human right and that the HIV/AIDS crisis is a human rights issue. Under such a circumstance, there is ample evidence that all nations have the duty—even in the absence of the contractual agreements discussed above—to respect and promote the right to health.\textsuperscript{477} It must be admitted that the duty to 'respect' primarily represents a negative obligation to refrain from interfering with a human right and the duty to 'promote' tends to be both subjective and aspirational in nature. Similarly, the duty to 'protect' that is incorporated into some human rights agreements,\textsuperscript{478} fails to establish the type of positive right that is essential for creating tangible and enforceable duties on the part of the State.

In contrast, there are a variety of human rights instruments that clearly recognize the existence of positive rights and corresponding duties. The U.N. General Assembly, for example, has taken the position that all States have the duty not only to protect and promote, but to "implement" all human rights, and that States are also obligated to take the steps necessary to create the social, economic, political, and legal conditions that are requisite for the enjoyment of those rights.\textsuperscript{479} Similarly, the Universal Declaration—

\textsuperscript{476} African Charter, supra note 474, art. 1.

\textsuperscript{477} See, e.g., Vienna Declaration, supra note 101, pmbl., paras. 1-2 (reaffirming the commitment of U.N. States to promote universal protection of "all human rights and fundamental freedoms . . . "); Universal Declaration, supra note 118, pmbl. (proclaiming the Vienna Declaration as a standard of achievement for all people and all nations to strive for in order to secure the universal observance of human rights); ICCPR, supra note 125, pmbl. (confirming the duty of individuals to observe universally recognized rights); U.N. CHARTER, art. 1 para. 3. (setting out, in various terms, the fundamental nature of certain rights, including in each case, by later language, the right to health).

\textsuperscript{478} See, e.g., Vienna Declaration, supra note 101, para. 5 (declaring that "all human rights are universal, indivisible and interdependent" and that it is the duty of States to promote and protect them); Universal Declaration, supra note 118, pmbl. (declaring that it is the goal of Member States to protect fundamental rights); Declaration on the Right and Responsibility of Individuals, supra note 1, pmbl., art. 2.1 (asserting that it is the duty of States, regardless of varying cultural, political, and economic systems to protect all human rights).

\textsuperscript{479} Declaration on the Right and Responsibility of Individuals, supra note 1, art. 2.1 (emphasis added).
unequivocally the authoritative and common standard for all nations\textsuperscript{480}—clearly states that "everyone is entitled to all the rights and freedoms set forth in this Declaration."\textsuperscript{481} Among the rights to which all individuals are "entitled" are the "economic, social and cultural rights" that are "indispensable" for a person's dignity and the free development of his or her personality.\textsuperscript{482} These rights, while subject to the progressive realization and available resources limitation,\textsuperscript{483} specifically include the right to a standard of living adequate for "health and well being" and specifically encompass both "medical care" and "security in the event of...sickness."\textsuperscript{484}

As a result, the human rights regime actually imposes some universal duties on all States that supplement the contractual duties created by agreements such as ICESCR and the CRC. Additionally, the inclusion of the right to health in the human rights regime should be viewed as interpretive. By its very nature, the right to health is a positive right that requires substantial State action for its assurance. By elevating the status of the right to health, the international community has taken the position that such governmental action, irrespective of treaty obligation, is no longer purely discretionary.

The right to the highest attainable standard of health also gains substantial support if one accepts the propositions that all human rights and fundamental freedoms are "universal, indivisible and interdependent and interrelated"\textsuperscript{485} and that civil and political freedoms cannot be enjoyed without an adequate foundation of economic, social and cultural rights.\textsuperscript{486} Under such circumstances, the right to health is bolstered by a substantial body of international law regarding such civil and political rights as self-determination, the freedom to pursue economic, social, and cultural development, the right to life, the rights to equality and in-

\textsuperscript{480} See supra notes 142-50 and accompanying text (explicating the Declaration's authority).

\textsuperscript{481} Universal Declaration, supra note 118, art. 2 (emphasis added).

\textsuperscript{482} Id. art. 22.

\textsuperscript{483} Id.

\textsuperscript{484} Id. art. 25.1.

\textsuperscript{485} Declaration on the Right and Responsibility of Individuals, supra note 1, at pmbl.; see Vienna Declaration, supra note 101, para. 5 (noting the importance of having certain fundamental freedoms and rights).

\textsuperscript{486} See supra note 125 and accompanying text (explaining the ideals expressed in the Universal Declaration).
herent dignity, and the rights to subsistence and security of person. It is important to recognize that these rights are not subject to the limitations of progressive realization and available resources. As a result, to the degree to which the right to health is a determinant in regard to the achievement of these other freedoms, a corresponding duty to pursue the right to health must be placed upon the States.

Finally, if one accepts the fact that the HIV/AIDS pandemic poses a threat to international peace and security, the right to health becomes further internationalized. Viewed in such a perspective, the Charter of the United Nations, including its provisions for the maintenance of international peace and security, becomes substantially more relevant. Arguments regarding the mere aspirational nature of the Charter in regard to the promotion of human rights become preempted by the fundamental purpose of the Charter. Additionally, the growing incidence of humanitarian intervention evidences the fact that the United Nations is continually willing to broaden the definitional scope of a threat to peace.

While the right to health finds substantial support throughout the international setting, such a fact cannot be equated with the duty to provide treatment to victims of HIV/AIDS. Since resources are always finite, it could be argued (as simply one example) that the highest attainable standard of health could best be progressively realized through HIV/AIDS education and prevention. Similarly, the overall health of a population may be proportionately increased (at least hypothetically) by dedicating a nation’s limited resources to the prevention of malaria, tuberculosis, river blindness, or malnutrition. The provision of food, shelter, or potable water may conceivably be viewed as a greater progression toward the realization of health than the provision of antiretrovirals.

Such policy decisions, of course, must be placed beyond the scope of this Article. What can be argued, however, is that contractual obligations, human rights norms, the interdependence of rights and freedoms, and the need to maintain international peace and security all demand that States honor their duty to engage in progressive realization. More particularly, all nations have the duty to exercise the lawful flexibility provided in the TRIPS Agreement as they engage in that progression. Whether through

\[487 \text{ See ICCPR, supra note 125, arts. 1.1, 1.2, 3, 6.1, 9, 10 (articulating a person’s fundamental rights).}\]
compulsory licensing, parallel importing, or the exporting of generics by drug-producing countries, States have the obligation—at a minimum—to take all lawful steps to ensure that pharmaceuticals are priced at the lowest possible level. Since a refusal to take such action would render a State’s progressive realization regime indefensible, the victims of HIV/AIDS are ‘entitled’ to no less.

5.3. The Domestic Setting

Pursuant to the international agreements discussed above, most nations have explicitly agreed to grant a variety of enumerated rights to their citizens. Under such circumstances—and despite issues surrounding non-self-execution—it would seem quite incongruent to argue that these States ‘really’ have no duty to do so. When one recognizes the universal duties to respect human rights, to maintain both national and international peace and security, and to ensure such rights as self-determination and the pursuit of development, such a position becomes even more indefensible. Whether viewed in terms of the rights of individuals or in terms of contractual duties between States, some form of legal obligation must have been created when nations ratified these instruments. To argue otherwise would be to reduce both the international treaty regime and customary law to a series of unenforceable guidelines. While determining the precise nature of these obligations is indeed complex, their complexity must never be equated with their non-existence.

As a result, the Committee on Economic, Social and Cultural Rights has taken the position that each Party to the ICESCR must use all the means at its disposal to give effect to the rights granted in the Covenant.488 They must recognize its norms in their domestic legal order; they must provide appropriate remedies to aggrieved individuals; and they must ensure appropriate means for governmental accountability.489 Since a Party may not invoke its domestic law as justification for its failure to perform a treaty, Parties should “modify” their internal legal orders whenever necessary to give effect to their international obligations.490 Similarly, municipal courts should interpret domestic law, at least as far as possible, “in a way which conforms to a State’s international legal  

489 Id.
490 Id. para. 3.
obligations," thereby avoiding interpretations that would place the State in breach of the Covenant.\textsuperscript{491}

Despite the argument that legally binding international human rights standards "should operate directly and immediately" within a Party's domestic legal system,\textsuperscript{492} the internal implementation of the ICESCR has been substantially mixed. While some States have adopted or incorporated the Covenant into domestic law or have given the Covenant direct effect by means of supplementing or amending existing legislation, other States have failed to engage in any meaningful implementation process.\textsuperscript{493} Collaterally, some domestic courts have applied the Covenant's provisions either directly or as interpretive standards, while others have refused to give any legal effect to the Covenant in cases where individuals have attempted to use its provisions as a basis for relief.\textsuperscript{494}

State practice regarding the implementation of the ICESCR in its totality, however, should not detract from the fact that the specific right to health has gained substantial support in domestic legal orders. In his recent report on the right to the highest attainable standard of health, Special Rapporteur Paul Hunt cited the preliminary findings of a study being performed by the International Commission of Jurists.\textsuperscript{495} While still in its early stages, this study indicates that over sixty constitutional provisions include the right to health or health care and over forty constitutional provisions include such health-related rights as reproductive health care and the right to a healthy environment.\textsuperscript{496} Additionally, a large number of constitutions establish a variety of duties on the part of the State—such as the duty to develop health services—from which the existence of health entitlements can be inferred.\textsuperscript{497} These findings can be supplemented by the fact that more than seventy nations have incorporated the Universal Declaration into their constitutions or statutes\textsuperscript{498} (which includes provisions on medical care

\textsuperscript{491} Id. para. 15.
\textsuperscript{492} Id. para. 4.
\textsuperscript{493} Id. para. 6.
\textsuperscript{494} Id. para. 13.
\textsuperscript{496} Id.
\textsuperscript{497} Id.
\textsuperscript{498} RAY AUGUST, PUBLIC INTERNATIONAL LAW, 274 (1995).
and security in the event of sickness), and that many States have provided their citizens with a variety of social benefits (including health care) by means of ordinary legislative action.

The South African Constitution, for example, squarely places substantial duties on the government regarding the provision of health care services. After recognizing the basic rights to life, inherent dignity, equality, and reproductive decision making, the Constitution provides that "everyone has the right to have access to . . . health care services, including reproductive health care," and that the State "must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights." Significantly, the Constitution also provides that the State must "respect, protect, promote and fulfill" these rights, that all organs of the State (including the legislative, the executive, and the judiciary) are bound by these rights, and that individuals are entitled to seek judicial relief when these rights have been infringed or threatened. Finally, when interpreting these constitutional provisions, South African courts must "consider international law," which would include, at a minimum, the African Charter and the CRC to which South Africa is a Party.

Similarly, the Constitution of Haiti provides that "the State has the absolute obligation to guarantee the right to life, health, and respect of the human person . . . in conformity with the Universal Declaration of the Rights of Man," and that the State must provide the "appropriate means to ensure protection maintenance and

499 Universal Declaration, supra note 118, art. 25.1.
500 See Herman Schwartz, Do Economic and Social Rights Belong in a Constitution?, 10 AM. U. J. INT'L & POL'Y 1233, 1236-37 (1995) (discussing how most countries have statutes creating rights to public health care and other social benefits).
502 Id. arts. 9, 10, 11, and 12(2)a.
503 Id. art. 27(1).
504 Id. art. 27(2) (emphasis added).
505 Id. art. 7(2) (emphasis added).
506 Id. art. 8(1).
507 Id. art. 38.
508 Id. art. 39(1)(b).
509 HAITI CONST.
510 Id. art. 19 (emphasis added).
restoration" of the health of its citizens. It is worthy to note that the Haitian Constitution actually prohibits the National Assembly from ratifying any international treaty or convention that contains terms contrary to these provisions. Viewed in such a light, any ratification of the TRIPS Agreement—if that Agreement were to be interpreted in a way that frustrated the right to health—would appear to be ultra vires.

Constitutions around the world tend to recognize similar rights. In Brazil, health care is viewed as both “a right of all” and “a duty of the State.” As a ‘social right,’ health is to be “guaranteed” by way of governmental policies that are aimed at reducing the risk of illness and providing universal access to services for the “promotion, protection and recovery” of an individual’s health. In Chile, the Constitution guarantees the right to life, the right to physical and psychological integrity, and the right to life of those about to be born. It also guarantees the protection of health and the “free and egalitarian access” to measures necessary for the “promotion, protection and recovery of the health and rehabilitation of the individual.” In Spain, the Constitution recognizes the “right to health protection” and places the burden on the State “to organize and watch over public health and hygiene through preventive measures and through necessary care and services.”

The right to health is constitutionally protected by a variety of other (perhaps less direct) methods as well. Some constitutions, for example, provide that international human rights treaties, once they have been ratified, are granted direct domestic effect. Under such circumstances, agreements such as the ICESCR and the CRC would become, upon ratification, internally binding. Other constitutions view the right to health in terms of fundamental objectives or directive principles that are to be used in creating all

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511 Id. art. 23 (emphasis added).
512 Id. art. 276.
513 BRAZ. CONST. art. 196.
514 Id.; see also arts. 6 and 227 (outlining universal social rights and guaranteeing specific rights for children).
515 CHILE CONST. art. 19.1.
516 Id. art. 19.9.
517 SPAIN CONST. Chap. III, art. 43(1).
518 Id. art. 43(2).
State policy. Finally, constitutional provisions are often directed at protecting the health and well-being of particular constituencies, such as families, women, children, and (at least from a national security perspective) the ‘people’ of the nation.

These constitutional provisions, of course, are finding support in an increasing body of case and statutory law. According to the Report on the Global HIV/AIDS Epidemic for example, an HIV-positive petitioner brought an action before the Supreme Court of Costa Rica demanding combination therapy that he could not afford on his own. The court ruled in the petitioner’s favor—immediately giving rise to similar petitions—and within weeks the national social security system was ordered to develop a plan to provide antiretroviral treatment to all citizens suffering from HIV/AIDS. In Venezuela, a suit was filed claiming that HIV/AIDS victims were not receiving proper medical attention as guaranteed both by the Venezuelan Constitution and the various Human Rights agreements that had been ratified by that nation. In choosing to uphold the lawsuit, the court ordered the Venezuelan Social Security System to provide free treatment to each of the claimants. Outside the HIV/AIDS context, the African Commission on Human and Peoples’ Rights found a violation of the right to the highest attainable standard of health by the State of Nigeria in relation to the activities of oil companies in the Niger Delta.

Certainly the most celebrated case, however, is Treatment Action Campaign wherein the court addressed the question of whether the South African government had taken “reasonable legislative

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520 See, e.g., NIG. CONST. Chap. II, arts. 16(2)(d) and 17(3)(d) (providing a minimum level of health care for all citizens).
521 See, e.g., S. AFR. CONST. art. 28(1)(c) (providing children with basic services); BRAZ. CONST. arts. 6, 203, 227 (protecting children and women through the political system as well as providing them with basic forms of social assistance); CHILE CONST. art. 1 (guaranteeing certain protections and services to the family unit); NIG. CONST. arts. 14(2)(b), 17(3)(f) (providing for the protection of children).
523 Id. at 64.
524 Id. at 64-65.
525 Id. at 65.
526 Id.
528 2002 (4) BCLR 356 (T) (S. Afr.).
and other measures within their available resources to achieve the progressive realization of the right to health care services” as mandated by Article 27(2) of the South African Constitution.529 More particularly, the court was confronted with the issue of whether the steps taken by the government in regard to the prevention of MTCT of HIV (by means of establishing eighteen pilot sites for dispensing Nevirapine, but confining its dispensation to those sites) was in compliance with the progressive realization requirement of Article 27(2).530 In addressing these issues, the court found that: the obligation of the State in terms of Article 27(2) was in fact justiciable;531 that the judiciary did have the power to decide the “reasonableness” of the steps being taken by the State in meeting its obligations; and that the court was indeed required to pass a “value judgment” as to whether the steps being taken toward the realization of the right to health care were reasonable.532

The court noted that the goal of the South African Constitution was to meet the basic needs of society, that the requirement of progressive realization “meant that the State must take steps to achieve this goal,” and that “accessibility should be progressively facilitated.”533 In light of the fact that Article 27(2) imposes a duty to achieve the progressive realization of this right in terms of “an ongoing obligation,”534 the prohibition of the use of Nevirapine outside the pilot sites was “not reasonable” and constituted an “unjustifiable barrier to the progressive realization of the right to health care.”535 After indicating that “a country-wide MTCT prevention programme is an ineluctable obligation of the State,”536 the court ordered that Nevirapine be made available to all pregnant women with HIV (as well as to their babies) who give birth in the public sector.537 The court also ordered the State to plan an effective and comprehensive national program to prevent or reduce MTCT of HIV through voluntary counseling and testing, the provi-

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529 Id. at 379.
530 Id.
531 Id.
532 Id. at 380.
533 Id. at 381.
534 Id. at 382.
535 Id. at 384.
536 Id. at 386.
537 Id. at 386-87.
sion of infant formula, and the provision of Nevirapine and other medicines.\textsuperscript{538} The constitutional requirement of progressive realization demanded no less.

While policy establishing a legal right to free HIV/AIDS medication (such as that found in the Republic of Brazil)\textsuperscript{539} is the most direct form of State intervention, cases such as those noted above provide an important new weapon against governmental indifference. As will be discussed later in this Section, the doctrine of progressive realization is in the process of being transformed from a defense used by nations seeking to avoid their responsibilities, to a mechanism by which responsibility can be imposed. Whether based on international agreement or the development of such internal law, the domestic setting regarding the right to the highest attainable standard of health is becoming increasingly dynamic.

5.4. The Requirement of Progressive Realization

5.4.1. Introduction

In order to appreciate the concept of progressive realization, it is necessary to briefly examine the goals toward which nations are required to progress. It is important to note, for example, that the right to health is not to be understood as the right to be "healthy"\textsuperscript{540} and that States are not to be viewed as ensurers of good health.\textsuperscript{541} On the other hand, the right to the highest attainable standard of health is a fundamental human right derived from the inherent dignity of the person,\textsuperscript{542} and must be viewed as both indispensable for and dependent upon the exercise and realization of other human rights.\textsuperscript{543} As a result, while Article 12 of the ICESCR provides a small sampling of components,\textsuperscript{544} the right to

\textsuperscript{538} Id. at 387.
\textsuperscript{539} See Report on Global HIV/AIDS, supra note 3, at 10 (citing policies of various countries regarding HIV/AIDS care and prevention).
\textsuperscript{540} Substantive Issues, supra note 3, para. 8.
\textsuperscript{541} Id. para. 9.
\textsuperscript{542} The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, supra note 441, pmbl.
\textsuperscript{543} See Substantive Issues, supra note 3, paras. 1, 3.
\textsuperscript{544} ICESCR, supra note 23, para. 12.1 (describing components including reduction of stillbirth-rate and infant mortality; healthy development of the child; environmental and industrial hygiene; prevention, treatment and control of epidemic, endemic, occupational and other diseases; creation of conditions which
health encompasses a broad range of "socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health." Such determinants include: adequate food, nutrition, and housing; access to portable water and sanitation facilities; healthy working and environmental conditions; access to health-related education and information; and the existence of a social and political system that values social progress, pursues elevated standards of living, and respects the rights to privacy, equality, and non-discrimination.

The right to health must also be viewed in terms of creating programs that are behavior-oriented, that tend to build life-skills, that are gender and youth-friendly, that are culturally appropriate for indigenous populations, and that are sensitive to resource distribution. National strategic plans must be developed—supported both legislatively and judicially—for the strengthening of the health care system and for the provision of the "facilities, goods, services and conditions" that are necessary for realizing the right to the highest attainable standard of health. These programs must be accompanied by attitudinal changes that are designed to improve all forms of maternal and child health by means of protecting women and children from domestic violence, sexual subservience, and harmful traditional cultural practices. Additionally, these national plans must address the needs for health insurance, immunization, the development of technology, and the creation of a medical infrastructure of hospitals, doctors, and related personnel.

As is apparent from this abbreviated listing, the issue of health has two related dimensions. The first concerns the actual physical state of individuals and encompasses rights surrounding the provision of preventive, curative, and rehabilitative health care. The second dimension addresses a wide variety of environmental con-

would assure medical service and medical attention).

545 Substantive Issues, supra note 3, para. 4.

546 See id. paras. 3, 4, 11, 15 (discussing various determinants of health).

547 See id. paras. 10, 16, 23, 27 (expanding on the right to health considerations).

548 Id. para. 9.

549 See id. paras. 10, 14, 16, 21, 22 (broadening the right to health care programs to include and address issues impacting women and children).

550 See id. paras. 19, 21, 36 (discussing further barriers that must be removed to establish effective national plans).
ditions that often dictate—or preordain—an individual’s physical state at some point in time. Within this setting, the right to health can be examined from several different perspectives. First, it can be argued that the right to health should be viewed in terms of both freedoms and entitlements. Not only do individuals have the freedom to control their own health and their own bodies, they also have the right of access to non-discriminatory systems of health protection. Second, the provision of health care facilities, goods, and services can be viewed from the perspective of their "availability," their physical and economic "accessibility," their "acceptability" (in terms of ethical, cultural and gender appropriateness), and their basic quality.

Third, the right to health can be examined in terms of three different types or levels of obligations that are imposed upon States: the obligations to respect, protect, and fulfill. As discussed earlier, the duty to "respect" requires States to refrain from interfering with (or limiting equal access to) preventive, curative, and palliative health services. It also requires States to refrain from marketing unsafe drugs, impeding traditional care, or censoring or misrepresenting health-related information. The duty to "protect" includes obligations to ensure that harmful social practices do not interfere with the right to health, that third parties do not limit the people’s access to health care services, and that the privatization of the health sector does not constitute a threat to availability, accessibility, acceptability, or quality. The duty to "fulfill" requires States to adopt national health policies that ensure the provision of health care, that ensure equal access to the underlying determinants of health, and that ensure the development of adequate public health infrastructures.

The right to health can also be viewed in the context of a series of "core" requirements and other obligations of "comparable prior-

551 Id. para. 8.
552 Id.
553 Id. para. 12.
554 Id. paras. 33-37.
555 See supra notes 450-63 and accompanying text (establishing a tripartite obligation by States to help realize the right to health).
556 Substantive Issues, supra note 3, para. 34.
557 Id. para. 35.
558 Id. para. 36.
ity." 559 While the right to health is inherently linked to the concept of progressive realization, these requirements appear to represent the minimum standards by which nations will be judged regarding their compliance with international agreements. As a result, it can be argued that these requirements impose a binding set of legal duties that are of immediate effect. Included within these obligations—and of particular importance to the HIV/AIDS crisis—are the duties to provide essential drugs, 560 to ensure reproductive, maternal, and child health care, 561 and to take measures to prevent, treat, and control epidemic diseases. 562

Finally, the right to health should always be assessed in terms of a proper international perspective. It has often been stated that Parties to agreements such as the ICESCR, the CRC, and the African Charter have internationalized issues that were previously domestic in nature. Such a statement, however, fails to reflect the fact that the right to health—as well as the effects that flow from a denial of that right—has always been an international issue regardless of multilateral agreement. The spread of disease across State borders, the migration of workers and refugees, the rise in regional instability, the decline in regional economies, and the threat to international peace and security all evidence the fact that the right to health is far more than merely a domestic concern.

As a result, the international setting can in fact be viewed from two distinct perspectives. On the one hand, Parties to international agreements have the duty to respect the right to health in other countries, to prevent third parties (who are under their influence) from violating the right to health in other countries, and to facilitate access to health-related goods and services to those other countries as resources permit. 563 All Parties also have the duty to negotiate, interpret, and implement international agreements in a manner that promotes the right to health in other nations and all Parties should create a domestic environment that encourages their social constituencies, including their private business sector, to help facilitate the right to health in other nations. 564

559 Id. paras. 43-44.
560 Id. para. 43(d).
561 Id. para. 44(a).
562 Id. para. 44(c).
563 Id. para. 39.
564 See id. paras. 39, 42 (encouraging parties to facilitate the right to health in other nations); A Human Rights-Based Approach to HIV/AIDS, supra note 3, para. 11
On the other hand, every nation has the inherent duty to protect the security of its own citizens and such an obligation arises out of the maintenance of sovereign legitimacy rather than international agreement. Since the physical health of the populace substantially determines the security of a nation, all sovereigns have both the right and the duty to take all actions necessary to secure that health. Those actions may include the manufacture and domestic sale of generic pharmaceuticals. They may also include the manufacture and export of generic pharmaceuticals to nations whose physical health (and accompanying economic and political health) are posing an external threat to security. Because the welfare of one nation is dependent upon the welfare of others, the performance of a 'domestic' duty may necessitate the taking of international action as foreign and domestic interests fuse.

It is beyond the scope of this Article, of course, to examine the right to health in light of such determinants as food, shelter, water, and sanitation. In less-developed countries, the duty of the State with regard to these determinants is subject to a substantial time dimension and it is recognized that the duty to actually provide these right-to-health components is not synonymous with the duty to progress toward their realization. To argue such congruence would be intellectually unsupportable. It is also beyond the scope of this Article to argue any particular allocation of limited resources. It is recognized that the achievement of the highest attainable standard of health—for a particular population at a particular point in time—may conceivably reflect an emphasis on education and prevention rather than treatment, or on the provision of food and potable water rather than pharmaceuticals, or on immunization rather than antiretrovirals. In a world lacking in infinite resources, a State's duty in this regard is admittedly fluid, subject to policy orientation, and extremely contextual.

What cannot be debated is that all nations have the duty to engage in a progression toward the highest attainable standard of health. The steps to be taken toward that progression, at any given point in time, will certainly vary substantially among nations and will reflect their different stages of economic development. What does not vary, however, is the duty to take all of the steps that are

(calling for international cooperation in health technologies and policies); Access to Medication, supra note 122, para. 4 (encouraging states to facilitate, individually and cooperatively, access in other countries to pharmaceuticals or technologies to treat pandemics).
in fact possible within legal and resource constraints. While not without cost in such terms as political capital, potential incentive for future R & D, and increased drug monitoring, the exercise of the flexibility found in the TRIPS Agreement would lower the cost of pharmaceuticals and increase their accessibility. As a result, a strong argument can be made that such an exercise is in fact possible since it is aimed at cost-savings rather than at additional State expenditure. If it can be admitted that the exercise of this flexibility is indeed ‘possible’ within relevant restraints, then that exercise becomes a duty rather than an option. Additionally, the inevitable clash between such a mandate and the protection of intellectual property rights will give the international community, as will be discussed in Section 6, a unique opportunity to progressively constitutionalize the right to health.

5.4.2. Progressive Realization as a Duty

The concept of progressive realization unquestionably places limitations on the right to health. It recognizes the fact that such a right—which is substantially, although not exclusively, positive in nature—cannot be achieved overnight. Even the most affluent of nations cannot guarantee the provision of all health-related determinants such as adequate food, shelter, and rehabilitation to every one of its citizens. Additionally, those nations that are experiencing the most dramatic of health concerns are also those which have the fewest resources by which to cope. As a result, to argue that the right to health is no different than the right to free speech would not only be naïve, it would denigrate those aspects of the right to health that are truly enforceable. The right to health must therefore be viewed in terms of the duties that are imposed upon a particular nation at a particular analytical point in time. Both the substantive nature and the magnitude of those duties will vary from State to State and will tend to reflect different points along the progressive continuum.

Nevertheless, almost all nations have agreed that such a continuum exists. The concept of progressive realization, and its application to various economic, social and cultural rights, has been incorporated not only into the ICESCR\textsuperscript{565} but into such international instruments as the CRC,\textsuperscript{566} the DRD,\textsuperscript{567} and the Universal

565 ICESCR, supra note 23, art. 2.1.
566 CRC, supra note 117, art. 4; see id. art. 24.4 (stating that countries should act
By becoming Parties to international covenants, or by recognizing the acceptance of certain minimum standards, most nations have agreed to submit themselves to external evaluation—albeit idiosyncratic—in regard to their progression along this legally binding continuum. As a result, the duty to engage in progressive realization is no longer subject to question and the focus of legal inquiry should now be directed at such issues as available resources, retrogression, and the degree of expectation at different stages of development.

In addressing the concept of progressive realization within the context of the ICESCR, the Committee on Economic, Social and Cultural Rights has taken the position that Parties to the Covenant have a variety of duties that are of "immediate effect." Despite the constraints of available resources, all Parties have the "immediate obligation" to take "deliberate, concrete and targeted" steps "towards" the realization of the right to health. As a result, the fact that progressive realization is inherently linked to a time dimension does not deprive these obligations of "meaningful content." Not only are retrogressive measures presumptively prohibited, but the requirement of progressive realization imposes "a specific and continuing obligation to move as expeditiously and effectively as possible."

By identifying a variety of actions or omissions that would constitute a violation of the Covenant's right to health, the Committee has provided further guidance regarding the nature and scope of the progressive realization doctrine. In determining whether a violation has occurred, for example, the Committee notes that it is necessary to distinguish between the "inability" of a nation to

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567 DRD, supra note 25, art. 4.1 (specifying that states have the duty to individually and collectively formulate international development policies).

568 Universal Declaration, supra note 118, pmbl., art. 22.


570 Substantive Issues, supra note 3, para. 30.

571 Id.

572 Id. para. 31.

573 Id. para. 32.

574 Id. para. 31.
comply with its obligations and an "unwillingness" to do so.\textsuperscript{575} A nation that is unwilling to use "the maximum of its available resources" to achieve the realization of this right would be in violation of the Covenant, and if resource limitations rendered full compliance impossible, a State would have the burden of demonstrating that every effort had been made in seeking that compliance.\textsuperscript{576} Additionally, the lack of available resources would never justify non-compliance with the "core" requirements incorporated in the right to health.\textsuperscript{577} Each of these observations, of course, supports both the existence of a binding continuum and the establishment of a minimum point of commencement below which no Party may fall.

Violations of the right to health can take the form of positive action on the part of the State or on the part of private entities insufficiently regulated by the State.\textsuperscript{578} Such actions might include the adoption of domestic or international policies that restrict access to health-related goods or services, that discriminate against certain constituencies, that stigmatize victims, that foster monopolization or price fixing, that misrepresent information, or that conflict with internationally recognized standards.\textsuperscript{579} On the other hand, many violations of the duty to engage in progressive realization will take the form of omissions. Acts of omission may include insufficient State expenditure, the failure to use resources that are in fact available, or the refusal to enforce health-related domestic legislation. They may reflect the failure to protect constituents from violence or harmful traditional practices or the failure to safeguard citizens from infringements of the right to health by third parties such as employers, food suppliers, or pharmaceutical manufacturers. They may also encompass a variety of failures that are not necessarily linked to the availability of resources, such as the failure to account for health-related concerns when negotiating international agreements, the failure to exercise the rights or the flexibility provided for in those agreements, or the failure to formulate domestic and international policy alternatives that may aid a nation's progres-

\textsuperscript{575} Id. para. 47.
\textsuperscript{576} Id.
\textsuperscript{577} Id. (referring to the core requirements set out in paragraph 43 of the ICESCR).
\textsuperscript{578} Id. para. 48.
\textsuperscript{579} See id. paras. 48, 50 (defining violations of the right to health and the obligation to respect).
sion without the need for additional resources.580

In Treatment Action Campaign,581 the South African Court directly addressed the requirements of progressive realization in order to determine whether the acts and omissions on the part of the State were in violation of those demands. In examining the question of whether the government had taken "reasonable legislative and other measures within their available resources to achieve the progressive realisation of the right to health care services,"582 the court admitted that the concept of progressive realization "clearly presupposes a situation" where the full realization of a right has not as yet been achieved and where it has been "contemplated" that such a right cannot be realized immediately.583 Despite these limitations, the court held that the requirement of progressive realization "means" that the State must take steps to achieve the realization of this right, that accessibility must be progressively facilitated, and that legal, operational, and financial "hurdles" must be lowered (whenever possible) over time.584 The fact that the "pace" of progression may be dictated by available resources does not alter the State's "ongoing obligation" to seek the "inexorable goal" of ultimate realization.585

The court also recognized the fact that there must be a realistic balance between the goals of a nation and the means at its disposal. In doing so, the court pointed out that while the attainment of a goal may be delayed by a lack of adequate means, the pursuit of a goal may serve as a catalyst to "enforce the creation of the means."586 As a result, while resources will remain an important factor in determining what constitutes "reasonable" behavior on the part of the State, measures must nevertheless be taken to achieve the right to health as "expeditiously and effectively" as possible.587 Policies that are merely "open-ended," that leave "eve-

580 See id. paras. 49-52 (discussing omissions and various violations of obligations by states).
581 2002 (4) BCLR 356 (T) (S. Afr.).
582 Id. at 379 (referring to the mandate of Article 27(2) of the South African Constitution).
583 Id. at 381 (discussing Gov't of Republic of S. Afr. v. Grootboom, 2001 (1) SA 46, 691-70B (CC)).
584 Id.
585 Id. at 382.
586 Id. at 385.
587 Id. at 381 (quoting Grootboom Court at 71A).
rything for the future," that are not "goal driven," and that lack a "built-in impetus" for maintaining momentum will fail the test of reasonableness under the requirements of progressive realiza-
tion.588

As is implicit in the Treatment Action Campaign decision, the is-
ue of available resources—while often central to the provision of positive rights—cannot preempt the more encompassing demands of progressive realization. It has been argued that binding legal norms and compliance with treaty regimes can only be established when States have the 'capacity' to adhere to those norms or those regimes.589 In response to such an argument, it can be posited that all nations, whether rich or poor, have the capacity to engage in progressive realization. 'Capacity' in such a context, of course, is extremely relative and may become manifest in a $500 billion social program or simply the provision of potable water to a single South African community. Capacity may also take the form of expenditure-free measures, such as a refusal to censor information, a refusal to stigmatize or discriminate, or the exercise of the new import/export/compulsory licensing flexibilities under the TRIPS Agreement. Since all nations have the capacity to progress—although in differing degrees and by differing methods—all na-
tions must be held to the duty to do so. Whether the result of a voluntary treaty undertaking or the development of an obligatory customary norm, States must be accountable for lack of measurable advancement. While the level of available resources may temper a nation's obligations, it cannot be used as a defense to inactivity, igno-
rance, or apathy.

Finally, it is of critical importance to recognize that the concept of progressive realization is not merely a parochial issue governing the relationship between a nation and its own citizens. Instead, progressive realization must also be viewed as encompassing obligations and relationships between nations. In light of the fact that generic producing States have now been given the right to export generics to poor countries lacking in production facilities (pursuant to the revised compulsory licensing regime),590 an actual duty to

588 Id. at 385.
589 For a brief discussion and citations in this regard see Koh, supra note 13 at 2635, 2638.
590 See supra notes 339-67 and accompanying text (discussing the evaluation of compulsory licensing under the TRIPS Agreement).
engage in such exporting must be established. Since access to medication in the context of pandemics such as HIV/AIDS "is one of the fundamental elements" in achieving the right to the highest attainable standard of health,591 the benefits of the progressive realization mandate would be significantly reduced if it were to be isolated from such an interstate perspective.

Viewing progressive realization of the right to health as a synthesis of interstate relationships—rather than merely as the sum of its domestic parts—can be supported in a number of ways. Many international treaties require Parties to "promote" or "encourage" international cooperation with a view toward achieving the realization of the rights that are contained therein.592 In other treaties, Parties have consented "to take steps" through international cooperation (including both economic and technical assistance) to "the maximum of" their available resources toward the realization of a variety of economic, social and cultural rights.593 While such terms are perhaps softer than might be desired, they cannot be viewed as meaningless—especially when the cooperation demanded is either costless or beneficial to the cooperating nation.

An interstate approach to progressive realization can also be supported by a variety of contractual obligations among nations regarding the promotion of technology transfer, the duty to provide incentives to domestic enterprises to encourage technology transfer to least-developed countries,594 the recognition of the right to share in the benefits of scientific progress and its application, and the duty to take steps toward the diffusion of scientific knowledge.595 It can also be supported by the duty to take progressive measures (both national and international) to secure the universal and effective observance of human rights and fundamental freedoms596 as well as by the duty to promote the realization of the in-

591 Declaration of Commitment, supra note 3, para. 15.
592 See, e.g., CRC, supra note 117, art. 24.4 (requiring such efforts to secure the rights of children).
593 See, e.g., ICESCR, supra note 23, art. 2.1 (calling for parties to take individual steps and to cooperate with each other).
594 See TRIPS Agreement, supra note 26, art. 66.2 (establishing a duty to provide incentives).
595 See, e.g., ICESCR, supra note 23, art. 15.1(b), 15.2 (creating both a right to benefit from scientific progress and to conserve, develop, and diffuse science and culture).
596 See, e.g., Universal Declaration, supra note 118, pmbl., art. 6 (pledging Member States to the promotion of human rights and fundamental freedoms).
alienable right to self-determination.\textsuperscript{597} It can also be based upon pledges to "develop friendly relations among nations," to achieve "international cooperation in solving international problems of . . . humanitarian character,"\textsuperscript{598} to create global conditions of "stability and well-being,"\textsuperscript{599} to promote economic and social progress,\textsuperscript{600} and to "maintain international peace and security".\textsuperscript{601}

Finally, such a synthesis can be based upon the fact that all nations have a fundamental responsibility to protect the security of their citizens from external threat. When that threat takes the form of an advancing pandemic, a strong argument can be made that States have the legal duty to take all measures—including the export of generics to nations in crisis—toward the reduction of that threat. Similar arguments can be made when threats take the collateral forms of political instability, civil unrest, or economic decline.

It should also be noted that while these duties are actually imposed upon States, it is generally accepted that all members of society, including the private business sector, have responsibilities in their regard. As a result, States should foster an environment in which private parties can carry out these responsibilities.\textsuperscript{602} Additionally, the duty to cooperate (whether on the part of the State or the private sector) should be viewed in relative terms. Where cooperation or assistance is extremely difficult or costly, a lack of cooperation becomes more understandable. Where cooperation is relatively costless, however, the duty to cooperate pursuant to international agreements must become more demanding. Setting opportunity costs aside, the building or expansion of generic production facilities, the hiring of additional personnel, and the export of generic drugs to less-developed countries at a price that is equal to (or slightly above) their total cost would tend to fall into the latter of these two categories.

\textsuperscript{597} See, e.g., ICESCR, \textit{supra} note 23, art. 1.3 (setting forth state obligations to promote self-determination and to conform to provisions of the U.N. Charter).

\textsuperscript{598} U.N. \textit{CHARTER} art. 1.2-1.3.

\textsuperscript{599} \textit{Id.} art. 55.

\textsuperscript{600} \textit{Id.} art. 55a.

\textsuperscript{601} \textit{Id.} art. 1.1.

\textsuperscript{602} See, e.g., \textit{Substantive Issues}, \textit{supra} note 3, para. 42 (noting that while only States are parties to the ICESCR, all members of society have responsibilities regarding the right to health under it).
5.5. An Interdependent System of Accountability

5.5.1. Introduction

Rigid distinctions between civil and political rights and economic, social, and cultural rights—as well as traditional views regarding the separation of positive and negative rights—can no longer be justified. Admittedly, it has been politically expedient to divide these rights into two separate Covenants, to argue that some rights impose immediate obligations while others are subject to policy judgment, and to provide an interstate and individual complaint system for one series of rights but not for the other. Such a tidy political approach ignores the fact that many rights, especially those surrounding the right to health, are truly hybrid in nature. As a result, an attempt to classify a right under one exclusive category or the other, and thereby determine which system of accountability shall apply, is doomed either to failure or to an exercise in hypocrisy.

Despite political demands for segregation, a variety of international instruments have taken the position that all human rights are indivisible, interrelated, and interdependent, and that civil and political freedoms cannot be realistically enjoyed without a strong foundation in the economic, social, and cultural rights that provide stability and structure to a society. More particularly, these two sets of rights are bound together by a number of undeniable linkages that bridge the gap between traditional notions of freedoms and more positive State obligations. For example, rights to equality, equal protection, security of person, life, subsistence, self-determination, and the protection of the family are all intricate

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603 See Porter, supra note 569, at 148-55 (discussing substantive obligations and substantive equality analysis).

604 See, e.g., Vienna Declaration, supra note 101, para. 5 (stating that “[a]ll rights are universal, indivisible, and interdependent and interrelated”); Declaration on the Right and Responsibility of Individuals, supra note 1, pmbl. (reiterating the universality of human rights); DRD, supra note 25, art. 6.2 (contending that “all human rights and fundamental freedoms are indivisible and interdependent”); Proclamation of Teheran, supra note 31, para. 13 (proposing that “human rights and fundamental freedoms are indivisible”); see also, ICESCR, supra note 23, pmbl. (stating that the ideal of free human beings can only be achieved if conditions are created where everyone can enjoy economic, social, and political rights, as well as civil and political rights); ICCPR, supra note 125, pmbl. (reiterating the need to secure fundamental rights to sustain certain freedoms); supra notes 123-50 and accompanying text (discussing the common source of all human rights).
components of the right to health. Nevertheless, each of these rights are specifically enumerated and specifically guaranteed in the ICCPR.605

The right to self-determination provides a meaningful illustration of the overlap between civil and political and economic, social and cultural rights. This right, identically recognized and defined in both the ICESCR and the ICCPR, provides that all peoples are not only free to determine their own political status, but they are free to "pursue their economic, social and cultural development" as well.606 These freedoms are in fact accompanied by a number of positive obligations on the part of the State. The ICCPR provides that the Parties "shall promote" the realization of this right,607 that they shall "ensure" this right to all individuals without distinction,608 and that they shall take "the necessary steps" to adopt such laws or other measures (including the provision of effective remedies) that may be needed to give effect to this right.609

In turn, the right to self-determination is inherently linked to the rights of development and social progress. The 'right to development' entitles all individuals "to participate in, contribute to, and enjoy economic, social, cultural and political development"610 and "implies the full realization of the right . . . to self-determination."611 As an inalienable right,612 its existence is not dependent upon the passage of domestic legislation or the implementation of an international treaty. Instead, all nations are innately bound to refrain from frustrating or interfering with its exercise. The DRD, however, also imposes a series of positive obligations that include the duty to formulate national and international developmental policies,613 the duty to create conditions favorable to the realization of the right to development,614 and the duty to cooperate with other

605 See ICCPR, supra note 125, arts. 1.1-1.2, 3, 6, 9, 14, 17, 23, 26 (concerning rights of self-determination, subsistence, equality, life, security, privacy, protection of family, and equal protection).
606 ICESCR, supra note 23, art. 1.1; ICCPR, supra note 125, art. 1.1.
607 ICCPR, supra note 125, art. 1.3.
608 Id. art. 2.1.
609 Id. art. 2.
610 DRD, supra note 25, art. 1.1.
611 Id. art. 1.2.
612 Id. art. 1.1.
613 Id. arts. 2.3, 4.1.
614 Id. art. 3.1.
nations "in ensuring development" and in "eliminating obstacles to development"\textsuperscript{615} that may result from the failure to observe either civil and political rights or economic, social, and cultural rights.\textsuperscript{616} Similarly, the collateral right to enjoy "the fruits of social progress"\textsuperscript{617} arguably broadens the scope of self-determination to include such rights as the right to the highest attainable standard of health\textsuperscript{618} and the right to both an "equitable sharing"\textsuperscript{619} and "increased utilization"\textsuperscript{620} of scientific and technological advances.

While the political gap between the basic rights to development and self-determination and the more particular right to health is substantial, such an admission does not alter the fact that these rights are both logically and legally interdependent. The concept of self-determination is based upon both the freedom to pursue one's own political, economic, social and cultural development and the freedom to choose between different courses of action in such a regard. Where individuals and communities are facing physical or economic extinction, these freedoms to pursue (or these freedoms to choose) are either irrelevant or nonexistent. As a result, the international community is increasingly taking the position that fundamental human rights cannot be recognized on a piecemeal basis. While many positive rights are incapable of being realized immediately, it has become obvious that their continued absence serves to restrict the realization of \textit{all} forms of rights including those that are more politically convenient.

The indivisibility of civil and political rights and economic, social and cultural rights is also based upon a number of common international norms. Both sets of rights, for example, are premised upon the inherent dignity of the human person.\textsuperscript{621} Both are viewed as absolutely necessary for the achievement and maintenance of in-

\textsuperscript{615} \textit{Id.} art. 3.3.

\textsuperscript{616} \textit{Id.} art. 6.3.


\textsuperscript{618} See \textit{id.} art. 10(d).

\textsuperscript{619} \textit{Id.} art. 13(a).

\textsuperscript{620} \textit{Id.} art. 24(c).

\textsuperscript{621} See, e.g., ICCPR, \textit{supra} note 125, pmbl. (declaring that certain human freedoms can only be achieved through the protection of civil, political, economic, social, and cultural rights); ICESCR, \textit{supra} note 23, pmbl. (stating that economic, social and cultural rights, in addition to political and civil rights, must be protected to allow the ideal of free human beings); \textit{Universal Declaration, supra} note 118, pmbl. (recognizing inherent dignity and rights of humans).
Both reflect the fact that all persons are entitled to "a social and international order" in which these rights can be realized and both demand the recognition of equality, equal protection, and the right to life.

As a result, while the ICCPR and the ICESCR are primarily directed at different classes of rights, they possess a number of identical mandates and common goals. Additionally, the existence of a symbiotic relationship of causes and effects make it impossible to view any particular right in isolation. The HIV/AIDS crisis, for example, is at least in part the consequence of inequality and the denial of equal protection. When viewed in the context of poverty, the HIV/AIDS crisis also reflects the absence of the rights to subsistence, development, and self-determination. Simultaneously, however, pandemics such as HIV/AIDS are also a direct cause of increased poverty, heightened discrimination, and an erosion of the rights to life, development, and self-determination.

Viewing health as an interlocking human right "indispensable for the exercise of other human rights" mandates a system of accountability that goes far beyond that envisioned by the ICESCR. Such a system must not only encompass the positive obligations imposed by the right to health, it must capture also its effects on civil and political freedoms, international peace and security, and interstate relationships.

5.5.2. Searching for Accountability

The U.N. General Assembly has taken the position that any person whose human rights or fundamental freedoms have been violated must be provided "a public hearing before an independent, impartial and competent judicial or other authority" and must be awarded, as circumstances require, an effective and enforceable form of legal relief. Similarly, the Committee on Economic, Social and Cultural Rights, while acknowledging that individual complaints are not expressly recognized in the ICESCR, has indicated that such remedies are presumptively implied by the all "ap-

622 Id.
623 Universal Declaration, supra note 118, art. 28.
624 See Report of the Special Rapporteur, supra note 475, para. 45 (indicating that ill health can be both a cause of poverty and a consequence of poverty).
625 Substantive Issues, supra note 3, para. 1.
626 Declaration on the Right and Responsibility of Individuals, supra note 1, art. 9.2.
appropriate means" requirement found in Article 2.1 of the Covenant.627 As a result, any Party seeking to justify a failure to provide domestic remedies would face the substantial burden of demonstrating that such remedies were either inappropriate or unnecessary.628

Certainly this ideal of an individual complaint procedure for violations of economic, social, or cultural rights can be the subject of substantial frustration. The positive connotations of these rights, the unavoidable subjectivity of progressive realization, and the realities of both political decision making and the availability of finite resources tend to temper the willingness of governments to acknowledge their liability. Such an observation should not be equated with a lack of accountability. In particular regard to the right to health, accountability may be imposed by means of a broad patchwork of domestic proceedings, international monitoring and 'adjudication,' individual and interstate complaints, global condemnation, multilateral sanctions, Security Council action, and humanitarian intervention. Whether viewed in terms of imposing monetary liability on States or in terms of 'punishing' nations for breaches of international covenants, an interdependent system of accountability can, in fact, be developed.

As discussed earlier, many nations have adopted constitutional provisions that guarantee their citizens the right to health or health care, as well as to a variety of other health-related entitlements. Additionally, many States have incorporated either the Universal Declaration or the ICESCR into their constitutions or statutory regimes, while others have granted their citizens health-related rights by means of domestic legislation.629 In light of the fundamental tenet that all nationals have the right to an effective remedy by a competent domestic tribunal for violations of rights that have been granted to them by their own constitution or domestic laws,630 it is relatively safe to assume (barring issues of justiciability) that accountability may be imposed by means of domestic proceedings.

627 See Substantive Issues (1998), supra note 459, para. 3 (emphasizing the importance of judicial remedies).
628 Id.
629 See supra notes 495-539 and accompanying text (discussing constitutional guarantees of health-related rights around the world).
630 See Universal Declaration, supra note 118, art. 8 (proclaiming the right to effective remedy by national tribunals for violations of fundamental rights granted by law).
In South Africa, for example, the constitution not only guarantees all citizens the right to health services,\textsuperscript{631} it specifically provides individuals with the right to institute legal proceedings in domestic courts if such a right has been violated.\textsuperscript{632} The judicial remedies that have been granted by courts in such nations as South Africa, Venezuela, and Costa Rica\textsuperscript{633} further testify to an increasing ability of individuals to domestically enforce the right to health.

Although subject to substantial qualification, it can also be argued that individuals have acquired the right to seek domestic remedies pursuant to the terms of international agreements even where those agreements have not been specifically incorporated into a State’s constitutional or legislative framework. Such an argument, of course, is limited by the concept of non-self-execution. Treaties that are not self-executing establish rights and duties between ratifying nations but do not establish binding relationships between a nation and its own citizens. Unless a Party adopts enabling legislation (thereby making the treaty binding internally) individuals are not awarded domestic rights by means of the treaty and have no grounds upon which to enforce its mandates against their own governments.\textsuperscript{634} Additionally, even self-executing treaties are not internally binding in some nations (such as the United Kingdom) unless the legislative body chooses to enact implementing legislation.\textsuperscript{635}

On the other hand, the Committee on Economic, Social and Cultural Rights has taken the position that the ICESCR “does not negate the possibility that the rights it contains may be considered self-executing” and that in most States it is the responsibility of the judiciary (and not the executive or legislature) to make such a determination.\textsuperscript{636} As a result, it is particularly important “to avoid

\textsuperscript{631} S. Afr. Const., art. 27(1)a.
\textsuperscript{632} Id. art. 38.
\textsuperscript{633} See supra notes 522-38 and accompanying text (discussing South African legal responses to HIV/AIDS).
\textsuperscript{634} See AUGUST, supra note 498, at 81-86 (discussing enabling legislation); Southard, supra note 439, at 42-43, 45, 47-49 (citing John H. Jackson, United States, in THE EFFECT OF TREATIES IN DOMESTIC LAW 141, 148-56 (Frances G. Jacobs & Shelley Roberts eds. 1987)); see also Sei Fujii v. State, 242 P.2d 617 (Cal. 1952) (holding that the California Alien Land Law “is invalid as in violation of the Fourteenth Amendment” and that no treaty between the United States and Japan gives plaintiff the right to own land).
\textsuperscript{635} AUGUST, supra note 498, at 335.
\textsuperscript{636} Substantive Issues (1998), supra note 459, para. 11.
any a priori assumption” that the Covenant’s norms are non-self-executing.\textsuperscript{637} Many of these norms, according to the Committee, “are stated in terms which are at least as clear and specific as those in other human rights treaties” that have been regularly deemed to be self-executing by domestic courts.\textsuperscript{638} In support of such a position, the Committee cites the fact that attempts to include a provision stating that the Covenant was non-self-executing “were strongly rejected” during the drafting process.\textsuperscript{639}

It should also be noted that the concept of non-self-execution is only applicable to treaty law and thus does not impose limitations on the individual enforcement of rights that have evolved from customary law.\textsuperscript{640} As will be discussed in more detail in Section 6, the interplay of domestic law, state practice, global declarations, and regional and international agreements is creating a body of customary human rights norms that actually transcends individual treaties. To examine each source of law in isolation—and to diagnose each treaty as to its internal effect—is to ignore the evolution of more unifying principles. In Filartiga v. Pena-Irala,\textsuperscript{641} for example, the court demonstrated that non-self-executing treaties such as the U.N. Charter and the Charter of the Organization of American States, as well as non-binding declarations and General Assembly resolutions, can in fact be used to carve out binding principles of customary international law.\textsuperscript{642} Similarly, an “expectation of adherence,”\textsuperscript{643} while originating in non-binding expressions, can gradually ripen into a legal rule conferring fundamental rights on citizens in relationship to their own governments.\textsuperscript{644}

Whether based upon domestic law or international treaty, economic, social and cultural rights (including the right to health) are inevitably associated with the issue of justiciability. It can be argued that these rights are not really ‘rights’ at all but are instead

\textsuperscript{637} Id.

\textsuperscript{638} Id.

\textsuperscript{639} Id.

\textsuperscript{640} Southard, supra note 439, at 54 (citing Jordan J. Paust, Litigating Human Rights: A Commentary on the Comments, 4 HOUS. J. INT’L L. 81, 139 (1981)).

\textsuperscript{641} Filartiga v. Pena-Irala, 630 F.2d 876 (2d Cir. 1980).

\textsuperscript{642} See id. at 880-85 (showing how international treaties affect the laws of nations, with a particular emphasis on human rights).

\textsuperscript{643} Id. at 883.

\textsuperscript{644} See id. at 884-85 (discussing how a non-binding expression can become a legal rule providing fundamental rights).
only aspirational governmental objectives.\(^{645}\) As a result, the ambiguities surrounding these objectives and the means for their progressive realization are best resolved through the policymaking of elected officials and not through the process of adjudication.\(^{646}\)

There is no doubt that some of the issues regarding economic, social and cultural rights are non-justiciable. Whether it is better to fund progressive realization by means of an increase in income tax rates or the imposition of a sales tax, for example, is certainly a question best left to policymakers. It would be absolutely ludicrous, however, to argue that economic, social and cultural rights are, in their entirety, beyond judicial adjudication. As Professor Schwartz has noted, modern courts have undertaken a variety of "affirmative activities" including the supervision of school desegregation and monitoring of unions.\(^{647}\) Whether viewed in terms of positive rights or in terms of the negative aspects of positive rights, courts have also chosen to address issues such as the right to education, affirmative action, abortion, housing, welfare benefits, and the equal protection ramifications of poverty.\(^{648}\)

It is also important to recognize that when courts examine positive rights, whether they arise from domestic law or international agreement, an exercise of the policy making function is not demanded. Instead, courts may simply adjudicate rights that have been legislatively granted—by constitution, statutory regime, or treaty ratification—in terms of their meaning, their scope and application, and their accompanying remedies. Such an interpretation of rights, despite the resource implications that may follow,\(^{649}\) is a function that courts perform on a daily basis.\(^{650}\)

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\(^{645}\) See Porter, supra note 569 (discussing how rights are actually just government aspirations).

\(^{646}\) See id. at 128, 137-45, 147-48, 155-60 (arguing that these issues are best resolved through the policymaking of elected officials and not through adjudication).

\(^{647}\) Schwartz, supra note 500, at 1237.

\(^{648}\) For a discussion of economic and social rights, positive and negative rights, and rights of a hybrid nature, see id.


\(^{650}\) As Bruce Porter indicated, "Poor people such as the claimants in Masse [v. Ontario (Ministry of Community and Social Services), 134 D.L.R. (4th) 20 (1996)] do not advance rights claims under the [Canadian] Charter on the assumption that courts are experts in social policy and on that account ought to redesign programmes. Rather, they seek from courts adjudication of constitutional rights . . ." Porter, supra note 569, at 157.
As a result, the segregation of civil and political rights and economic, social and cultural rights in terms of justiciability would not only be erroneous, but "arbitrary" and "incompatible" with their indivisibility and interdependence. Implicitly recognizing such a fact, the court in Treatment Action Campaign took the position that the reasonableness of steps taken by the government in fulfilling its constitutional obligation to progressively realize the right to health was indeed a justiciable issue. In response to the argument that a grant of relief would involve both policymaking and a breach of the separation of powers, the court indicated that when the judiciary "sits in judgment on the reasonableness of steps taken by the executive arm in the fulfillment of its constitutional obligations, it is exactly a perfect example of how the separation of powers should work." To rule otherwise would be to negate the supremacy of the Constitution. Similarly, a refusal by the courts to enforce legislatively recognized rights or to provide remedies for their breach would be to allow an executive to dilute the power of a legislating body.

In addition to the provision of domestic remedies, a substantial degree of accountability could also be developed at the regional and international levels. A variety of multilateral agreements, while employing differing sets of jurisdictional prerequisites, have already established both human rights monitoring mechanisms and individual and interstate complaints systems. In regard to regional agreements, for example, the African Charter has established the African Commission on Human and Peoples' Rights to promote and ensure the protection of human rights throughout the continent. The Commission is designed to formulate rules aimed at solving legal issues relating to human rights, to make recommendations to member governments, and to interpret the provi-

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653 Id. (emphasis added).
654 See id at 380 (referencing Mohammed and Another v. President of the Republic of S. Afr. and Others, 2001 (3) SA 893 (CC)).
655 Special Rapporteur Paul Hunt has indicated that a variety of laws and decisions at the national, regional, and international levels confirm the justiciability of the right to health. Report of the Special Rapporteur, supra note 475, para. 20.
656 African Charter, supra note 474, arts. 30, 31, 41.
sions of the Charter. The Commission is also empowered to hear interstate complaints regarding violations of the Charter (and to issue reports and recommendations in their regard) and to consider "other communications," (including those from individuals) that reveal "a series of serious or massive violations" of human rights. Additionally, a protocol to the Charter, although not yet in force, would establish a permanent African Court on Human and People's Rights.

Other regional bodies, such as the European Commission on Human Rights, the European Court of Human Rights, the European Committee of Social Rights, and the Inter-American Commission on Human Rights can also assume a larger role in ensuring the observance of fundamental rights and freedoms. While employing varying prerequisites and distinctions—such as the need for recognizing the competence of a particular body, the separation of civil and political rights from economic, social and cultural rights, the distinguishing of individual and systemic violations, and the need for exhaustion of domestic remedies—several of these institutions have already addressed violations of the right to health and other health-related issues. Additionally, the competencies of these bodies are generally supplemented by a regional monitoring process, such as that found in the African Charter and the Protocol of San Salvador, that require States to submit periodic reports regarding the progressive measures they have taken to realize the rights set forth in the relevant treaty.

At the international level, each of the major human rights treaties—including the ICCPR, the ICESCR, the CRC, and the CEDAW—establish a similar monitoring process under the au-

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657 Id. art. 45.
658 Id. arts. 47-54.
659 Id. art. 55.
660 Id. art. 58.1.
662 See Report of the Special Rapporteur, supra note 475, paras. 17-19 (illustrating examples of international bodies answering fundamental rights and freedoms).
663 African Charter, supra note 474, art. 62.
664 Protocol of San Salvador, supra note 471, art. 19.
665 ICCPR, supra note 125, arts. 28-45; ICESCR, supra note 23, arts. 16-25; CRC, supra note 117, arts. 43-45; CEDAW, supra note 119, arts. 17-22.
pices of various U.N. Human Rights Committees. States will submit periodic reports describing the measures adopted and progress made toward the achievement of treaty rights. Periodic reviews of State action will be conducted by the Committee charged with supervising State compliance and Concluding Observations (including statements of treaty violation or non-compliance) will be issued by that Committee. In particular regard to the right to health—which encompasses rights of women and children, rights to equality and non-discrimination, and rights to self-determination and development—several treaty-based Committees are capable of legitimately monitoring State progress.

The Committee on Economic, Social and Cultural Rights is of particular interest in light of the fact that it is responsible for ensuring compliance with the ICESCR but lacks the power to hear individual complaints. In addressing this issue and the evolutionary role of the Committee, however, Bruce Porter has indicated that while “lacking a jurisprudence arising from an individual complaints procedure . . . the Committee has adopted an adjudicative framework” for examining claims regarding social and economic rights. Such an observation is based upon the fact that the Committee has now decided to allow oral submissions by nongovernmental organizations (“NGOs”) as part of the consideration of periodic reports and to grant NGOs the right to appear in the context of the periodic review of a State’s compliance. Such an “adjudicative model,” Porter argues, “facilitates what amounts to a hearing—considering allegations of non-compliance advanced by domestic groups and then considering ‘responses’ from governments.” This new process represents “a critical means for bringing to light violations of social and economic rights.” With a focus on the availability of economic resources, the conditions of vulnerable constituencies, and the need for measurable progress under the concept of progressive realization, the monitoring process of the Committee on Economic, Social and Cultural Rights has been transformed into a legitimate and “influential human

666 Porter, supra note 569, at 126.
667 Id. at 124-25.
668 Id. at 125.
669 Id. (citation omitted).
670 Id. at 129-30.
In regard to an international complaints system, Resolution 1235672 authorizes the Human Rights Commission "to examine information relevant to gross violations of human rights and fundamental freedoms," to make a thorough study of situations that reveal a "consistent pattern" of violation, and to report their findings (with accompanying recommendations) to the Economic and Social Council.673 Additionally, Resolution 1503674 authorizes the Commission (through its Sub-Commission on Prevention of Discrimination and Protection of Minorities, its Working Groups, and its ad hoc committees) to consider "all communications," as well as governmental replies, received by the Secretary General with the similar purpose of determining whether there is a "consistent pattern of gross and reliably attested violations of human rights."675 In carrying out 1503 complaint investigations, ad hoc committees have the right to hear witnesses and review all communications676 and the Commission is authorized to report and make recommendations in such a regard. Unfortunately, the need for State consent, along with the requirement of confidentiality and the general political nature of the Commission, tend to detract from the legitimacy of the 1503 complaint procedure.677

Throughout this Article it has been consistently argued that economic, social and cultural rights and civil and political rights are indivisible, interdependent and interrelated. It has also been argued that the right to the highest attainable standard of health, while generally viewed as a positive right, has a substantial influence on the realization of such civil and political rights as life, equality, and self-determination. Consistent with this position, it can also be argued that the provisions of the ICCPR—including its complaint procedures—are capable of being applied to the right to

671 Id. at 127.
673 Id. paras. 2, 3.
675 Id. paras. 1, 5.
676 Id. para. 7(b).
677 See id. paras. 5, 7(c), and 8 (discussing confidentiality); id. paras. 6(b) and 7 (discussing consent); The U.N. Human Rights Regime, supra note 21, at 462 (containing remarks by Markus G. Schmidt).
health in a variety of contexts. As a result, the opportunity to enforce the right to health under the interstate and individual complaint mechanisms found in the ICCPR and its Optional Protocol should not be ignored.

By becoming a Party to the Optional Protocol to the ICCPR, a State recognizes the competence of the Human Rights Committee to "receive and consider" complaints from individuals who claim to be victims of a violation (on the part of the State) of the rights set forth in the ICCPR. While certainly not universally accepted, it is promising that more than one hundred nations have become parties to this Protocol and have thereby agreed to submit themselves (subject to comity and exhaustion requirements) to an individual complaints procedure before an international treaty-monitoring body.

In regard to interstate complaints, Article 41 of the ICCPR provides that a Party may declare that it recognizes the competence of the Human Rights Committee to receive and consider complaints in which one State Party claims that another State Party is not fulfilling its obligations under the Covenant. To date, forty-eight States have made such a declaration, including such nations as South Africa, Russia, and the United States. It should also be noted that Article 41 only deals with the process of bringing interstate complaints before the Human Rights Committee. It specifically applies "without prejudice" to other procedures "prescribed in the field of human rights" in other instruments of the United Nations and its specialized agencies. As a result, this article does not prevent States from having recourse to alternative systems for the settlement of interstate disputes regarding the violation of civil and political rights.

The availability of these ICCPR proceedings could serve to increase governmental accountability in regard to the right to the highest attainable standard of health. It is certainly conceivable, for example, that a denial of reproductive rights could infringe

679 Id. pmbl., art. 1.
680 Id. art. 5.2.
681 ICCPR, supra note 125, art. 41.1.
682 Id. art. 44.
683 Id.
upon the rights of equality or equal protection, that a denial of antiretroviral treatment could infringe upon the right to life, and that the denial of an HIV/AIDS prevention program could infringe upon the right to self-determination or development.

Irrespective of these remedies, every State has an absolute right to expect that all other States will adhere to their treaty commitments. Such an expectation is based upon the fact that even non-self-executing treaties—which create no binding relationships between a nation and its own citizens—are nevertheless binding between the nations that are parties to those agreements. As a result, and despite its status within any particular country, a treaty unquestionably creates a "legal obligation . . . on the international plane." Additionally, because a State is sovereign for the purpose of limiting its own sovereignty, States can legally bind themselves to other nations on issues of internal policy and thereby internationalize those domestic issues. Even when internal enforcement mechanisms are lacking, it is generally accepted that once a State has undertaken a treaty obligation—for example, agreeing to provide its citizens with certain human rights—it can no longer assert to its treaty partners that those obligations are within its exclusive jurisdiction. If such an international principle is to have meaning, Parties to an agreement must have the right to seek enforcement of treaty provisions and to take action in the event of their breach. Any argument to the contrary would negate the legitimacy of treaty regimes.

The concept of enforcement, of course, is subject to interpretation. It could be argued, for example, that in the absence of the power to enforce, no legal duty can exist. On the other hand, it could also be argued that the concepts of 'duty' and 'enforcement' are in fact distinct and that duties—both in moral and legal


686 See August, supra note 498, at 253 (stating that "a state may agree by treaty to limit its sovereignty and thus internationalize a subject").

687 Id. (discussing the holding in the Advisory Opinion on Nationality Decrees Issued in Tunis and Morocco, 1923 P.C.I.J. (ser. B) No. 4).
terms—can be assumed by nations even when enforcement is impractical or abstract. In either event, this Article takes the position that treaty duties—including the duty to provide the highest attainable standard of health—are enforceable by means of a number of individual and interstate complaint systems at the domestic, regional, and international levels.

Additionally, enforcement can also be viewed in terms of the ability to 'punish' even when actual treaty performance cannot be mandated. The existence of lawful international mechanisms that can be used to punish nations that violate treaty obligations supports the position that human rights treaties establish recognizable duties that can in fact be 'enforced' by other Parties. Lawful punishment may take the form of formal international condemnation which, contrary to common understanding, is a response that most countries are eager to avoid. Punishment may also take such forms as withholding privileges under the treaty that has been breached, the reduction or elimination of unilateral or multilateral aid, the denial of loans by national or international lending institutions, the imposition of travel bans, or the freezing of individual or State assets. In particular regard to the HIV/AIDS crisis, a State's denial of the right to the highest attainable standard of health—or a refusal by an infected State to take all possible steps to combat the epidemic—could be punished by means of embargoes or other economic sanctions imposed by nations potentially endangered by such neglect. If those nations viewed such a refusal (and the resulting spread of the HIV/AIDS pandemic) as a threat to their security, such a response (while admittedly draconian) would be legally justified.

Additionally, it can be argued that the U.N. Security Council is empowered under Chapter VII to take similar measures whenever necessary to maintain or restore international peace and security. Since the U.N. Security Council has already recognized the HIV/AIDS epidemic as a potential threat to international security, it would seem logical that the Council would have the authority to intervene in such a regard. From a broader perspective,

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688 RULE OF POWER OR RULE OF LAW?, supra note 684, at 138 (discussing participation in intergovernmental organizations to avoid such condemnation).
689 Id.
it can be argued that massive violations of human rights also constitute a threat to the peace that can justify U.N. Security Council intervention. As Lodico has noted, States have become bound, whether through treaty or customary law, to protect the basic human rights of their citizens and such protections can be enforced when their violation jeopardizes international security. While the existence of an HIV/AIDS epidemic does not in itself constitute a violation of human rights, the lack of a progressive realization of the right to health (or the refusal to take all possible measures for the prevention, treatment, and containment of the HIV/AIDS crisis) would in fact constitute such a violation. Under such a circumstance, the concept of sovereignty or territorial integrity would not prevent the use of multilateral sanctions or humanitarian intervention if the global community was being threatened.

The availability of both lawful punishment and valid intervention underscore the fact that the welfare of a population is no longer the sole domain of national governments. By viewing 'enforcement' in these terms, it seems clear that States owe a variety of duties to their citizens that can be externally 'enforced'. States can be held accountable for ignoring human rights norms as third parties (both unilaterally and in concert) have the right to demand treaty compliance.

The arguments advanced above can in fact be supported by a relatively traditional treaty law approach to international relations. It will now be argued, however, that in the limited context of human rights a 'constitutional law' approach must be adopted that transcends any particular agreement and is unencumbered by treaty-based notions of self-execution, implementing legislation, and the consent of individual States. Unlike agreements that

691 See supra notes 411-413 and accompanying text (addressing the universal rights of all humans and the Congressional adoption of international sanctions against Fidel Castro's regime).
692 Lodico, supra note 21, at 1028, 1031.
693 See id. at 1027-50 (discussing how military force is justified if gross violations of human rights threaten international peace and security and providing examples of when international force has been used).
694 In the context of the European Union, Eric Stein has authoritatively argued that:

[T]he Court of Justice of the European Communities has fashioned a constitutional framework for a federal-type structure in Europe . . . has construed the European Community Treaties in a constitutional mode rather than employing the traditional international law methodology . . . [and]
merely establish relationships among nations, human rights treaties are directed toward individuals and are designed to acknowledge the inherent dignity and fundamental rights of each citizen. They are oblivious to nationality, governmental structure, and territorial boundaries and they view human rights solely in terms of international universality. Additionally, these agreements are supplemented by a substantial body of customary law—primarily reflecting the tenets of the Universal Declaration and the expectations of the United Nations—as well as by a variety of principles that have arguably reached the status of jus cogens.

The enforcement of human rights on the basis of constitutional law requires a reassessment of the fundamental nature of constitutions, the premises upon which they are based, and the process by which they may come into being. Additionally, a State's consent to the imposition of duties must no longer be assessed in terms of treaty ratification, but in terms of a legal prerequisite for membership in the community of legitimate nations. Such attitudinal changes toward the concepts of enforcement and duty must initially be based upon the recognition that a constitutive system need not be finite in order to exist and that binding constitutional principles can develop—even in the absence of traditional machinery—by means of a dynamic and fluid process of progression.

6. THE HIV/AIDS CRISIS IN A CONSTITUTIONAL PERSPECTIVE

6.1. Introduction

The HIV/AIDS crisis represents a substantial failure of both domestic and international polities. Such a failure may be viewed in terms of a lack of respect for human rights and treaty obligations or a lack of respect for the value of human life. It may reflect the existence of poverty, the acute differentials in standards of living,

has established and obtained acceptance of the broad principle of direct integration of Community law into the national legal orders.

Eric Stein, Lawyers, Judges, and the Making of a Transnational Constitution, 75 AM. J. INT'L. L. 1, 1 (1981). In arguing an evolution from a traditional treaty approach to a direct effects constitutional approach, Stein addresses such issues as the direct effects principle, supremacy, and the individual as the subject of Community treaties. Id. at 3-27.

695 For a discussion of individual rights and the 'direct effect' principle within the context of the EU, see id. at 3-10. In regard to individuals as the subjects of treaties, see Southard, supra note 439, at 43.
the condoning of traditional practices, or the apathy of those nations less affected. Whatever the cause, the failure of current regimes has not only become evidenced by the deaths of millions, it portends future failure in regard to other health crises as well.

These failures also present an unprecedented opportunity for the global community to redefine its fundamental common values and to internalize a new international identity. Such a transformative process may take the form of a 'higher lawmaking' on the part of the 'people,' a mandate from the increasing pool of public and private international actors, or an acknowledgment by States (in their capacity as individual citizens of a global regime) that rights and interests are indeed hierarchical in nature. While not designed to create a world government or to establish a global constitution governing all aspects of international relations, such a process is replete with constitutive properties that can withstand constitutional analysis, that can impose constitutional duties, and that can identify a progressive global constitutionalism in the specific domain of human rights.

It has been argued throughout this Article that the HIV/AIDS crisis is fundamentally an issue of human rights whether examined in terms of the right to health, the right to equality and non-discrimination, the right to self-determination and development, or the right to realize civil and political freedom. By placing these rights within a constitutional dimension, a variety of universal principles may be imposed. Not only would individuals be the central object of these rights, their constitutive nature would provide all citizens with the right to judicially enforce individual claims. All interstate actors—including States, national and international institutions, and the private sector—would be bound to respect these rights and to refrain from interfering with their realization, irrespective of whether they have consented to their recognition. In specific regard to positive rights such as the right to

696 In regard to re-defining fundamental values and developing a new identity in the national setting, see ACKERMAN, FOUNDATIONS and ACKERMAN, TRANSFORMATIONS, supra note 17. In regard to the process of "internalization", see Koh, supra note 13.

697 See ACKERMAN, FOUNDATIONS and ACKERMAN, TRANSFORMATIONS, supra note 17 (focusing on constitutional politics, thought, formation, and foundations in the United States).

698 See supra notes 32-151 and accompanying text (providing an in-depth analysis of the nature and human rights ramifications of the HIV/AIDS crisis).
health, it is admitted that global actors may ultimately meet these ‘constitutional’ responsibilities by engaging in bona fide attempts at progressive realization. Nevertheless, a constitutional perspective would inherently create a hierarchy of values in which these human rights would prevail over those that are more property or contract related.

In order to establish the existence of a progressive constitutive process, historical conceptions of textualism, domesticity, totality, and formal rulemaking must be questioned. From a traditional perspective, a constitution is endowed with a variety of characteristics that serve to differentiate its supremacy from lower-order norms, laws, or treaties. Fundamentally, a constitution represents a practical compromise by which a ‘community,’ in order to protect and ensure the freedoms of every member of society, agrees to impose a limited number of restraints on those freedoms. This agreement to maximize rights for all—subject to restrictions on the ability to interfere with the rights of others—must be enforced, in Kant’s words, by the “coercive laws” of a “supreme power.” Under such a rule of law, self-interest defers to the greater social interest whenever the two are in conflict.

More particularly, a constitution establishes the relationships between the government and the people being governed. In doing so, it provides for substantial limitations on the exercise or abuse of governmental power by means of reserving certain inalienable rights for all citizens and by creating a system of checks and balances among governmental institutions. These checks and balances are realized by means of a separation of powers under which the authority to create, implement, and interpret the law are divided among distinct institutions. This division among legislative,

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699 See KANT, supra note 12, at 41-53, 73, 74, 76, 127, 134 (providing the history of democratic participation and mechanisms for protection against government abuses, such as a system of checks and balances).

700 Id. at 73.

701 Id. at 127.

702 See Stone, supra note 16, at 465, 473 (explaining how a constitution helps promote societal interests, not self-interest).

703 See Fassbender, supra note 13, at 532-38, 569 (stating that constitutions create a “complex of fundamental norms governing organization and performance of governmental functions . . . and describing the relationship between state authorities and citizens”); Petersmann, supra note 18, at 758-61 (surveying the five major political interventions of Constitutionalism); and Reisman, supra note 13, at 95 (discussing the use of constitutions to help prevent government abuse).
executive, and judicial units creates a fundamental legal structure that is viewed as requisite for a constitutional form of government.\(^{704}\) The supremacy of the rule of law, the existence of autonomy among institutions, the recognition of an internal hierarchy, the provision for lawful change, and the universality of application further characterize the traditional constitutional regime.

In light of these qualities, the concept of constitutionalism has been primarily associated with the legal frameworks of individual nation-states.\(^{705}\) Additionally, it has been argued that the lack of such constitutional elements as supremacy, institutional autonomy, lawmaking capacity, identifiable community, and a system of checks and balances render theories of constitutionalism inapplicable in the international setting.\(^{706}\) On the other hand, it has also been argued that "what counts as a constitution" should not be based exclusively on posited rules\(^{707}\) and that "constitution building" should not be viewed in a purely "legalistic fashion."\(^{708}\) In terms of the metaphysical, binding constitutional principles can in fact develop outside the boundaries of traditional thinking and without the sanction of traditional political theory. Constitutional communities can indeed exist wherein all members of society are bound (with or without their consent) to certain subject matter tenets that can be created, administered, and interpreted through more innovative means.

While the elements of a constitution are fairly well established, it does not follow that the creation—and thus the existence—of a constitution must be predicated upon a momentous, one-time event. Instead, the creation of constitutional rights and duties may result from an evolutionary process along a progressive contin-

\(^{704}\) See Stone, supra note 16, at 449-54, 473 (recognizing that constitutions specify the responsibilities of a country's formal institutions); Fassbender, supra note 13, at 532-38, 548, 553, 556-57, 569, 574 (describing the separation of powers as a central tenet of the American and European constitutional state); Petersmann, supra note 18, at 758-61, 766 (noting that constitutions establish a basic legal framework).

\(^{705}\) See Fassbender, supra note 13, at 555-61 (exploring the dichotomy between domestic and international laws).

\(^{706}\) For a discussion and various citations in this regard, see id. at 616; Koh, supra note 13, at 2616; Macdonald, supra note 18, at 228-31; Reisman, supra note 13, at 95; and Stone, supra note 16, at 449-54.

\(^{707}\) Macdonald, supra note 18, at 230.

\(^{708}\) Reisman, supra note 13, at 99.
uum, whereby rights and duties can become constitutionally binding even in the absence of a full-blown, formally recognizable constitution. By viewing constitutional construction in such a way, formal State action becomes less central to constitutional development. Informal State action, as well as the practical demands of interstate actors and the increasing expectations or mandates of the 'people', can force a re-definition of global political identity over time. While evidence of a broader movement toward constitutionalism can be found in the activities of such bodies as the United Nations, the WTO, and the International Criminal Court—as well as in such concepts as universal jurisdiction—constitutional guarantees can develop in distinct subject matter areas as well. Such subject matter constitutions are not merely 'constituent treaties' designed to create the legal structures of international organizations. Instead, they are capable of creating universally binding relationships and enforceable rights on the part of individuals and they are also capable of being developed (at least in substantial part) outside any formal treaty regime.

Additionally, by viewing the constitutive process progressively, the establishment of binding rights and duties can be incremental in nature and need not await the ultimate completion of such a process. While the breadth of these rights may expand over time—and may be accompanied by more recognizable forms of international constitutional machinery—there is no doubt that constitutional rights can be established along the way. The nature and scope of these rights will reflect particular points along the continuum both in terms of societal change and the presence, absence, and strength of particular constitutional elements. For example, the erosion of both State sovereignty and the principle of non-intervention, the gradual expansion of liberalism, and the increasing desire to be accepted by the international community (whether the result of peer pressure or the simple pursuit of international trade) cannot be dismissed as irrelevant to the evolution of individual rights. Increasing interaction and decision making by public and private actors, as well as the substantial growth of positive law aimed at the conditions of individuals, tend to reduce the importance of achieving unanimous State consent. Whether based on

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709 In regard to a continuum of regime forms, see Stone, supra note 16.
710 For a discussion of the term 'constituent treaties', see Fassbender, supra note 13, at 532, 538-41.
natural law or self-preservation, a hierarchy of common values seems to be emerging (as evidenced by the Decision on Implementation of the Declaration on TRIPS)\(^{711}\) that places social interest above self-interest and that is capable of being enforced by means of humanitarian intervention and economic punishment. Anarchy, at least in part, appears to be giving way not only to Koh's internalization,\(^{712}\) but to an international 'community building' that is capable of supporting constitutional principles in the area of human rights.

6.2. Philosophical Foundations

Constitutionalism is not an all-or-nothing proposition. Constitutionally binding relationships, including the duty to engage in the progressive realization of the right to the highest attainable standard of health, can be established between nations even in the absence of a comprehensive document governing all subjects of international law. Constitutional elements need not exist in their entirety before they are capable of imposing a degree of obligation reflective of their stage of development.

Such a progression toward a global constitutionalism, while admittedly being argued from different perspectives, gains context from a variety of schools of thought. Immanuel Kant, for example, believed in the steadily advancing development of man's original and natural capacities and that each generation passes its enlightenment on to the next.\(^{713}\) He also believed that antagonism among men, at least in the long run, inevitably leads to social order. Antagonism, distress, violence and other forms of social evil compel individuals to create civil States for their own protection and to discipline themselves by means of creating a domestic constitution.\(^{714}\) Kant also recognized that the establishment of a domestic constitution was in fact subordinate to the creation of a law-governed external relationship with other nations. A civil constitution among individuals would be of little value in the absence of a

\(^{711}\) Decision, Implementation of Paragraph 6 of the Declaration on TRIPS, supra note 260.

\(^{712}\) See Koh, supra note 13 (discussing why nations obey international law and finding that looking at the transnational legal process can help in understanding obedience to international law).

\(^{713}\) KANT, supra note 12, at 41-43.

\(^{714}\) Id. at 44-47.
federation among States.\footnote{Id. at 47-49.}

As a result, just as violence and distress inevitably leads individuals to create a civil State, antagonism among nations will inevitably lead to the creation of an international federation of States.\footnote{Id. at 47-49, 90.} Such a federation, however, would not be in the form of a cosmopolitan commonwealth or an international State since such a republic could not be governed geographically and could arguably result in despotism.\footnote{Id. at 90-92, 102.} Since the ideal of an international State cannot be realized (at least according to the conception of international right and the will of nations existing at that time), a "gradually expanding federation" would be the best "negative substitute."\footnote{Id. at 105.}

Kant envisioned this federation as limited in nature, primarily designed to protect States from one another and to secure the freedom of each. It would not represent a supreme sovereignty and it would not interfere with the internal affairs of individual States.\footnote{Id. at 104, 127, 165.} Nevertheless, Kant also recognized that fundamental human rights are the basis for constitutionalism,\footnote{See, e.g., id. at 74, 84, 125 (stating that a lawful state is based on a priori rights of the people, and that the rights of man must be held sacred).} that all nations are interdependent,\footnote{Id. at 51.} and that there will be a natural unification of States (based on mutual self-interest) that will inevitably result from international commerce and economic relations.\footnote{Id. at 114.} While Kant's vision of corollary international rights was somewhat restricted, he recognized that nations will enter into mutual relations that may "eventually" be regulated by public laws, "thus bringing the human race nearer and nearer to a cosmopolitan constitution."\footnote{Id. at 106.} As Petersmann has characterized the Kantian argument, "national and international constitutional rules and problems are interdependent and require a mutually consistent constitutional theory based on human rights."\footnote{Petersmann, supra note 18, at 767.}

In his seminal article on international regimes, Alec Stone viewed constitutions as bodies of metanorms, higher order norms
that govern how lower order norms are produced, applied and interpreted.\footnote{Stone, supra note 16, at 444.} These metanorms actually "constitute a polity," "enhance the legitimacy of legal norms," and "fix the rules of the game."\footnote{Id. (emphasis deleted).} Since regimes are merely highly demanding forms of community, and constitutional regimes are merely highly demanding forms of regimes, Stone argues that there is nothing inherent in the nature of international regimes that excludes the possibility of constitutionalism.\footnote{Id. at 448.} Instead, both national and international regime forms can be viewed along a continuum—from the most primitive to the supranational constitutional—that encompasses a "sequence" of norm-based cooperation, institutionalization, the generation of legal norms, the codification of metanorms, and the inseparability of regimes from organic metanorms.\footnote{Id. at 470, 441.} Such a "regime continuum" captures the relative status or formality of regime norms (from tacit norms to metanorms) and the relative degree of institutionalization of the social interest (from simple norm-based behavior to formal organizations with autonomous capacity).\footnote{Id. at 470-75.} The existence of Stone's continuum, of course, implies that international regimes may progress toward the creation of constitutionally binding relationships among nations. However, issues remain regarding whether these binding relationships can be created 'along the way' and the degree to which obligations may be imposed prior to actual constitutionalization.

Viewing constitutional duties in terms of a progression may also find support within the context of the New Haven School. W. Michael Reisman, for example, takes the position that a constitution "is a continuing process, not a single event,"\footnote{Reisman, supra note 13, at 96.} and that a constitution results from "a unique and continuing constitutive process."\footnote{Id. at 99.} A constitutive process, in New Haven language, refers to authoritative power exercised to allocate fundamental functions and to provide an institutional framework for decision making.\footnote{Fassbender, supra note 13, at 544 (quoting Myres S. McDougal et al., The World Constitutive Process of Authoritative Decision, in MYRES S. MCDougAL & W. MICHAEL REISMAN, INTERNATIONAL LAW ESSAYS: A SUPPLEMENT TO INTERNATIONAL}

\url{https://scholarship.law.upenn.edu/jil/vol25/iss3/1}
The "constitutive decisions" that result from such a process are directed at such issues as identifying decision makers, specifying community policies, allocating bases of power, and securing performance of decision functions. Additionally, by emphasizing legal decision making "as part of a higher and complex societal process," formal rules are in no way equated with 'actual' international law. As Koh has noted, the New Haven School has "consistently argued that international law is not a body of rules, but a process of authoritative decision making." By downplaying the need for formality and by placing constitutionalism within a more social/process/realism context, such an approach arguably allows for constitutional duties to be more particularized.

The idea that binding obligations can be created by less traditional processes, or at least by means that are outside formal law-making mechanisms, also supports the argument that constitutional duties can be imposed progressively. At the national level, for example, Bruce Ackerman has argued that the United States is a dualist democracy based upon a two-track system of democratic lawmaking. These two decisional tracks consist of normal lawmaking regarding the ordinary decisions made by governments and higher lawmaking by the 'people' reflecting crucial transformative periods or acts of constitutive authority. These higher lawmaking constitutional moments, which include the Founding, the Reconstruction, and the New Deal, "failed to follow well-established rules and principles . . . and did not respect established norms for revision . . . ."

Antonio Perez has extended these ideas of dualism and higher lawmaking to the international setting. Perez argues that the collective intervention on the part of the U.N. Security Council since

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733 Id. (quoting HAROLD D. LASWELL & MYRES S. MCDOUGAL, I JURISPRUDENCE FOR A FREE SOCIETY: STUDIES IN LAW, SCIENCE AND POLICY 93 (1992)).
734 Id. at 551.
735 Koh, supra note 13, at 2620. For a discussion of the New Haven School and its leading proponents (and a series of citations in such regard), see id. at 2618, 2620, 2622-24, and Fassbender, supra note 13, at 544-46, 551.
736 ACKERMAN, FOUNDATIONS, supra note 17, at 6, 12, 32; ACKERMAN, TRANSFORMATIONS, supra note 17, at 5.
737 ACKERMAN, TRANSFORMATIONS, supra note 17, at 7, 11, 409.
738 Id. at 11-12.
739 Perez, supra note 18.
the end of the cold war clearly represents an informal amendment to the U.N. Charter by means of supranational constitutional politics on the part of a supranational political community.\footnote{See \textit{id}. at 355, 357, 384, 397-98, 449 (drawing on parallels between Acker- man's theories and those of the United Nations).} Such a constitutional moment, whereby the U.N. Charter was amended without employing the formal procedures set forth therein, represented a constitutional change by the 'people' and a constitutionalization of higher values rather than simply an interpretation of existing law.\footnote{\textit{Id}. at 384.}

By recognizing the existence of dualism within the international community, theories like those of Perez can serve as another basis for arguing that human rights (and the duty to progressively realize the right to the highest attainable standard of health) can actually be created outside, or in the absence of, formal legal structures. It has often been argued, for example, that natural rights \textit{precede} the State and are not established \textit{by} the State.\footnote{See \textit{Kant}, \textit{supra} note 12, at 74 (stating that freedom, equality, and independence are \textit{a priori} principles); Petersmann, \textit{supra} note 18, at 760 (summarizing \textit{John Locke, Two Treatises of Civil Government} (Dent 1962) (1690)).} As a result, Eisner has posited that the extension of natural rights principles to the international system may provide individuals with international law protection even in the absence of traditional conventions or treaties.\footnote{Eisner, \textit{supra} note 21, at 211 (explaining the strength and importance of tacit norms between countries).} Whether based on State practice, customary law, or extremely powerful (even if tacit) norms,\footnote{See Stone, \textit{supra} note 16, at 462-63 (describing how tacit norms can cause nations to conform to a standard of conduct).} both 'peoples' and individuals can demand that a hierarchy of values be enforced irrespective of national or international governmental consent. Common values, as expressed in the form of inalienable rights, are simply not dependent upon a system of structural confirmation. As a result, a binding higher law may \textit{precede} (rather than be the product of) formal global institutionalization.

The progressive imposition of constitutional obligations can also be supported by the fact that a constitution need not be reduced to a single, textual document. As a result, this Article does not take the position that the U.N. Charter is \textit{the} constitution of the international community. Instead, it is argued that a global consti-
tution can be based upon an integration of a substantial number of international instruments and a variety of sources of unwritten law. Such an integration implies the existence of an ongoing constructive process where legal duties can be created in different settings (at different points in time) and where the need to meet an all-or-nothing threshold can be discarded.

Tomuschat, for example, clearly recognizes that the judicial, administrative, and lawmaking functions are necessary elements of any constitution.745 Nevertheless, he also believes that "the international community can . . . be conceived of as a legal entity, governed by a constitution . . . ."746 In reaching such a conclusion, Tomuschat argues that States exist within a legal framework of a limited number of common values or basic rules which bind all States irrespective of their consent.747 The global constitution is defined as the entirety of these basic principles,748 and a variety of "world order treaties" (such as the U.N. Charter, the ICCPR, and theICESCR) serve to "concretize" these basic constituent elements or constitutional premises.749 Since these fundamental axioms exist independently from treaty law, world order treaties are of constitutional rank to the extent that they mirror those preexisting constitutional norms.750

In contrast, Fassbender believes that the U.N. Charter is in fact the constitution of the international community with regard to all subjects of international law and that the Charter supervenes related principles of customary law.751 He nevertheless recognizes that other international treaties can have constitutional rank, that constitutional prescriptions may exist in the form of customary law, and that the ICCPR and ICESCR "are part of the constitutional foundation of the international community."752 These sources of law can be granted "constitutional quality" if they characterize or

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745 Tomuschat, supra note 15, at 216 (emphasizing that "every modern system of governance is operated through law making, administration and adjudication").
746 Id. at 236.
747 Id. at 211.
748 Fassbender, supra note 13, at 549 (characterizing Tomuschat's approach).
749 Tomuschat, supra note 15, at 269.
750 See Fassbender, supra note 13, at 550 (characterizing Tomuschat's approach).
751 Id. at 529, 531-32, 586.
752 Id. at 588.
further develop the law of the Charter.\textsuperscript{753}

Finally, the progressive nature of constitutionalism can also find support in Koh’s theories of internalization.\textsuperscript{754} While Koh examined the more general issue of why nations obey international law, his observations can arguably be applied to the process by which constitutional obligations are created over time. Koh described a “transnational legal process” of interaction, interpretation, and internalization through which an international norm penetrates a nation’s domestic legal system, becomes part of that nation’s “internal value set,” and reshapes the national interest and identity of that nation.\textsuperscript{755} Repeated interactions between transnational actors force interpretation or enunciation of global norms and, when internalized through legislative, judicial, or executive acceptance, generate legal rules that will guide future interactions.\textsuperscript{756}

In such a context, it could be argued that as an international norm (such as the duty to engage in the progressive realization of the right to the highest attainable standard of health) becomes more universally internalized, the distinctions between domestic law, international law, and global constitutional law become increasingly indistinct. The gradual process of creating enforceable global norms, whether those norms are ultimately enforced by international or domestic machinery, can be viewed as a progression that is constitutive in nature.

6.3. Liberalism and a Focus on Individuals

Whether viewed in terms of constitutional moments, authoritative decision making, universally binding common values, or steps in an internalization or integrative constitutive process, the Council’s Decision on the Implementation of Paragraph 6 of the Declaration on TRIPS\textsuperscript{757} represents a substantial attitudinal change in the global polity. While certainly encumbered by a number of practi-

\textsuperscript{753} Id.

\textsuperscript{754} See Koh, supra note 13 (describing the reasons why nations obey international law).

\textsuperscript{755} Id. at 2602-03, 2641, 2645-58.

\textsuperscript{756} Id. at 2646.

\textsuperscript{757} See supra note 260 (discussing the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health).
cal, political, and implementational problems, this Decision clearly defines a hierarchy of basic values wherein private property rights and parochial self-interests are subordinated to the global social interest of protecting public health and attacking the HIV/AIDS epidemic. The ability of nations to unify in the face of such an overriding crisis, and to actually modify existing international law in the field of intellectual property rights, reflects an increasing global liberalism in which the rights of individuals can no longer be territorialized.

The inevitability of progressive liberalization cannot be open to dispute. A 'liberal' State can be defined, for example, in such terms as the existence of democratic or representative forms of government, the enjoyment of civil and political rights, or the availability of judicial remedies. Viewed in such a perspective, the Secretary-General has argued that authoritarian regimes are in fact giving way "to more democratic forces and responsive Governments." The concept of a progressive liberalism, however, must be more fundamentally defined in terms of international trade and economic development which actually serve as the catalysts for democratization and the recognition of basic human rights. These catalysts not only create wealth, they give rise to demands by individuals for the protection of that wealth against any arbitrary interference by governments. They also stimulate transnational interactions that give rise to demands for enforceable legal norms upon which rights can be predicated and effects can be predicted. As wealth continues to be created and interactions continue to broaden, individuals increasingly demand the right to engage in their own social, political, and economic decision making. The result of these demands is the intensification of universal rules of law that not only bind nations to a set of common values, but serve as a foundation for international constitutional principles.

The relationship between trade, liberalism, and constitutionalism has been recognized since the late eighteenth century when

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758 See supra notes 351-67 and accompanying text (describing the various problems that plague the resolution of global health care issues).

759 See, e.g., Koh, supra note 13, at 2633; Stone, supra note 16, at 459 (describing attributes of "liberal" states).


761 McGinnis & Movsesian, supra note 18, at 588.
Kant concluded that the "spirit of commerce" will eventually (and quite naturally) unite all nations and will compel those nations to promote the international peace that is necessary to engage in that commerce.\textsuperscript{762} Such observations, of course, must be modernized and Kant’s vision of ‘perpetual peace’ must encompass far more than merely the avoidance of war. In the current environment the HIV/AIDS epidemic is substantially more destructive than traditional notions of armed conflict. Not only does this epidemic create both domestic unrest and regional and international instability, it completely negates the ability of affected nations to engage in the wealth-creating process of international trade. As a result, the international action necessary to ensure a level of peace that is conducive to global commerce has become substantially more inclusive.

Additionally, the scope of international commerce, and its effect on the willingness of nations to unite for common purposes and to develop universally binding rules of law, could not have been anticipated even by Kantian visionaries. World exports of merchandise and commercial services, for example, recently reached $7.84 trillion.\textsuperscript{763} Evidencing a geographic expansion of liberalism, trade in the so-called transition economies expanded at double-digit rates for both imports and exports and the economies of those nations experienced both the highest annual rates of trade expansion\textsuperscript{764} and the strongest levels of economic growth.\textsuperscript{765} Similarly, ten African nations experienced more than a 5% growth in their economies, while five African nations saw their GDP’s increase by more than 10%.\textsuperscript{766} One hundred and seventy-six regional trade agreements were in force at the end of 2002\textsuperscript{767} and membership in the WTO, currently at 146, continues to grow.

This expansion of liberalism has both domestic and international effects. In terms of the former, McGinnis and Movsesian have suggested that international trade helps to democratize na-
Since democracy and prosperity are in fact highly correlated, citizens increasingly demand more democratic forms of government (as well as more civil and political rights) as their wealth continues to grow. From an international perspective, liberalism increases economic interdependence, provides incentives for interstate cooperation, and mandates a regime of constitutive principles aimed at the broader-based prerequisites for international peace. As Stone has suggested, the more relative autonomy that a regime possesses, such autonomy being more likely to develop within a zone of liberalism, the closer it can come to constitutionalism. Similarly, the intensification of international trade (along with a growing interdependence and the resulting need for legal security) is, in Fassbender’s words, the driving force behind the process of constitutionalization.

Progressive liberalism must also be viewed in terms of its symbiotic relationship with individuals both as participants in international affairs and as subjects of international law. In regard to participation, a variety of private actors—including individuals, multinational business enterprises, fundraising organizations, consultants, lobbyists, NGOs and other watchdogs—are wielding substantial influence over both domestic policies and interstate relationships. NGOs, for example, are now playing a more critical role in the human rights monitoring system. Multinational businesses are requiring more open international trading practices, increased transparency, nondiscriminatory treatment, and legal structures conducive to direct investment. Private organizations continue to gain credibility and (at least in some cases) are directly taking part in negotiation and implementation processes. The Clinton Foundation HIV/AIDS Initiative, for example, has dealt directly with foreign governments in the development of detailed

768 See McGinnis & Movsesian, supra note 18, at 588 and accompanying citations (“[A]s citizens become richer, they increasingly demand more democracy and civil rights to protect their wealth from the arbitrary actions of government.”).

769 See id. and accompanying citations (“[D]emocracy and prosperity are highly correlated.”).


771 Id. at 464.

772 Fassbender, supra note 13, at 618.

773 See notes 666-71 and accompanying text for a description of the Committee on Economic, Social and Cultural Rights’ incorporation of non-governmental organizations into its human rights monitoring system.
operational plans for the treatment of AIDS patients and has acted as an intermediary between those governments and pharmaceutical companies. In each of these instances, modifications of inter-state relationships (as well as modifications in the relationship between a State and its own citizens) are in fact stimulated by private actions and interactions rather than by governmental initiative. In a very real sense, the development of 'inter-national' law is no longer the sole domain of national (or public) regimes.

Both increasing liberalism and private-party participation in the development of global norms have been accompanied, whether as a cause or as an effect by the emergence of the individual as a fundamental subject of international law. Whether the result of an advancing civilization, an exercise of fashionable politics, or a simple recognition of a progressive ideal, the community of nations has clearly been replaced by a community of individuals in the field of human rights.

As discussed throughout this Article, the Universal Declaration, a variety of U.N. resolutions, and such agreements as the ICCPR, the ICESCR, the CRC, the CEDAW, and the ICERD are directly focused on the rights and conditions of individuals rather than on the relationships between States. These instruments represent only a part of a fundamental shift in emphasis away from state-centric theories of international relations. The new permanent International Criminal Court ("ICC"), for instance, has been empowered to prosecute individuals accused of genocide, war crimes, or crimes against humanity. Individuals may be tried before this tribunal even if they are nationals of non-party States (when the crime occurred within the territory of a Party) and even if they hold an official capacity such as Head of State. The ICC, of course, builds upon such ad hoc tribunals as those established in Rwanda and Yugoslavia for the imposition of individual accountability for human rights violations. Similarly, the doctrine of universal jurisdiction, while apparently subject to the dip-

774 See Mark Schoofs, Clinton Program Would Help Poor Nations Get AIDS Drugs, WALL. ST. J., Oct. 23, 2003 at B1 (reporting on Clinton’s success dealing with pharmaceutical companies and foreign governments).
775 See supra notes 1, 25, 116-20, 125.
776 Rome Statute, supra note 22, art. 5.1.
777 Id. art. 12.2.
778 Id. art. 27.
779 For a discussion of these tribunals, see Lodico, supra note 21, at 1034-35.
lomatic immunity exception of Congo v. Belgium, not only grants States the right, but imposes the duty to prosecute individuals for crimes that offend the international community as a whole no matter where (or by whom) they are committed. Under Doe v. Unocal Corp., private corporations may also be held accountable under international law if they participate or assist in certain human rights violations. It has also been suggested that the U.N. Security Council has the power to address the conduct of both individuals and corporations if that conduct poses a threat to international peace and security.

This increasing focus on the rights and responsibilities of individuals is manifested in more subtle ways as well. The new WTO Agreement is not designed to merely protect the wealth of nations or the welfare of national economies, but to protect and promote the interests of the various constituents of those economies. As a result, individuals (generally in the form of private enterprises) are protected from the effects of foreign subsidies, dumping, discrimination, non-tariff barriers, and the infringement of intellectual property rights. Additionally, while this Agreement is aimed at enhancing international trade, such a goal is merely a means by which to accomplish a more comprehensive result. The true spirit of the WTO Agreement lies in its attempt to create additional global wealth, to raise global standards of living, and to ensure that poorer nations (and the individuals who populate those nations) share in the benefits that accrue from the Agreement. In order to do so, both the WTO Agreement and its GATT predecessor have accorded special treatment to less-developed nations in an attempt to stimulate their growth and these agreements have recognized that the promotion of trade with these nations is one of the "primary objectives of the Contracting Parties."

More particularly, the whole purpose of Part 4 of the Agree-

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781 Rule of Power or Rule of Law?, supra note 684, at 120 (citing Ian Brownlie, Principles of Public International Law (4th ed. 1990)).
783 Fassbender, supra note 13, at 610.
784 See Cann, supra note 175, at 80 and accompanying citations for a discussion of the true spirit of the WTO Agreement.
785 Gatt Analytical Index, supra note 378, at 1040.
ment\textsuperscript{786} is to alleviate the specific problems facing less-developed countries and to enhance their economic and social development by means of raising standards of living and ensuring the availability of essential imports.\textsuperscript{787} Pursuant to the so-called Enabling Clause, contracting parties have been specifically authorized to “accord differential and more favourable treatment to developing countries, without according such treatment to other contracting parties.”\textsuperscript{788} These provisions, of course, are not simply aimed at abstract national entities, but at individuals who are experiencing substantial need. In such a sense, the WTO Agreement is in fact a social compact whereby national governments have agreed to act for the benefit of all global citizens.

By attempting to stimulate trade with less-developed countries, the WTO Agreement is addressing the inevitable link between poverty and the absence of human rights. In conjunction with such an approach, the international community is also attempting to develop a more meaningful human rights regime that will bind nations to a standard of progressive realization. As discussed earlier,\textsuperscript{789} this regime consists of a variety of Charter-based and Treaty-based bodies as well as mechanisms for periodic reporting, monitoring, investigation, and both individual and interstate complaints. While certainly not without problems, this regime has experienced unprecedented growth both institutionally and in the establishment of international norms directed at the rights of individuals.\textsuperscript{790}

The expansion of this regime has also been accompanied by an increasing willingness of the U.N. Security Council to take action, whether in the form of embargoes, economic sanctions, or humanitarian intervention, when the violation of human rights is so deplorable as to constitute a threat to international peace and security.\textsuperscript{791} In Somalia, the U.N. Security Council took action under

\textsuperscript{786} GATT, supra note 370, arts. XXXVI-XXXVIII.

\textsuperscript{787} Id.; see also Cann, supra note 14, at 443.

\textsuperscript{788} Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries, Nov. 28, 1979, GATT B.I.S.D. (26th Supp.) at 203 (1980).

\textsuperscript{789} See, e.g., supra notes 656-95 and accompanying text.

\textsuperscript{790} The U.N. Human Rights Regime, supra note 21, at 460 (remarks of Thomas Buergenthal) (addressing whether such growth affects protection of human rights).

\textsuperscript{791} See Lodico, supra note 21, at 1028, 1031, 1038, 1041-47 (discussing the ap-
Chapter VII of the Charter to "ensure the delivery of humanitarian assistance" and to prevent the "looting of relief supplies destined for starving people." 792 Similar action was taken in Haiti based upon "the incidence of humanitarian crisis" and the "mass displacements of population." 793 The fact that such interventions are authorized—despite the claims of sovereignty—underscores the position that human rights are no longer within the sole discretion of national governments. The fundamental rights of individuals have been placed at the pinnacle of global values and actually serve to preempt the traditional rights of nations.

6.4. A Constitutional Foundation for the Right to the Highest Attainable Standard of Health

The expansion of liberalism, the increasing importance of the individual, and the recognition that binding international norms may be created outside the formal lawmaking process provide substantial impetus for a progressive global constitutionalization. At least in the area of human rights, there is in fact an adequate foundation of international community, hierarchical norms and institutions, and rulemaking and enforcement mechanisms to create a constitutional regime. Under such a regime, the duty to engage in the progressive realization of the right to the highest attainable standard of health, including the duty to take all realistically available measures for the prevention and treatment of the HIV/AIDS epidemic, is a duty that is constitutional in nature.

6.4.1. The Existence of a Community

Immanuel Kant believed that before any form of international right was possible, a "lawful State" must already be in existence and that without a State there can be no "public right." 794 Neither individuals nor a group of nations can constitute a State if they are living in a "lawless freedom." 795 Whether the existence of such a community must actually precede the creation of a constitution (or whether the existence of a constitution must actually precede the appropriate course of action in cases of extreme human rights violations).

794 KANT, supra note 12, at 129.
795 Id. at 164.
creation of a community) is an issue that remains open to debate.\textsuperscript{796} In either event, there is unquestionably an interdependence between the two concepts. As Fassbender has argued, a constitution needs a community "as its substratum," but a community also needs "to be constituted."\textsuperscript{797}

It is the position of this Article that an international community does in fact exist that is sufficient both in its identity and its construction to impose constitutional duties in the area of human rights and, more particularly, in regard to the right to health. Such a community may be viewed in terms of a community of States, or a community of individuals. It may also be viewed as a community of States or individuals within the borders of a particular 'subject matter' such as human rights or international peace and security.

Whatever label is ultimately attached, the existence of an international community is fundamentally dependent upon the relationship between social interest and self-interest. A 'community' should be defined as any relationship among individuals or sovereign States wherein self-interest (whether of the individual or of the State) has become subservient to the social interest of the whole. The preeminence of social interest within an identifiable group, whether that group is defined territorially or as adherents to a particular set of subject matter norms, creates a community or a communal foundation upon which constitutive principles can be based.\textsuperscript{798} Such an argument acknowledges that both nations and individuals exhibit substantial cultural, economic, and political differences and that the practical implementation of international norms varies tremendously among nations. It is undeniable, however, that there are a number of common values (or minimum standards) that bind all global constituencies such as the inherent dignity of the person, the right to self-determination and development, the inalienability of fundamental human rights, and the duty

\textsuperscript{796} See Fassbender, \textit{supra} note 13, at 561-68 (discussing two conflicting views on the relationship between community and constitution).

\textsuperscript{797} Id. at 567.

\textsuperscript{798} Stone has indicated that "a liberal regime, like a constitution, may create, reinforce, and disseminate the social interest, while delegitimizing narrow self interest." Stone, \textit{supra} note 16, at 465. Similarly, Fassbender has indicated that "the notion of the constitution offers a coherent explanation of current developments in international law which more and more emphasize interests of the international community as a whole over those of individual states." Fassbender, \textit{supra} note 13, at 553. For a discussion of the nature of a community, see \textit{id}. at 561-68.
to promote international peace and security. Through the recognition of such basic principles, the international community acquires an identity, while far from complete, that serves to create expectations, advances predictability, establishes a basis for condemnation, and encourages further value identification and cooperation.

In regard to both the realization of human rights and the maintenance of international peace and security—each of which is inextricably linked to the HIV/AIDS crisis—it can no longer be argued that nations exist in a "lawless freedom." If the position is taken that the individual States are in fact the citizens of the international community, it seems apparent that these citizens are engaged in a progression that is fundamentally changing the global political identity. Ackerman has indicated that a constitution may actually be viewed "as the culminating expression of a mobilized citizenry." By way of analogy, it may be argued that 191 States (as a 'mobilized citizenry') are now members of an organization whose charter is primarily focused on the promotion of human rights and the maintenance of international peace. Pursuant to Article 2.6, even those few States who are not members of the United Nations are nevertheless bound by the basic principles of this community.

Similarly, the 192 Parties to the CRC, the 147 Parties to the ICESCR, and the 192 Member States of WHO have specifically bound themselves to provide the right to the highest attainable standard of health. Perhaps as a culminating expression of this citizenry, the Declaration on TRIPS and its Implementing Decision make it clear that the private rights of individuals will not be allowed to frustrate the greater social good of global public health. When combined with the other substantial components of the human rights regime, as well as with an increasing willingness to intervene during humanitarian crises, the resulting absence of

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799 For a discussion of the concept of common values and determinative or elementary rules, as well as citations in this regard, see Fassbender, supra note 13, at 548-51 (discussing the views of Tomuschat), and at 566 (discussing the existence of basic, universal standards of human rights). See also Perez, supra note 18, at 384 (discussing the "constitutionalization of higher values").
800 ACKERMAN, FOUNDATIONS, supra note 17, at 291.
801 See supra notes 447, 465-70 and accompanying text (providing health care rights for all).
802 Declaration on TRIPS, supra note 28 (emphasizing the importance of solving serious global health issues).
803 Implementation of Paragraph 6 of the Declaration on TRIPS, supra note 260.
lawless freedom implies the existence of a community for human rights purposes. While issues surrounding the potential for a 'constitutional community' will be addressed shortly, there is no doubt that a community (that may conceivably give rise to constitutional relationships) can be identified.

It may also be argued that States need not be communal for all purposes. Just as one State (out of the totality of States) may create a distinct territorial community, a consensus of States may create a particular subject matter community to which all adherents belong. Since the protection and enforcement of public rights are the primary purposes of a legitimate community, a communal human rights 'State' may exist if the presence of such mechanisms can be identified. As a result, while an international community may not yet exist in terms of some objectives (for example, the application of uniform labor standards), it may in fact exist for others.

Finally, it can be alternatively argued that the real citizens of a human rights community are not the States who express their agreement through treaties and declarations, but the individuals who are entitled to human rights protection. While some of the provisions of the U.N. Charter do in fact address the 'peoples' of the world rather than its States, the existence of the Universal Declaration, the substantial customary law to which it has given rise, and the expansion of the concepts of natural and inalienable rights to the international legal setting all seem to indicate that individuals are endowed with fundamental rights irrespective of State action or condonation. Additionally, any State that engages in activities designed to frustrate the enjoyment of these rights becomes illegitimate and theoretically ceases to exist as a 'State' for human rights purposes. This recognition that individuals possess a series of common rights that transcend any concept of 'State' suggests the presence of something more than a mere community of nations. It suggests the existence of an independent, identifiable, human rights community composed of individuals. The suppression of individuals in non-democratic States

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804 See, e.g., U.N. CHARTER pmbll. ("We the Peoples of the United Nations . . ."); id. art. 1, para. 2 ("self-determination of peoples").

805 See Eisner, supra note 21, at 211 (establishing the existence of certain fundamental human rights).

806 For a discussion regarding the relationship among the recognition of human rights, legitimacy, and the doctrines of sovereignty and non-intervention, see Petersmann, supra note 18, at 762.
does not alter such a fact.

6.4.2. The Existence of Hierarchy

6.4.2.1. The Erosion of Sovereignty

As Kant anticipated, mutual self-interest has driven nations towards more international cooperation. The WTO Agreement, for example, has given rise to the implementation of a variety of economic and socio-economic rules governing international trade relationships. It has also established a Dispute Settlement Body and provided for various forms of economic punishment in the event of a breach. While this is certainly a high-profile reflection of the transfer of sovereign powers to an international organization, it can still be argued that participation in the WTO is merely voluntary and therefore subject to rescission by way of withdrawal.

In contrast, a nation’s membership in the human rights community, wherein the inalienable rights of individuals cannot be denied, is neither voluntary nor subject to withdrawal. The existence of these fundamental rights and the potential for multilateral humanitarian intervention represent a true erosion of the principle of sovereign community. In concert with a human rights regime that monitors, investigates, and provides complaint mechanisms, the international community is now taking the position that human rights violations (at least when they endanger the very subjective notion of peace and security) are no longer shielded by the doctrines of sovereignty and non-intervention. 807 Despite a tradition of State centricity (wherein international law was directed at the rights and obligations of States and not of individuals), 808 and despite the U.N. Charter’s recognition of both the principle of non-intervention 809 and the territorial integrity and political independence of nations, 810 the international community now recognizes

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807 See Lodico, supra note 21, at 1031-35 (discussing the changing notions of State sovereignty in the context of humanitarian intervention); Petersmann, supra note 18, at 762 (discussing the framework of humanitarian intervention). For a discussion regarding human rights and the erosion of the doctrines of sovereignty and non-intervention, see generally, Eisner, supra note 21; Lodico, supra note 21; The U.N. Human Rights Regime, supra note 21; and Perez, supra note 18.

808 Eisner, supra note 21, at 196 (discussing the historically dominant position of the state).

809 U.N. CHARTER art. 2.7.

810 Id. art. 2, para. 4.
that human rights are truly universal in nature. As a result, their protection can be ensured globally rather than merely domestically.

The erosion of sovereignty, non-intervention, and State-centricity has been generally acknowledged by legal scholars. Koh has indicated that the transformation of international law has been characterized by a decline in national sovereignty and a corresponding proliferation of global decision making by States, international regimes, intergovernmental organizations, regional compacts, NGOs, and informal networks.\textsuperscript{811} Nevertheless, it is of fundamental importance to acknowledge to whom these traditional sovereign powers have been transferred and to whom the responsibility for ensuring their enforcement has been delegated. In a very real sense, these powers can be neither created nor destroyed, but merely transferred upstream to international institutions, downstream to individual citizens, or to some combination thereof. In either event, identifying such a transfer is critical for imposing an international constitutional duty regarding the progressive realization of the right to the highest attainable standard of health.

6.4.2.2. The Non-exclusivity of International Hierarchy and Anarchy

Certainly such treaties as the ICESCR and the CRC impose a variety of duties in regard to human rights and the right to health. However, in order to impose a ‘constitutional’ duty among States, whereby certain relationships between a State and its own citizens may be preempted by an international authority, the global community must exhibit some form of hierarchical structure.

Traditionally, the international community has been described as anarchic where all States are viewed as both equal and sovereign and all cooperation is viewed as voluntary. The centrality of States, their undifferentiated functions, and their status as “like units” leads to a system of domestic hierarchy and international anarchy.\textsuperscript{812} As evidence of such a dichotomy, it is argued that the international system lacks both the rule of law and autonomous institutions. It is argued that there are no separation of powers, no

\textsuperscript{811} Koh, supra note 13, at 2604, 2631 (arguing that norm-based cooperation is possible in international society).

\textsuperscript{812} Stone, supra note 16, at 449-55. Stone, of course, disagrees with such an assessment. See id. at 469-70.
checks and balances, no enforcement and rulemaking mechanisms, and no compulsory judicial review.\textsuperscript{813}

On the other hand, there are those who believe that an international hierarchy does in fact exist and that the U.N. Charter represents its constitution.\textsuperscript{814} In support of such a position, it may be noted that the supremacy clause of Article 103 provides that Charter obligations will prevail over all other obligations that Members have undertaken pursuant to other international agreements. Article 2.6 binds non-members to the Charter's basic principles whenever necessary to maintain international peace and security, while Article 2.7 excepts Chapter VII enforcement measures from the concept of non-intervention.

All members have also agreed to accept and carry out the decisions of the U.N. Security Council pursuant to Article 25 of the U.N. Charter. By binding themselves in advance to Chapter VII decisions, the U.N. membership has created a ruling body with substantially subjective jurisdiction.\textsuperscript{815} This discretionary authority has been recently exercised in order to engage in a variety of humanitarian interventions and to form and secure the post-Taliban regime in Afghanistan.\textsuperscript{816} It has also been used to justify the adoption of Resolution 1373\textsuperscript{817} (requiring Members to implement measures regarding terrorists) which has been described as a creation of "instant global law", a means for avoiding the "cumbersome and time-consuming" treaty process, and "an order from on high to the world's states."\textsuperscript{818} Such a combination of subjectivity, supremacy, and advanced approval apparently "trumps all contrary non-Charter legal obligations."\textsuperscript{819}

The international community need not be exclusively hierar-

\textsuperscript{813} For a discussion in such a regard, see, e.g., Macdonald, \textit{supra} note 18, at 228-31 (debating whether the U.N. Charter serves as a constitution); Petersmann, \textit{supra} note 18, at 765-79 (addressing whether the U.N. Charter is a constitution).

\textsuperscript{814} See, e.g., Fassbender, \textit{supra} note 13; see also, id. at 577-78 (discussing a hierarchy of values).

\textsuperscript{815} See Reisman, \textit{supra} note 13, at 88, 93 (discussing the broad powers of the U.N. Security Council under Chapter VII of the U.N. Charter).

\textsuperscript{816} Rule of Power or Rule of Law?, \textit{supra} note 684, at 38 (discussing the United Nations' role as an international mediator).


\textsuperscript{818} Rule of Power or Rule of Law?, \textit{supra} note 684, at 39-40.

\textsuperscript{819} Reisman, \textit{supra} note 13, at 93 (referring to the "synergy of Articles 25 and 103" of the U.N. Charter).
chical or exclusively anarchic. As has been argued throughout this Article, this community is engaged in a progressive constitutionalization in the area of fundamental human rights which need not possess either a finite beginning or a finite end. The right to the highest attainable standard of health, whether viewed as actually constituting such a fundamental human right or as an inextricable influence on the realization of those rights, must be incorporated into that constitutive process. Additionally, the existence of a hierarchy must not be judged solely by ‘upstream’ transfers of power or by the presence of formal institutions. If the U.N. Security Council can lawfully intervene to prevent gross violations of human rights, then the international community cannot be exclusively anarchic. If individuals have rights that the international community will protect, then the presence of some supremacy or hierarchy must be implied. There is no doubt that some entity has imposed limitations on the powers of national governments in the field of human rights and there is also no doubt that the imposition of restrictions to combat potential abuse is at the heart of constitutionalism.820

It may also be argued that the presence of anarchy, equality, and self-interest actually serve to stimulate (rather than to impede) international cooperation. While Kant limited his vision of cooperation to the creation of a federation of free states,821 he would undoubtedly agree that anarchy eventually gives way to some form of coercive public law. In a sense, anarchy is self-destructive. In the particular area of human rights, demands for public law will continue to increase as liberalization continues to spread. Nations are neither static nor “like units”—with identical polities and identical demands from their citizens—nor liberal States are much more likely to engage in international cooperation.822 As Stone has indicated, both compliance and enforcement of international law may be extremely high within a liberal international regime and this law “may have relatively more status, autonomy, and legitimacy

820 Petersmann has indicated, for example, that “Constitutionalism emerged in response to negative experiences with abuses of political power as a means to limit such abuses . . . .” Petersmann, supra note 18, at 758.

821 See supra notes 713-24 and accompanying text (arguing for an inevitable progression towards a federation of states).

822 See Stone, supra note 16, at 461-63, 469-70 (stating the proposition that legal norms govern the interaction between liberal states and promote cooperation through economic ties).
than legal norms in many domestic settings."\textsuperscript{823} Stone rejects the domestic/hierarchy and international/anarchy dichotomy\textsuperscript{824} and believes that "the distinction between international regimes and domestic constitutional forms is relative not absolute.\textsuperscript{825}

It should also be recognized that international hierarchy can be created by means of transfer of power downstream to individuals. While it could be argued that individuals (at least in theory) have always held such 'powers' as the right to equality, life, inherent dignity, self-determination and development, the ultimate power to determine human rights policies was vested in the State. Under classical theory, domestic policies that frustrated the enjoyment of these rights were beyond reproach under the doctrines of sovereignty and non-intervention. As a result of the evolution in international law, the power to deny human rights—at least when those denials affect international peace and security—has been taken from domestic regimes. The true governance of these rights has now been transferred to the individual in the form of an inalienable power to govern oneself that is capable of being internationally enforced. The fact that certain rights can no longer be qualified by governmental fiat enhances the fundamental quality of those rights by placing them above national sovereignty and principles of non-intervention in the international legal hierarchy.

While somewhat out of context, it can also be argued that these fundamental rights, whether linked to the U.N. Charter, international covenants, or customary law, have a constitutional 'direct effects' application. Despite their origin, they inherently constitute the domestic or internal law of all nations and they are neither treaty-dependent nor reliant upon any form of implementing legislation. Despite the absence of domestic judicial procedures to enforce these rights in some nations, they are nevertheless capable of being protected by an international machinery that is restricted only by a very subjective peace and security standard.

In order to ultimately determine the presence of an international hierarchy that is capable of creating constitutional rights it is also necessary to briefly examine a number of collateral issues. These issues involve the ability to bind non-members or objecting nations, the ability to engage in lawmaking, the presence of some

\textsuperscript{823} Id. at 470.
\textsuperscript{824} Id. at 469.
\textsuperscript{825} Id. at 474.
form of judicial intervention, and the ability to engage in enforcement or hierarchical coercion.

6.4.2.3. The Inclusive Nature of Human Rights Obligations

In order to be constitutional in nature, a rule of law must be binding on all members of a community with or without their consent.\textsuperscript{826} As Kant noted, the “principle of being content with majority decisions must be accepted unanimously” in order for a constitution to exist.\textsuperscript{827} If members of a community may lawfully exempt themselves from the application of an objectionable (but valid) rule, or if they may avoid that application by simply exercising a contractual right of withdrawal, then such a rule would lack constitutional quality.

Identification of the actual composition of a community, as well as identification of the rule of law allegedly governing that community, is essential for determining the presence of constitutionalism. If it is argued, for example, that the U.N. Charter is the constitution of the whole international community and is binding on all members and constituencies within that community, issues regarding those few States that are not Members of the United Nations must be addressed. As discussed earlier, it can be argued that Articles 2.6, 2.7, and 103 clearly indicate that non-Members are in fact bound by the U.N. Charter’s basic principles and objectives\textsuperscript{828} and by its enforcement mechanisms contained in Chapter VII. Similarly, Article 32 of the Charter provides that “any state which is not a Member of the United Nations, if it is a party to a dispute under consideration by the Security Council, shall be invited to participate . . . in the discussion relating to the dispute.”\textsuperscript{829} Such a provision explicitly indicates that the U.N. Security Council can hear disputes involving non-Members and can take action in their re-

\textsuperscript{826} For a discussion in this regard, see, e.g., Fassbender, supra note 13, at 548-49 (discussing Christian Tomuschat), 581-84, 617 (explaining the U.N. Charter applicability to non-Members); Perez, supra note 18, at 447 (noting that the U.N. Charter is better understood as a constitution that confers rights and imposes duties on members of communities that have not given their consent to be governed by it).

\textsuperscript{827} KANT, supra note 12, at 79.

\textsuperscript{828} See supra notes 814-19 and accompanying text (citing evidence that the U.N. Charter will be enforced against non-Member nations); see also, e.g., Fassbender, supra note 13, at 593 (noting that viewing the U.N. Charter as a constitution best explains the demands made on non-Members).

\textsuperscript{829} U.N. CHARTER art. 32.
gard. As Fassbender notes, under such a system of collective security, a non-member State that breaches the U.N. Charter would, "in the very second" of the breach, be subject to its provisions. Finally, the conception of 'unanimity in the majority' is also evidenced by the fact that fundamental amendments to the U.N. Charter come into force "for all Members" when adopted by two-thirds of the General Assembly and ratified, in accordance with their respective constitutional processes, by two-thirds of the Members (including all of the permanent Members of the U.N. Security Council). As a result, as many as one-third of the Members of the United Nations may be absolutely bound by an amendment to the U.N. Charter despite their substantial opposition.

On the other hand, this Article has chosen to define a community not in terms of those who are subject to the U.N. Charter but in terms of those who either possess human rights or have human rights obligations. Whether based upon the U.N. Charter, international conventions, common values, customary law, or *jus cogens*, such a community of human rights is (by definition) all inclusive. There are in fact no 'non-members'. Certain rights are fundamental and while some nations may exercise the 'power' to suppress those rights (since international intervention is far from consistent) no State has the 'right' to do so.

While the U.N. Charter expressly recognizes the importance of human rights and fundamental freedoms, problems surrounding

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830 Fassbender, *supra* note 13, at 583.
831 U.N. CHARTER art. 108.
832 For a discussion in this regard, see Fassbender, *supra* note 13, at 578-79. Fassbender argues, of course, that non-Members are bound by the U.N. Charter, that the Charter is the constitution of the international community, and that the Charter is binding on all Members of the international community including States, intergovernmental organizations, individuals, etc. *Id.* at 529, 531-32, 584, 609-15. For a discussion and citations regarding the debate as to whether the U.N. Charter is the constitution of the international community, see *id.* at 616; MacDonald, *supra* note 18, at 228-31 (citing commentators who claim that the U.N. Charter is a "world constitution"); Perez, *supra* note 18, at 357 (presenting "a new hermeneutic based on constitutional theory"); 402 (arguing that "a supranational constitution has emerged around the U.N. Charter as its textual source"); Reisman, *supra* note 13, at 95 (stating that "checks and balances" are held to be "crucial in modern constitutional theory"); *id.* at 100 (claiming that the U.N. Charter is part of an "ongoing world constitutive process").
833 See, e.g., U.N. CHARTER art. 1. 3 ("promoting and encouraging respect . . . for human rights and for fundamental freedoms").
non-self-execution and the creation of internally binding domestic law will continue to persist. In contrast, international law, at least when taken in its entirety, is in fact part of the law of each nation. Rules based on customary law can be binding on all nations that do not consistently object to the existence of those rules and it is quite unlikely that a nation would consistently object (at least outwardly) to the existence of human rights and fundamental freedoms. Even when rights are not actually observed in a particular State, their purported (or facial) acceptance would make it extremely difficult to subsequently deny their applicability. Additionally, it should be emphasized that rules based upon customary law are not subject to the doctrine of non-self-execution and that norms that develop over time based on generally accepted treaty provisions may actually become binding on States that are not parties to those agreements.

In regard to the Universal Declaration, it can be strongly argued that this Declaration has reached the status of binding customary law. The Universal Declaration has been viewed as "a common standard of achievement" for all nations, as a "yardstick" by which to measure the degree of compliance with international human rights, and as the fundamental source of philosophy for "all subsequent work in the field of human rights." It has been accepted as "authoritative" by all States (regardless of whether they are parties to the ICCPR or ICESCR) and it has served as both the basis and the justification for actions taken by the United Nations. Being "universal in scope" it is binding on all nations regardless of whether or not Governments have formally accepted its

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834 See, e.g., Sei Fujii v. State, 242 P.2d 617, 620 (Cal. 1952) ("A treaty does not automatically supersede local laws which are inconsistent with it unless the treaty provisions are self-executing.").

835 See, e.g., The Paquete Habana, 175 U.S. 677, 700 (1900) ("International law is part of our law.").

836 Rule of Power or Rule of Law?, supra note 684, at 29.

837 See, e.g., Southard, supra note 439, at 54 (arguing that customary international law has an advantage over treaty law in U.S. courts because "the doctrine of non-self-execution does not apply").

838 See Rule of Power or Rule of Law?, supra note 684, at 29 (noting that "compliance with the NPT obligation . . . is reasonably good" even by nations not party to that agreement).

839 Universal Declaration, supra note 118, pmbl.

840 Fact Sheet No. 2 (Rev. 1), supra note 143, at 4-5.

841 Id. at 10.
principles." As a result, the Declaration's specific recognition of the right to health, medical care, and security in the event of sickness must be given substantial stature.

Non-agreeing members can also be bound by a variety of peremptory norms or *jus cogens*. By definition, these norms are binding on all members of the international community and are immune from State objection. While certainly subject to debate, it can be legitimately argued that a variety of principles have in fact achieved *jus cogens* status including the right to life and inherent dignity, the duty to promote and encourage respect for human rights and fundamental freedoms, the duty to maintain international peace and security, and the duty to refrain from interfering with self-determination and development.

Whether viewed solely in terms of customary law or as a substantial determinant in the achievement of the principles of *jus cogens* noted above, all nations have the duty to engage in the progressive realization of the right to the highest attainable standard of health. While such a statement may seem overly inclusive, it is simply incomprehensible that customary law would allow a standard by which nations would have no duty to even *attempt* to engage in such a progression. Not only are most States parties to the ICESCR, CEDAW, and ICERD, near unanimity has been achieved in regard to the CRC. Additionally, those States that have chosen not to become parties to these agreements generally abstain out of fear that a *formal* recognition of these rights will result in additional domestic liabilities on the part of national governments. In reality, State practice in these non-members (such as the United States) would arguably serve to support rather than deny the recognition of the right to adequate prevention, treatment, and health care facilities. To equate the fear of formal liability with a consistent objection to the right to health would be both disheartening and erroneous.

6.4.2.4. A Progression Toward Human Rights Governance

Modern constitutional theory places a substantial emphasis on

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842 Id.

843 Universal Declaration, supra note 118, art. 25 para. 1.

844 RULE OF POWER OR RULE OF LAW?, supra note 684, at 29.

845 For a discussion in this regard, see Macdonald, supra note 18, at 206-09 (providing a list of principles that have achieved the status of *jus cogens*).
the need for autonomous institutions that perform distinct legislative, judicial, and enforcement functions and that provide a system of checks and balances in regard to institutional power.\textsuperscript{846} Such an emphasis substantially reflects the fact that constitutional theory has primarily developed out of an analysis of national polities. As a result, the current approach to constitutionalism is inherently encumbered by domesticized baggage that may prove less applicable, or at least too rigid, in the international setting. In order to witness the progression towards human rights governance, traditional political thinking must be adjusted to recognize the influence that the international community is exerting on legal relationships.

6.4.2.4.1. The Presence of Lawmaking

It would be naïve to argue the existence of a world government or the presence of a formal legislative entity. It would be equally unrealistic, however, to deny the existence of an international body of law (that is more than a mere combination of interstate agreements or the result of an association of free States) or to ignore the fact that the sources of this law are rooted independently from the will of individual nations.

While certainly in less traditional ways, the ability to legislate this international law is becoming increasingly apparent. Ronald MacDonald notes, for example, that despite the fact that the U.N. Security Council is not explicitly endowed with lawmaking capacity, its exercise of humanitarian intervention seems to indicate the establishment of new norms of international law.\textsuperscript{847} Similarly, while the U.N. Security Council lacks any formal lawmaking competence over individuals, the Council (without any official objection from the U.N. membership) established International Tribunals in Rwanda and the Former Yugoslavia that were directed at the activities of individual persons.\textsuperscript{848} There is also no doubt that international lawmaking has proscribed such activities as torture, genocide, war crimes, and crimes against humanity and has legislated mechanisms for imposing accountability (at least under cer-

\textsuperscript{846} See, e.g., notes 703, 704, and 706 and accompanying text (stating that a constitution implements a separation of powers to create a system of checks and balances).

\textsuperscript{847} MacDonald, supra note 18, at 215.

\textsuperscript{848} Id. at 216 (relating how the U.N. Security Council established International Tribunals for both Yugoslavia and Rwanda in 1993 and 1994, respectively).
tain circumstances) irrespective of the contractual consent of governments.\textsuperscript{849} Whether viewed in terms of creating "instant global law"\textsuperscript{850} or in terms of legislating fundamental changes to the U.N. Charter,\textsuperscript{851} the condemnation of mass displacement, starvation, and terrorism\textsuperscript{852} further underscores the increasing scope of international lawmaking.

The powers vested in the U.N. Security Council, however, are far from being fully utilized. Pursuant to Article 24 of the U.N. Charter, "Members confer on the Security Council primary responsibility for the maintenance of international peace and security" and, under the terms of Articles 25 and 48, agree to accept and carry out Council decisions in such a manner. As the Security Council continues to interpret the concept of 'primary responsibility' as well as the global and domestic conditions requisite for the maintenance of international peace and security, its international lawmaking function will continue to expand. This decision making, accompanied by a mandate that those decisions be accepted and implemented by all States, may certainly be characterized as quasi-legislative in nature.

Of critical importance will be the willingness of the U.N. Security Council to exercise this lawmaking power when faced with such health crises as HIV/AIDS, malaria, tuberculosis, and similar epidemics that may develop in the future. As has been argued throughout this Article, jurisdiction to do so (whether based upon a foundation of human rights or international security) is beyond question. Nations that do not recognize their duty to engage in the progressive realization of the right to health, assuming that such a failure frustrates the realization of fundamental human rights or endangers international peace and security should be subject to such lawmaking power.

International lawmaking in the field of human rights is not limited to the actions of the U.N. Security Council. As Koh has indicated, while human rights treaty regimes have been notoriously

\textsuperscript{849} See, e.g., Rome Statute, supra note 22, arts. 5-8, 12 (establishing an International Criminal Court with jurisdiction over genocide, crimes against humanity, war crimes, and the crime of aggression).

\textsuperscript{850} Rule of Power or Rule of Law?, supra note 684, at 39.

\textsuperscript{851} See Perez, supra note 18 (arguing that the United Nations has created a supranational government complete with a supranational constitution).

\textsuperscript{852} See supra notes 791-93, 816-18 and accompanying text (describing recent United Nations actions).
weak, core customary norms have nevertheless been clearly defined and often have become peremptory in nature.\textsuperscript{853} This customary law is in effect 'enacted' by the international community as a whole and may emanate from such 'institutions' as treaty relationships, state practice, or common values represented by inalienable rights. Whatever its institutional basis, the body of law that is created is just as binding as that enacted by more traditional forms of legislative entities.

The creation of customary law requires substantially more than mere custom or political rhetoric. It requires both consistent and recurring state practice \textit{(usus)} and recognition by States that the customary practice is in fact legally obligatory \textit{(opinio juris)}.\textsuperscript{854} When such conditions are met, customary law (while not necessarily granting individuals the right to institute actions against their own governments) can create binding constitutional relationships among States that are capable of being externally enforced.

Evidence of both state practice and obligatory nature in regard to the right to the highest attainable standard of health appears to be compelling. A variety of treaties, declarations, U.N. General Assembly resolutions, international conferences, Commission/Committee comments and domestic laws all serve to testify to such a fact. Treaties such as the ICESCR, CEDAW, ICERD, and CRC not only create binding contractual obligations among States, they also provide substantial evidence of state practice and serve to support (or to articulate) global norms of customary international law.\textsuperscript{855} As discussed earlier, these treaties are supplemented by a variety of regional agreements such as the Protocol of San Salvador and the African Charter that similarly recognize the right to health.\textsuperscript{856} Additionally, not only have many nations chosen to incorporate the right to health or other health-related entitlements into their domestic statutes or constitutions (or have chosen to in-

\textsuperscript{853} Koh, supra note 13, at 2655.

\textsuperscript{854} AUGUST, supra note 498, at 60. For a discussion in this regard see id. at 60-65 ("The psychological element in showing that a customary practice has become law is the requirement that states . . . must regard it as binding.").

\textsuperscript{855} Eisner, supra note 21, at 211; see also, RULE OF POWER OR RULE OF LAW?, supra note 684, at 133 (demonstrating how State practice by a "powerful and influential state" may be seen by other States as "a justification to relax or withdraw from their own commitments").

\textsuperscript{856} See supra notes 471-76 and accompanying text (discussing the effects of the Protocol of San Salvador and the African Charter).
corporate the Universal Declaration), such rights are being increasingly recognized by domestic and regional tribunals.\textsuperscript{857}

These formal indicia of state practice and obligatory intent are further validated by a substantial body of secondary evidence. While U.N. General Assembly resolutions are not legally obligatory, they are nevertheless relevant to the development of customary international law. As MacDonald has argued, a resolution that restates or clarifies an existing principle of customary law signifies that "the majority of states consider the interpretation . . . to be representative of the current opinio juris on the subject."\textsuperscript{858} In support of such an observation, it can be underscored that the whole purpose of Article 13.1.a of the U.N. Charter is to provide the General Assembly with the ability to initiate studies and to make recommendations "for the purpose of . . . encouraging the progressive development of international law and its codification."\textsuperscript{859}

In such a context, it may be noted that the Universal Declaration, including its provision on the right to health, medical care, and security in the event of sickness\textsuperscript{860}, has in fact been proclaimed by way of a U.N. General Assembly resolution.\textsuperscript{861} Similarly, the Vienna Declaration—which recognizes that the universality of the rights contained in the Universal Declaration are "beyond question,"\textsuperscript{862} that such rights are the "birthright of all human beings,"\textsuperscript{863} and that respect for these rights without distinction "is a fundamental rule of international human rights law"\textsuperscript{864}—has also been endorsed by means of a General Assembly resolution.\textsuperscript{865} Pursuant to the Declaration on Principles of International Law Concerning Friendly Relations, the General Assembly has also taken the position that the promotion of universal respect and observance of human rights and fundamental freedoms, as well as the maintenance of global peace and security, "constitute basic principles of

\textsuperscript{857} See supra notes 495-539 and accompanying text (laying out the mechanisms for tribunals).

\textsuperscript{858} MacDonald, supra note 18, at 214.

\textsuperscript{859} U.N. CHARTER art. 13.1.

\textsuperscript{860} Universal Declaration, supra note 118, art. 25, para. 1.


\textsuperscript{862} Vienna Declaration, supra note 101, para. 1.

\textsuperscript{863} Id.

\textsuperscript{864} Id. para. 15.

international law." 866

This combination of formal legal recognition and recurring secondary validation must be viewed as giving rise to customary norms in regard to the right to health. 867 Perhaps as a climactic recognition of such a fact, the U.N. General Assembly adopted the Declaration of Commitment 868 which recognized that access to medicines in the context of pandemics "is one of the fundamental elements to achieve progressively the full realization of the right of everyone to . . . the highest attainable standard of physical and mental health." 869 Pursuant to this Declaration, all U.N. Members agreed to take action against a global emergency that was threatening international security, undermining social and economic development, and frustrating the enjoyment of human rights and fundamental freedoms. 870 Despite treaty affiliation (or lack thereof), all nations indicated support for an emerging international norm in the area of global public health.

It is the existence of peremptory human rights, however, that can actually bridge the gap between customary law and constitutional law. Kant suggested that respect for the rights of individuals is "obligatory," "unconditional," and "absolutely imperative". 871 John Locke similarly argued that the only legitimate purpose of a government was to protect the natural rights of those being governed, since such rights actually precede the existence of the State. 872 In the international setting, the ICJ has recognized that human rights may transcend treaty relationships and that the absence of a legally binding agreement between States would not imply an ability to engage in human rights


867 It should also be noted that complete unanimity is not required to achieve such a result since the existence of a few objecting nations would not serve to defeat a norm's applicability to all other States.

868 Declaration of Commitment, supra note 3.

869 Id. para. 15 (emphasis added).

870 See, e.g., id. at paras. 2, 5, 8, 11, 13, 14, 16 (providing examples of the damage caused by HIV/AIDS).

871 KANT, supra note 12, at 129.

872 Petersmann, supra note 18, at 760 (summarizing the position of John Locke).
violations.  

If a right is truly natural or 'inalienable,' it would defy all logic to argue that States may lawfully deny that right by means of consistently objecting to its existence. Inalienable rights are in fact independent from the State and need neither State conferral nor State acquiescence. Since no State may lawfully exempt itself from the recognition of these rights, inalienability and a lack of peremptory status would be inherently contradictory.

The difficulty, of course, lies with identifying which rights are actually inalienable and thus peremptory in nature. Rights to be free from genocide, torture, slavery, or forced labor clearly fall within such a designation. Rights to life, inherent dignity, equality, equal protection, self-determination and development should also be similarly categorized. Unfortunately, some of these rights tend to defy precise parameters and the distinction between inalienability and social policy choices becomes legitimately blurred. The right to 'life' and the right to a particular 'quality' of life, for example, are fundamentally different issues. The right to live in dignity and the right to a particular standard of living would be similarly distinct.

Nevertheless, there is a sufficient core of inalienable rights—including the inalienable right of all 'peoples' to self-determination and the inalienable right of "every human person" to enjoy economic, social, political, and cultural development—upon which to base a set of peremptory rules that are binding on all States under a constitutional human rights regime. In order to give practical effect to these laws there must also be an implied lawmaking power on the part of the global community in regard to the progressive realization of the right to health. Without such an implication, the indivisibility and interdependence of these rights will substantially undermine any notion of their inalienability.

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873 See, e.g., Military and Paramilitary Activities (Nicar. v. U.S.), 1986 I.C.J. 14, 134 (June 27) ("[T]he absence of such a commitment would not mean that Nicaragua could with impunity violate human rights.").

874 In regard to forced labor, see John Doe I v. Unocal Corp., Nos. 00-56603, 00-57197, 00-56628, 00-57195, 2002 WL 31063976 (9th Cir. Sept. 18, 2002), reh'g en banc granted, Nos. CV-96-06959 RSWL, CV-96-06112 RSWL, 2003 WL 359787 (9th Cir. Feb. 14, 2003).

875 See, e.g., Vienna Declaration, supra note 101, para. 2.

876 DRD, supra note 25, art. 1.1.
6.4.2.4.2. A Rudimentary Patchwork of Judicial and Enforcement Functions

In order to impose a constitutional duty among States to engage in progressive realization, some form of fact-finding and interpretive mechanism must be identified. The ICJ has been designated the "principle judicial organ of the United Nations" and could conceivably hear disputes between Member States regarding breaches of treaty-based, customary-based, or constitutionally-based duties to provide the highest attainable standard of health. The resulting ICJ decision would be binding on all U.N. Members who were parties to the action and could be enforced by way of appropriate U.N. Security Council measures.

Unfortunately, the ICJ lacks compulsory jurisdiction over international disputes and can acquire such jurisdiction only by way of consent or acceptance by the States who are parties to the dispute. Since only a minority of Members have chosen to accept the compulsory jurisdiction of the ICJ (and even those acceptances have often been subject to substantial reservations), the ICJ cannot be currently viewed as an effective arbiter of human rights issues.

On the other hand, there are a number of less traditional mechanisms that can in fact contribute to an adjudicative approach to human rights. It could be argued, for example, that the holding of individuals and States accountable for human rights violations constitutes a form of judicial intervention. While there is no doubt that the protection of human rights would best be served by granting access to individual complaint procedures, the ability of some international bodies to interpret human rights violations, to render decisions against both individuals and States, and to impose some form of punishment on offenders should not be ignored. Whether stimulated by complaints from individuals or from other global actors, the cumulative reaction of the international community to human rights violations serves to create more identifiable human rights jurisprudence and enforcement standards.

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877 U.N. CHARTER art. 92.
878 Id. art. 94.
879 Petersmann, supra note 18, at 771. In regard to a lack of compulsory jurisdiction, see also, Fassbender, supra note 13, at 575; RULE OF POWER OR RULE OF LAW?, supra note 684, at 37 (discussing how the United States undermined the authority of the International Court of Justice).
In regard to holding individuals judicially accountable for human rights violations, it has already been noted\(^{880}\) that the U.N. Security Council established ad hoc tribunals in Rwanda and the former Yugoslavia precisely for such a purpose. Similarly, the Rome Statute\(^{881}\) has now created a permanent International Criminal Court that is empowered to prosecute individuals (including, under certain circumstances, nationals of non-member States) for a variety of serious human rights offenses.\(^{882}\) The ICC, with 139 Signatories and more than 90 Parties, is in fact a separate institution (rather than an arm of the United Nations) and is therefore largely independent from the U.N. Security Council.\(^{883}\) Its jurisdiction over crimes against humanity includes widespread or systematic rape, forced pregnancy, sexual violence, and persecution based on gender.\(^{884}\) The court also has jurisdiction over "other inhumane acts of a similar character intentionally causing great suffering, or serious injury to body or to mental or physical health."\(^{885}\) In addition to its fact-finding function, the ICC will be compelled to interpret the substantial breadth of such language as "inhumane acts," "great suffering," and "serious injury" to physical or mental health. Whether an intentional denial or interference with the right to health—such as a conscious failure to provide available pharmaceuticals during pandemics or a refusal to engage in any form of progressive realization—would constitute the imposition of such suffering or serious injury is a question in need of resolution.

Individuals can also be held accountable by means of an international judicial system that is composed of domestic courts en masse. The concept of universal jurisdiction, for example, applies to crimes and other grave breaches of international law that are so substantial that they offend the international community as a whole. As a result, all States not only have the right, but the obligation to prosecute offenders no matter where the act occurred and no matter what the nationality of the individual actor.\(^{886}\) As Beth

\(^{880}\) See supra note 848 and accompanying text (discussing tribunals set up by the U.N. Security Council).

\(^{881}\) Rome Statute, supra note 22.

\(^{882}\) See supra notes 776-79 and accompanying text (listing examples of human rights offenses).

\(^{883}\) RULE OF POWER OR RULE OF LAW?, supra note 684, at 122-23.

\(^{884}\) Rome Statute, supra note 22, art. 7.1(g), (h).

\(^{885}\) Id., art. 7.1(k).

\(^{886}\) RULE OF POWER OR RULE OF LAW?, supra note 684, at 120 (citing IAN
Stephens has indicated, universal jurisdiction "dispenses completely with a requirement of a particular connection between a state and the activities under review" and instead relies upon the collective interest of all States.\textsuperscript{887} The concept "permits domestic legal systems to assert extraterritorial jurisdiction over a growing list of international offenses"\textsuperscript{888} and, in Stephen's opinion, should include the assertion of domestic jurisdiction over civil human rights claims.\textsuperscript{889} A similar issue remains, however, as to whether governmental officials who breach their duty to engage in a progressive realization of the right to the highest attainable standard of health would be subject to such jurisdiction in the event of massive human suffering.

In regard to the accountability of States, U.N. Security Council powers include a substantial quasi-judicial component. Determinations regarding whether humanitarian intervention is authorized, whether the use of force is appropriate, or whether economic sanctions should be imposed all require fact-finding and interpretive decision making symptomatic of the judicial function. In order to make such determinations, it would seem logical that the U.N. Security Council would also be required to determine whether a State was 'guilty' of violating international law, whether particular conduct represented a gross violation of human rights, and whether international peace and security were being endangered. Additionally, the fact that both targeted sanctions and humanitarian intervention are increasing would seem to indicate that the powers of the U.N. Security Council, and the nature of human rights violations giving rise to U.N. Security Council action, are subject to judicial' interpretation in light of changing global philosophies.

International judicial machinery has also been substantially strengthened by the new WTO Agreement. While admittedly in a different context,\textsuperscript{890} this Agreement incorporates a large social

\textsuperscript{887} Stephens, \textit{supra} note 24, at 40-44.
\textsuperscript{888} \textit{Id.} at 49.
\textsuperscript{889} See, e.g., \textit{Id.} at 5-6, 34-57 (discussing a multinational approach to domestic remedies).
\textsuperscript{890} See \textit{supra} notes 784-88 and accompanying text (discussing the spirit of the WTO Agreement).
component that recognizes the interdependence of international trade, social and economic development, and the eradication of poverty. By doing so, the WTO is positioned to play a more important role in encouraging the practical realization of human rights by means of promoting higher standards of living, by encouraging special treatment for less-fortunate nations, and by prohibiting discriminatory practices and protectionist measures by more politically sensitive nations. As a result, dispute resolution panel reports that are designed to enforce these mandates and protect the legitimate interests of less powerful nations can in fact have considerable long-term human rights effects. Under the old GATT Agreement, adoption of these reports was dependent upon the unanimous consensus of all GATT members including the actual parties involved in the dispute. Under the new WTO Agreement, this process has been reversed and a report will be adopted (and become binding on the parties) unless there is a consensus against its adoption. Such a reversal has added substantial importance to the WTO dispute settlement function and may contribute not only to the economic development of poor nations, but also to the realization of human rights that generally accompanies that development.

Finally, each of these judicial or quasi-judicial components serves to supplement the more traditional adjudicative functions of the human rights regime addressed earlier in this Article. As discussed in Section 5, adjudicative accountability can be imposed by a number of regional and international bodies both by means of adjudicative monitoring and the use of individual and interstate complaint systems. The African Commission on Human and People’s Rights, for example, is not only empowered to interpret the provisions of the African Charter, but also to hear interstate complaints and to consider “other communications,” including those from individuals. The Committee on Economic, Social and Cultural Rights has transformed its monitoring function into an “influential human rights adjudication procedure” by adopting an

891 LEGAL TEXTS, supra note 26, at 365.
892 See supra notes 626-95 and accompanying text (referring to the adjudicative functions of the human rights regime).
893 See supra notes 656-61 and accompanying text (discussing the powers of the African Commission on Human and People’s Rights).
894 Porter, supra note 569, at 127. For a discussion of Porter’s position, see supra notes 666-71 and accompanying text (stating that Porter believes the Commit-
“adjudicative framework”\textsuperscript{895} for examining claims and by granting NGOs the right to participate in the context of periodic reviews.\textsuperscript{896} The Human Rights Committee has been empowered to hear both interstate and individual human rights complaints in regard to nations that have (respectively) declared under Article 41 of the ICCPR or become parties to its Optional Protocol.\textsuperscript{897} This Committee is of particular import in light of the indivisibility of civil and political rights and economic, social, and cultural rights and in light of the fact that the right to health exerts a determinative influence on the realization of each.\textsuperscript{898} As a result, this Committee has the potential to exert some independent adjudicatory jurisdiction in regard to the right to health by redefining the determinants of civil and political freedoms.

The totality of such human rights bodies—whether emanating from the U.N. Charter, multilateral treaties, regional agreements, or domestic policy—makes it increasingly difficult to deny the progression toward international adjudication. Additionally, the results of these adjudications are in fact subject to enforcement both in terms of coercion and punishment. While it is true that the ultimate performance of an international obligation cannot always be practically mandated, much like the remedy of specific performance cannot always be mandated in civil proceedings, substantial penalties may be imposed for noncompliance. Offending nations may experience international condemnation, the withholding of privileges under a treaty that has been breached, or a retaliation or suspension of concessions under the WTO Agreement or other trade arrangement. Nations may also be subject to a reduction of international aid, a denial or rescission of loans from lending institutions, or a freezing of individual or State assets.\textsuperscript{899}

Both punishment and coercion may also be imposed by means

\textsuperscript{895} Id. at 126.
\textsuperscript{896} Id. at 124-25.
\textsuperscript{897} See supra notes 678-83 and accompanying text (discussing the elements of the Optional Protocol to the ICCPR).
\textsuperscript{898} For a discussion in this regard, see supra notes 603-25 and accompanying text (discussing the indivisibility, interrelation, and interdependency of human rights).
\textsuperscript{899} For a discussion and citations in this regard, see supra notes 688-93 and accompanying text (referring to availability of lawful punishment and valid intervention).
of embargoes or other forms of economic sanction. Some security-based sanctions, for example, can “actually be implemented for humanitarian purposes and are designed to force nations to alter abhorrent policies” or reverse systematic denials of human rights.\textsuperscript{900} It must be admitted, however, that economic sanctions generally hurt people more than their governments. The effects of foreclosing consumer markets, denying economic aid, withholding essential goods and services, and blacklisting the identity of a nation are primarily borne by those most in need.\textsuperscript{901}

On the other hand, the increasing use of ‘smart’ sanctions that apply a particularized approach focusing on the coercion, isolation, containment, and punishment of decision making elites tends to substantially reduce the impact of sanctions on both the civilian population and surrounding geographic region. Such targeted sanctions as travel bans, arms embargoes, diplomatic reductions, and freezes on the assets of governmental leaders and their families also lend themselves to monitoring, inspection and periodic review mechanisms as well as to the use of Sanctions Committees and Panels of Experts.\textsuperscript{902}

Finally, international adjudications may also be enforced by means of humanitarian intervention whenever massive human rights violations or an extreme crisis in public health endangers international peace and security.\textsuperscript{903} While the institutions of the human rights regime are far from perfect,\textsuperscript{904} human rights norms are becoming more clearly defined.\textsuperscript{905} As a result, as the determinants of international peace and security become more comprehensive, and as international trading relationships become more inclusive,

\textsuperscript{900} See Cann, supra note 14, at 465.
\textsuperscript{901} Id. at 466 (citing The Costs and Benefits of Economic Sanctions: The Bottom Line, 89 AM. SOC'Y. INT'L. L. 337, 339-40, 351, 359 (1995) (remarks by Laurence Boisson de Chazournes and W. Michael Reisman)).
\textsuperscript{902} For a discussion in regard to “smart” sanctions, see U.N. Sanctions Secretariat, Smart Sanctions, The Next Step: Arms Embargoes and Travel Sanctions (Dec. 3-5, 2000) (informal paper presented at the Second Expert Seminar, Berlin) (proposing that sanctions directed at specific targets could minimize the adverse humanitarian effects of sanctions).
\textsuperscript{903} For citations regarding the humanitarian intervention debate, see supra note 21.
\textsuperscript{904} See, e.g., Petersmann, supra note 18, at 768, 770, 777, 780-81, 789 (providing examples of regime imperfections and the lessons to glean from them).
\textsuperscript{905} The U.N. Human Rights Regime, supra note 21, at 460 (remarks by Thomas Buergenthal); see also Koh, supra note 13, at 2655-56 (discussing the development of human rights norms).
the likelihood of humanitarian intervention to enforce these norms will continue to grow.\textsuperscript{906} The limitations imposed by the concepts of sovereignty and non-intervention will continue to naturally erode as fundamental common values alter the domestic identities of nations. Whether based exclusively on U.N. Security Council action or on the delegation of U.N. authority to national or regional enforcement organizations,\textsuperscript{907} the exercise of this collective action will in turn alter the realities of global governance.

6.4.3. The Rights of Self-Determination and Development

The existence of an international community, a growing normative and institutional hierarchy within that community, and an identifiable (although limited) set of lawmaking, adjudicatory, and enforcement powers all suggest a progression toward the creation of constitutional relationships both between States and between States and their own citizens. While such a progression is based upon an increasing recognition of a variety of rights, those of self-determination and development are particularly dependent upon the constitutionalization of the right to health.

Both the ICCPR and the ICESCR specifically recognize that all “Peoples” have the right to self-determination. By virtue of this right, they may freely pursue their own economic, social, and cultural development, and they may not be deprived of their own means of subsistence.\textsuperscript{908} This right also recognizes that all Peoples have control over their own “natural wealth and resources”\textsuperscript{909}—including biological and genetic resources\textsuperscript{910}—and that these resources can be traded by those Peoples for a variety of rents such as access to technology, scientific research, and the fruits of utilization or commercialization.\textsuperscript{911} The right of self-determination has been incorporated into the U.N. Charter,\textsuperscript{912} the Vienna Declara-

\textsuperscript{906} See Eisner, supra note 21, at 210-13 (discussing the ascendancy of human rights).
\textsuperscript{907} See Perez, supra note 18, at 421-36 (providing examples of U.N. delegation).
\textsuperscript{908} ICCPR, supra note 125, arts. 1.1, 1.2; ICESCR, supra note 23, arts. 1.1 and 1.2.
\textsuperscript{909} ICCPR, supra note 125, art. 1.2; ICESCR, supra note 23, art. 1.2.
\textsuperscript{910} See CBD, supra note 189, pmbl., arts. 2, 15-19 (discussing the access and exchange of various information and resources).
\textsuperscript{911} See id. arts. 15-19.
\textsuperscript{912} U.N. CHARTER arts. 1.2, 55.
tion,\textsuperscript{913} and the DRD\textsuperscript{914} and it has been consistently mandated by a variety of other General Assembly resolutions and proclama-
tions.\textsuperscript{915} It has been categorized as an "inalienable" right by the United Nations\textsuperscript{916} and is believed, at least by some, to constitute a principle of \textit{jus cogens}.

Unfortunately, the right of self-determination has been traditionally linked to the concept of colonization and the preemption of domestic governance by foreign or alien nations.\textsuperscript{918} Even under such a restrictive perspective, it can be argued that a form of \textit{de facto} colonization results from the external domination of intellec-
tual property rights and the external power to impose universal definitions of those rights.\textsuperscript{919} Domination over production facili-
ties, manufacturing processes, and pricing may also be viewed as a form of colonialism in light of the fact that pharmaceuticals are far from luxury goods. The ability to control the availability of these essential products can be translated into a power to influence the political, economic, social, and cultural structures of a nation. The actual imposition of substantial restrictions on availability, of course, could result in the destruction of those internal structures. While this Article is not suggesting the existence of such a conscious destructive scenario, the mere presence of these powers under-
mines the concept of self-determination by placing the internal health of a nation under the dominion of foreign States. As a re-
sult, the right of self-determination should in fact be applicable to the creation and interpretation of intellectual property rights and it

\textsuperscript{913} Vienna Declaration, \textit{supra} note 101, para. 2.
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\textsuperscript{914} DRD, \textit{supra} note 25, pmbl.
\
\textsuperscript{915} See, e.g., Declaration on the Right and Responsibility of Individuals, \textit{supra} note 1, pmbl.; Declaration on the Use of Scientific and Technological Progress, \textit{supra} note 198, pmbl. (providing examples of resolutions mandating the right of self-
determination).
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\textsuperscript{917} See Macdonald, \textit{supra} note 18, at 207 ("[T]he obligation to promote and encourage respect for human rights... appears to have reached the status of \textit{jus cogens}").
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\textsuperscript{918} For a discussion regarding self-determination, decolonization, and an expansion of this right, see Perez, \textit{supra} note 18, at 405-12.
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\textsuperscript{919} In regard to issues surrounding the TRIPS Agreement and imperialism, see Marci Hamilton, \textit{The TRIPS Agreement: Imperialistic, Outdated, and Overprotective}, 29 \textit{VAND. J. TRANS. L.} 613 (1996); Oddi, \textit{supra} note 29.
should serve as a foundation for imposing legal limitations on external forces that might frustrate its realization.

It can also be argued that the concept of self-determination should not be limited to the relationships between nations (and the exercise of power by one State over another), but should also include the constitutional relationship between a State and its own citizens. Such an argument would reflect the fact that States do not have the right of self-determination. Instead, this right has been specifically vested in the various "Peoples" of the international community. If Peoples have been endowed with this right, it would seem logical that a State, as personified by its current governmental regime, would not have the right to interfere with the self-determination of its people.

Because 'States' and 'Peoples' are independent concepts, the Peoples' right to self-determination must be protected from State interference whether that interference be foreign or domestic in origin. If this were not so, there would be no logic in the distinction between 'States' and 'Peoples' that has been recognized in all human rights instruments addressing this particular right. Similarly, if self-determination is in fact an inalienable right, it is not an inalienable right of the State but a collective right of the people of that State. As with all inalienable rights, the right to self-determination precedes the State, is not created by the State, and is independent from the State. It can not be denied by means of foreign interference or by means of the domestic policies of a particular Peoples' territorial government.

While the right to self-determination is collective in nature, the right to development provides both collective and individual rights. In the DRD, the U.N. General Assembly described development as "a comprehensive economic, social, cultural and political process, which aims at the constant improvement of the well-being of the entire population and of all individuals on the basis of their active, free and meaningful participation."920 The Declaration recognizes the human person as the "central subject" of this process and as both its main participant and its primary beneficiary.921 The right to development is also viewed as an "inalienable human

920 DRD, supra note 25, pmbl. (emphasis added).
921 Id. pmbl., art. 2.1; see also Vienna Declaration, supra note 101, para. 10 (echoing the Universal Declaration by recognizing that the "human person is the central subject of development").
right" by which all Peoples and all individuals are entitled to enjoy economic, political, social and cultural progress. While certainly a more 'positive' right in nature, the right to development is also viewed as interdependent with the right of self-determination and as an integral part of all fundamental human rights.

The right to development also possesses a substantial distributive component that fundamentally influences the relationships among nations. All people, for example, have the right to share in the benefits resulting from social and economic development including those emanating from scientific advancement and its applications. Such a fact is specifically recognized in the Universal Declaration and it can be argued that a variety of other international instruments reflect similar distributive obligations. The TRIPS Agreement recognizes that the protection of intellectual property rights should contribute to the transfer and dissemination of technology to the mutual benefit of producers and users and should be employed in a manner that is conducive to social and economic welfare. It also specifically mandates that developed country Members provide incentives to their domestic enterprises and institutions for the purpose of promoting and encouraging technology transfer to least-developed countries. The CBD speaks in terms of an "equitable sharing" between developed and developing nations of the benefits arising from the utilization of traditional knowledge. It also provides for the promotion of broader participation in scientific research, the exchange of information among States, the facilitation of both public and private sector technology transfer, and the sharing in a fair and equitable way of the results of R&D and the fruits of genetic resource com-

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922 DRD, supra note 25, art. 1.1; see also Vienna Declaration, supra note 101, para. 10 (stating that "the right to development [is] a universal and inalienable right and an integral part of fundamental human rights").

923 See, e.g., DRD, supra note 25, art. 1.2 ("[T]he human right to development also implies the full realization of the right of peoples to self-determination.").

924 Vienna Declaration, supra note 101, para. 10.

925 See, e.g., id. para. 11; ICESCR, supra note 23, art. 15.1(b); DRD, supra note 25, pmbl.; Declaration on Social Progress and Development, supra note 617, art. 13(a).

926 Universal Declaration, supra note 118, art. 27.1.

927 TRIPS Agreement, supra note 26, art. 7.

928 Id. art. 66.2. This mandate was reaffirmed in the Declaration on TRIPS. Declaration on TRIPS, supra note 28, para. 7.

929 CBD, supra note 189, art. 8(j).
mercialization.\textsuperscript{930}

In recognizing the importance of scientific and technological progress to the social and economic development of poorer countries (and that the transfer of science and technology is one of the principle ways for accelerating both development and the realization of human rights and fundamental freedoms), the U.N. General Assembly has taken the position that States have the duty to cooperate in establishing and strengthening the scientific and technological capacity of developing nations.\textsuperscript{931} As a result, the country of origin of a particular form of development and the country of origin of the potential recipients of developmental benefits should no longer be separated by strict national or proprietary boundaries.

These international agreements recognize that the creation of the conditions necessary for development is the "primary responsibility" of the domestic State.\textsuperscript{932} Each State owes a duty to its own citizens to formulate appropriate national policies (both internal and external) for the promotion of this right and to take the practical measures necessary to advance its realization.\textsuperscript{933} Individual States also have the duty to prevent outflows of capital that are detrimental to economic and social development\textsuperscript{934} and to take appropriate action to extend the benefits of science and technology "to all strata of the population."\textsuperscript{935}

Simultaneously, all States (both individually and collectively) also have the duty to create international conditions that are favorable to the realization of this right in countries other than their own. Accordingly, all States have the duty to cooperate with each

\textsuperscript{930} Id. arts. 15-19. In such a regard, see also Declaration on Social Progress and Development, supra note 617, arts. 13(a), 24(c) (calling for the "equitable sharing of scientific and technological advances" and "increased utilization of science and technology for social and economic development . . . ").

\textsuperscript{931} Declaration on the Use of Scientific and Technological Progress, supra note 198, pmbl., paras. 1, 5, 7 ("All States shall co-operate in the establishment, strengthening, and development of the scientific and technological capacity of developing countries with a view to accelerating the realization of the social and economic rights of the peoples of those countries.").

\textsuperscript{932} DRD, supra note 25, pmbl.

\textsuperscript{933} See id. arts. 2.3, 8.1; see also Declaration on Social Progress and Development, supra note 617, pmbl. (stating that it is "of cardinal importance to accelerate social and economic progress everywhere" and that "the primary responsibility for the development of the developing countries rests on those countries themselves").

\textsuperscript{934} Declaration on the Social Progress and Development, supra note 617, art. 16(d).

\textsuperscript{935} Declaration on the Use of Scientific and Technological Progress, supra note 198, para. 6.
other to ensure universal economic and social development, to eliminate obstacles to that development, to supplement national efforts aimed at raising standards of living, and to formulate international policies for the purpose of facilitation.⁹³⁶ In light of the fact that the promotion of economic and social progress is one of the fundamental purposes of the United Nations⁹³⁷, and in light of the fact that developmental status (or social and economic condition) is a fundamental determinant of international peace and security⁹³⁸, the recognition of such universal duties is quite understandable.

The interplay between the inalienability of self-determination and development and the duties that are imposed upon individual States and the international community evidences something more than mere contractual relationships. While these rights are consistently recognized in a variety of treaties and declarations, they are not created by those instruments. Instead, these rights exist independently and define the relationships (in terms of limitations on governmental powers) between domestic governments and their citizens and between the international community and the nations and individuals that constitute its global citizenry. The duty to protect these rights, as well as the duty to refrain from interfering with their realization both domestically and in other nations, is a responsibility that is inherent in the definition of a lawful State. When combined with domestic and international adjudicatory, lawmaking, and enforcement mechanisms, these duties take on a progressively constitutional nature.

As has been consistently argued, the physical health of a citizenry determines the health of its economic, social and political structures. Whether viewed in terms of stability, educational op-

⁹³⁶ See DRD, supra note 25, arts. 3.1, 3.3, 4.1 ("States have the primary responsibility for the creation of national and international conditions favourable to the realization of the right to development."); see also Vienna Declaration, supra note 101, para. 10; Declaration on Social Progress and Development, supra note 617, art. 9 ("Social progress and economic growth require recognition of the common interest of all nations . . . beyond the limits of national jurisdiction.").

⁹³⁷ See U.N. CHARTER pmb., art. 55 ("[T]he United Nations shall promote . . . conditions of economic and social progress.").

⁹³⁸ See, e.g., Declaration on Social Progress and Development, supra note 617, pmb. ("Convinced that international peace and security . . . and social progress and economic development . . . are closely interdependent and influence each other."); see also U.N. CHARTER art. 55 (stating that the U.N. promotes economic and social progress "with a view to the creation of conditions of stability and well-being").
portunity, productivity, or agricultural and industrial infrastructure, the rights of self-determination and development are absolutely dependent upon the progressive realization of the right to the highest attainable standard of health. To recognize ‘constitutional’ duties in regard to one and not the other would represent an exercise in futility.

6.4.4. Restraining Interference and Increasing the Capacity to Obey

Not only do all nations have the duty to engage in progressive realization, they also have the duty to refrain from interfering with legal obligations that have been validly undertaken by other States. Treaties such as the ICESCR, for example, have established contractual relationships between nations which reflect mutual promises to pursue the progressive realization of the right to the highest attainable standard of health. As a result, activities that interfere with the ability of a nation to honor its treaty commitments to other nations or that frustrate the fulfillment of those contractual obligations should be viewed with substantial suspicion. Similarly, actions that interfere with the ability of a State to meet its domestic contractual obligations—created by means of valid domestic legislation establishing duties between a State and its citizens—must also be severely questioned.

The proper balance between lawful IPR policy and unlawful interference is difficult to establish. While all nations have the sovereign right to create their own domestic IPR regime, mandating the domestic IPR policy of another nation would constitute interference. Requiring a foreign nation to adopt a particular exhaustion policy would also fall within the latter of these categories. Similarly, while nations may not have the duty to supply particular products (such as pharmaceuticals), no State should have the right to dictate the export policy decisions of other countries such as India, China, or Brazil.

The notion of interference is particularly important in light of the nature of IPR regimes. Developed countries, for example, have no duty to ensure that the contractual obligations undertaken by other countries are in fact fulfilled where those obligations are between different States or between a State and its own citizens. Instead, the fulfillment of those responsibilities is the duty of the ob-
ligated State. Thus, it can be argued that developed nations have no legal duty to ensure the provision of adequate education, housing, food, or other necessities for the citizens of foreign countries. At the same time, developed nations have not chosen to establish a statutory regime that actually withholds the provision of these necessities or that inhibits the realization of these rights.

In contrast, IPR regimes inherently create a legal framework by which access to pharmaceuticals is restricted and barriers to realization are governmentally condoned. By their very nature, such regimes legalize market dominance, allow monopolistic pricing, and prevent other producers from meeting the demands of consumers. While the need to provide incentives and rewards for inventive activity is beyond question, the unique problems created by IPR policies must be carefully scrutinized. Not only may these policies interfere with the realization of the right to health, they may also interfere with the realization of civil and political rights, the rights of self-determination and development, the rights to subsistence and to family, and the rights to social and cultural advancement.

Perhaps in recognition of such a fact, numerous international instruments have acknowledged both the duty to refrain from creating "obstacles" to the realization of human rights and the duty to "eliminate" obstacles to global development. Nations have also been directed to "respect the enjoyment of the right to health in other countries" to prevent both third parties and international agreements from interfering with the global realization of this right and to refrain from activities that are inconsistent with the achievement of higher standards of living, economic and social progress and the resolution of health-related problems.

At the opposite end of this spectrum lies the issue of 'capacity.'

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939 See, e.g., Vienna Declaration, supra note 101, paras. 10, 13, 31 ("States should eliminate all violations of human rights . . . as well as obstacles to the enjoyment of these rights."); see also DRD, supra note 25, art. 6.3 (stating that States "should take steps to eliminate obstacles to development resulting from failure to observe civil and political rights").

940 Substantive Issues, supra note 3, para. 39 (emphasis added). While this particular provision is aimed at Parties to the ICESCR, this Article takes the position that its basic objectives are in fact applicable to all States.

941 Id.

942 See U.N. CHARTER arts. 2.4, 55, 56 ("All Members shall refrain in their international relations from the threat or use of force against the territorial integrity or political independence of any state.").
In order for binding constitutional principles to develop, and in order to create a global legal framework wherein nations must obey those principles rather than merely comply with them, States must possess the actual capacity to adhere to those constitutional mandates. International norms that establish standards that are impossible to carry out cannot give rise to a breach of duty when adherence is lacking. The willingness of a particular nation to recognize certain fundamental principles—whether by means of ratifying a treaty, enacting domestic legislation, or recognizing customary law—becomes irrelevant for all practical purposes in the presence of incapacity.

In theory, all nations inherently possess the capacity to engage in the progressive realization of the right to the highest attainable standard of health. The level of that capacity (and thus the speed of that progression) will of course vary dramatically from State to State. Nevertheless, any nation that devotes even one dollar of public funds toward the provision of health care services is in fact engaged in a 'progression.'

On the other hand, the capacity of poor nations to meet progressive constitutional obligations can be enhanced in a variety of ways. Increased international trade, for example, does not merely redistribute global wealth, but also creates additional wealth that can benefit less-developed nations. Both the philosophy of the WTO Agreement and its exceptions, preferences, and diminished expectations of reciprocity can also serve to expand the ability of poorer nations to obey international law. Increasing the interaction of international constituents whether they be governmental officials, businesspeople, NGOs, students, or even tourists, can enhance the economic capacity to obey and can serve to stimulate social demand for practical solutions to the problems that accompany incapacity. As global actors become more aware of both potentialities and the obstacles to their achievement, pressure for change inevitably follows.

Viewed from its most basic perspective, the capacity to meet developing constitutional duties is primarily a function of money.

943 In regard to elements necessary for creating obligatory norms and treaty regime compliance (including the element of capacity), see Oscar Schachter, Towards a Theory of International Obligation, 8 VA. J. INT'L L. 300 (1968) and ABRAM CHAYES & ANTONIA HANDLER CHAYES, THE NEW SOVEREIGNTY: COMPLIANCE WITH INTERNATIONAL REGULATORY AGREEMENTS (1995) (both cited and discussed in Koh, supra note 13, at 2622 n.113, 2638).
Political and social recognition, even when accompanied by an absolute willingness to comply, must be supplemented by the financial resources upon which progression is based. Third World debt, for example, has reached unacceptable levels. According to the World Bank’s Global Development Finance database 2004, the total external debt of developing countries was over $2.33 trillion at the end of 2002.\textsuperscript{944} Of that amount, $872 billion was owed to public-sector creditors\textsuperscript{945} while $1.466 trillion was owed to creditors in the private sector.\textsuperscript{946} The external debt of AIDS-stricken Sub-Saharan Africa reached $210 billion, while that of Latin American and the Caribbean was over $727 billion.\textsuperscript{947} In light of the tremendous burdens involved in the servicing of this debt, arguments in favor of debt cancellation have gained substantial credence. While debt cancellation may represent a cost to creditors, those costs may be far outweighed by the benefits that could result. Increased standards of living, the creation of vast numbers of new consumers, the amelioration of economic, social, and political instability, the enhancement of the capacity of nations to obey and implement international law, and the prevention of future epidemics would all ultimately benefit the international community.

The lack of financial resources can of course be addressed by a variety of other mechanisms as well. Foreign aid (without expectation of repayment) and increased direct foreign investment can both enhance a nation’s capacity to obey. The provision of technical assistance, the legislating of incentives for the purpose of encouraging technology transfer from domestic enterprises to poorer nations,\textsuperscript{948} and the creation of a more equitable balance of benefits between the owners of IPRs and the owners of traditional knowledge and biological resources\textsuperscript{949} would all serve to increase the ability of nations to meet their constitutional responsibilities. Sub-

\textsuperscript{945} Id. at 224 tbl.B.47.
\textsuperscript{946} Id. at 225, tbl.B.48.
\textsuperscript{947} Id. at 219, tbl.B.42.
\textsuperscript{948} See TRIPS Agreement, supra note 26, art. 66.2 (requiring agreement Members to provide "incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country" Members).
\textsuperscript{949} See, e.g., CBD, supra note 189, arts. 1, 8(j), 15, 16 (stating that parties should share results of research and development).
stantial catalysts could also be provided by recognizing that traditional knowledge is an IPR, by creating royalty systems for the suppliers of genetic materials, and by using differential pricing mechanisms that reflect both the limited purchasing power and the fundamental contributions of the developing world. Whatever the mechanism selected, investing in the financial health of other nations, and supplementing the willingness to obey with the capacity to obey, would provide a practical stimulus to the progression toward global constitutionalism in the area of human rights.

6.5. A Concluding Synthesis: Constitutionalizing Global Public Health

Since the United Nations issued its Declaration of Commitment in 2001,950 the HIV/AIDS crisis has widely been accepted as an issue of human rights. While such a recognition was landmark in nature, global public health must now be viewed in terms of the constitutional rights of individuals and the constitutional duties of the domestic and international communities. The right to the highest attainable standard of health—whether recognized as a fundamental human right under the Universal Declaration and its prodigies or as an absolute determinant for the achievement of rights that are in fact viewed as fundamental—imposes a constitutional mandate on all governments in regard to progressive realization. Additionally, in order to give practical effect to universally recognized human rights, the global legal structure must assume the implied authority to enforce this mandate. Without such an implication, the indivisibility of these rights will transform their inalienability into legal fiction.

The establishment of constitutional rights and duties in regard to the HIV/AIDS epidemic and other public health crises is based upon both the totality of the international legal regime and its capacity to engage in incremental constitutionalization. A conception of international law that focuses upon the frailties of individual instruments or the lack of traditional structural mechanisms ignores the fact that universally binding principles have developed from a totality of treaties, customary law, and other expressions of global unity, and that international institutions possess the legal capacity (although not always the political willingness) to enforce

950 Declaration of Commitment, supra note 3.
those principles. It also ignores the fact that constitutional rights and duties may result from an evolutionary process (with no finite beginning or end) whereby relationships become constitutionally binding even in the absence of a formally recognizable constitution. The right to be free from torture, for example, need not await the creation of a global legislature.951

By viewing the constitutive process progressively, this Article has argued that constitutional rights and duties may be created incrementally and need not be dependent upon the completion of such a process. While the nature of these relationships will become more defined over time (and more recognizable international enforcement machinery will be developed), this Article suggests that constitutional relationships can in fact be created along the way. Because these obligations are capable of developing outside traditional lawmaking mechanisms, formal State action becomes less critical for their evolution and binding law may precede (rather than be a product of) formal international institutionalization.952

This incremental process has resulted in the creation of a number of peremptory human rights principles that cannot be defined as voluntary or contractual in nature. These fundamental norms establish a global hierarchy of values that preempts the traditional rights of individual sovereigns and reflects a transition from international law to international constitutional law in the field of human rights. Based upon the logic that inalienability and the need for consent are contradictory notions, these rights require neither State conferral nor State acquiescence. Additionally, their indivisibility mandates that they cannot be recognized on a piecemeal basis, that their particular origins cannot be examined in isolation, and that they cannot be neatly categorized into exclusive groups with artificially distinct mechanisms of accountability.

Similarly, the right to the highest attainable standard of health cannot be reduced to the provisions of multilateral agreements. While extremely important, these treaties form only a part of a more fundamental global, regional, and normative framework that has created a series of unifying principles in the area of public health. Under such a structure, the withholding of available treatment or the refusal to undertake the degree of progressive realiza-

951 See, e.g., supra notes 709-56 and accompanying text (discussing how rights and duties may be established incrementally).
952 See id.
tion that is congruent with available resources should be viewed as an interference with the achievement of inalienable rights and as a threat to international peace and security.

A requirement of 'congruence' would inherently recognize that the reasonableness of the relationship between progression and available resources is subject to both measurement and judicial (or quasi-judicial) review. It would also acknowledge the fact that the doctrine of progressive realization is not a defense to be used to escape responsibility, but a lens through which governmental activity may be evaluated and accountability may be imposed. While a requirement of congruence would certainly not equate the duty to 'progress' with a duty to 'fulfill,' it would demand that the issue of available resources be examined in the context of a broader and more rigorous analysis. The availability issue would be relevant in regard to the tempering of obligations and the reduction of external expectations, but it would not be dispositive of governmental compliance. All nations would be held to possess some capacity to progress whether based upon the existence of financial resources, the ability to promote human rights, the ability to refrain from interfering with fundamental freedoms, or the ability to exercise the lawful flexibilities provided for in international agreements. As a result, while the definition of reasonable progression would remain variable, the duty to pursue progressive realization would remain constant.

While the concept of congruence is primarily directed at the duties of national governments, the demands of progressive realization are not limited to the domestic setting. The refusal of a State to engage in progressive realization, as well as foreign interference with the ability of a nation to meet its domestic obligations, would constitute a violation of international law. Additionally, all nations have already accepted a variety of contractual and customary duties that have public health implications, including those surrounding human rights, technology transfer and scientific advancement, self-determination and development, and international peace and security. As argued earlier, the synthesis of these international

953 See supra notes 540-602 and accompanying text (discussing the necessity of requiring a right of health, while simultaneously allowing a period of progression).

954 See supra notes 590-602 and accompanying text (discussing the responsibility of various countries and the private sector to progressively realize the right of health).
relationships creates a duty of progressive realization that far exceeds the sum of its domestic parts.

By viewing fundamental human rights within a context of global constitutionalism, and by establishing progressive realization of the right to the highest attainable standard of health as an implicit constitutional duty, issues surrounding global public health acquire symmetry with similar preemptive norms. Like other human rights, the concept of public health is directed at individuals rather than at the relationships among nations. Nationality and territorial boundaries give way to universality. Consent by treaty ratification gives way to consent by means of membership in the community of lawful States. While such an approach necessitates a reassessment of the nature of constitutions and the process by which they come into being, this Article has suggested that the fundamental components of constitutionalism can be identified within the international human rights setting.

This Article has argued that the rigid distinction between domestic hierarchy and international anarchy must be discarded in favor of non-exclusivity and a theory of progressive hierarchy-building. It has also argued that there is in fact an international 'community' where that term is defined as a relationship among individuals or States by which the self-interest of those constituencies has become subservient to the common interests of the whole. The preeminence of social interest within an identifiable group, whether that group is identified territorially or in terms of adherence to a particular set of subject matter norms, creates the foundation for a constitutional community in which all members are bound irrespective of consent. In the area of global public health, a subject matter constitutional community is developing wherein parochial values and domestic economic interests are deferring to more universal needs. Such a progression will be stimulated by the inevitable pursuit of liberalism, by which individuals refuse to accept a territorialization of human rights and increasingly demand the ability to participate in economic, social, and political decision making. As fundamental principles continue to be recognized, the international community gains an identity that will be

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955 See supra notes 812-25 and accompanying text (explaining the need for an international hierarchy, as well as the existence of a "relative" international hierarchy).

956 See supra notes 794-806 and accompanying text (noting the ways in which an international community already exists).
progressively redefined over time by the increasing expectations of the people and the practical demands of interstate actors.957

This Article has also suggested that despite the lack of traditional forms of autonomous institutions that are generally associated with domestic constitutional settings, there is an undeniable progression toward a system of international accountability.958 The totality of domestic proceedings, regional and international monitoring and adjudication, and individual and interstate complaints, implies the existence of hierarchical coercion in regard to fundamental common values. These procedures are also combined with a variety of formal and informal lawmaking mechanisms,959 fact finding and interpretive procedures, and a means for imposing punishment through multilateral sanctions, financial penalties, U.N. Security Council measures, and humanitarian intervention.960 Since there can be no legitimate non-members of the human rights community, such a system is, by definition, binding upon all States. The ability of this subject matter community to impose lawful mandates on all constituencies and to take lawful action (even if sporadic) against States that violate those mandates certainly suggests the presence of a continuum upon which constitutional rights and duties are being developed.

The premise of a progressive global constitutionalism is accompanied by a variety of practical and legal ramifications. It may be initially noted that while progress is being made within the area of global public health, the lack of adequate resources continues to frustrate the realization of significant goals. The WHO's HIV/AIDS initiative to treat three million individuals by 2005, for example, may already be collapsing from the lack of financial support,961 and donations to the Global Fund to Fight AIDS, Tuberculosis and Malaria are now reaching only 20% of the yearly target

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957 See supra notes 757-93 and accompanying text (referring to the spread of liberalism and individual rights across national boundaries).

958 See supra notes 626-95 and accompanying text (discussing the development of accountability of states for the provision of international human rights).

959 See supra notes 846-76 and accompanying text (mentioning the organizations that work to insure international human rights).

960 See, e.g., supra notes 877-907 and accompanying text (discussing institutional and non-institutional sources of international judicial and executive action).

set by Secretary General Kofi Annan. As a result, substantial tensions will continue to exist between the undeniable need to spur innovation through the provision of financial incentives and rewards and the need to acquire access to pharmaceuticals at the lowest possible price. Elevated notions regarding the status of IPRs within the global hierarchy of values, as well as western conceptions of property, ownership, and exclusivity, will continue to erect artificial (State created) barriers to the fulfillment of inalienable rights.

This Article has argued that pursuant to the substantial flexibility found in the TRIPS Agreement, these ideological differences (and the ultimate provision of greater access to pharmaceuticals) need not create a conflict as a matter of law. A nation's consent to be bound by the terms of the Agreement cannot be equated with its consent to enforce all western notions of IPRs or to adopt the judicial history of western systems. Ample discretion exists under the subjective language of articles 7, 8, and 27—as well as under the exceptions found in articles 30, 31, and 73—for nations to develop an IPR policy that is consistent with their individual social, economic, and public health needs.

Under the progressive constitutionalism argument being advanced in this Article, the ability to exercise this discretion in the pursuit of the highest attainable standard of health is transformed from a sovereign right to a constitutional duty. The political and ideological conflict that will result from the fulfillment of this duty can give rise to either increased tensions between rich and poor nations or a new concept of international relations in the area of public health. Nations should take the opportunity to acknowledge that IPRs are only one of the values within a total value hierarchy and recognize that existing conflicts and their resulting compromises can be approached as constitutive in nature.

This Article also suggests that the international community is

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962 Id.

963 See supra notes 152-77 and accompanying text (discussing the rise of intellectual property as property with rights and contrasting it with other views of "rights").

964 See supra notes 277-437 and accompanying text (discussing the flexibility of the TRIPS Agreement).

965 See supra notes 438-602 and accompanying text (stating a duty to exercise the flexibility of the TRIPS Agreement).
already in the midst of a 'constitutional moment'\textsuperscript{966} in regard to the issue of global public health. The Declaration on TRIPS and its Decision on Implementation, as well as the moratorium against non-violation complaints,\textsuperscript{967} the tremendous expansion of private actor involvement, and the repeated global expression that some rights are in fact superior to others, all indicate that binding norms are developing even in the absence of traditional lawmaking machinery. These actions—together with the increasing number of human rights treaties and declarations, the growth of humanitarian intervention, and the developing emphasis on the rights of women, children and other disadvantaged groups—are actually signaling a new understanding of global duties and interstate relationships. Such an understanding no longer reflects the policy decisions of individual governments, but the fundamental rights and fundamental needs of the people in the face of an overwhelming public health crisis.

From a domestic perspective, one of the major ramifications of constitutionalizing the right to the highest attainable standard of health would be a substantial increase in the availability of legal relief. Since the right to health would inherently constitute the domestic constitutional law of all nations, each State would have the constitutional duty to engage in progressive realization irrespective of whether its actual domestic constitution or statutory regime provided for such a right. All citizens would be empowered to bring individual complaints before competent local tribunals whenever those domestic constitutional rights were being violated. While individual complaints could not seek the impossible, and the validity of complaints would be judged in light of the availability of resources, the existence of constitutional rights and a total absence of judicial enforcement would logically constitute an oxymoron.

As was held in Treatment Action Campaign,\textsuperscript{968} judicial systems are in fact capable of determining the reasonableness of govern-

\textsuperscript{966} In regard to "constitutional moments," see ACKERMAN, FOUNDATIONS, supra note 17; see also supra notes 736-41 and accompanying text (discussing Ackerman’s beliefs).

\textsuperscript{967} See supra notes 431-32 and accompanying text (stating that Article 64 prohibited non-violation complaints for five years, and that this prohibition has been extended by the Ministerial Declaration at Doha).

\textsuperscript{968} See supra notes 528-38 and accompanying text (discussing Treatment Action Campaign v. Minister of Health, 2002 (4) BCLR 356 (T) (S. Afr.)).

https://scholarship.law.upenn.edu/jil/vol25/iss3/1
mental action and whether that action has complied with the demands of progressive realization. While courts should not be allowed to substitute their own policy judgments for those of executive or legislative bodies, courts have always had the duty to interpret constitutional rights and to determine whether those rights have been violated. Deference to governmental decision making has never been interpreted as requiring deference to governmental indifference. Accordingly, the ability to institute individual complaints would logically flow from the duty of judiciaries to enforce *domestic* constitutional mandates whether those mandates were created by means of a traditional domestic constitution or by means of a domestically binding international constitutive norm.

The imposition of a constitutional duty to engage in progressive realization may also mandate a variety of other fundamental changes within domestic statutory regimes. This Article has argued, for example, that the capacity to progress is not solely dependent upon the availability of financial resources. A 'progression' toward the right to the highest attainable standard of health also encompasses the elimination of discrimination against women, the abolition of harmful traditional practices, the prohibition of both invasions of privacy and the dissemination of misleading information, and the development of policies aimed at raising needed capital. Since the promotion of such policies can often be accomplished without adverse economic effect, even the poorest of nations can be held to constitutional responsibilities in their regard. In order to meet those responsibilities, substantial statutory revision may become necessary.

From an international perspective, this Article has argued that the constitutionalization of the right to health primarily imposes three fundamental responsibilities on the global community. First, regional and international human rights regimes (including the U.N. Security Council) have the duty to enforce constitutional norms and to punish those governments that fail to comply with lawful expectations. Second, all nations have the duty to refrain from unlawful interference with the realization of the right to health in other nations. While interference is admittedly elusive, its application will ultimately depend upon the distinction between mere passivity and active policy making, the degree of socioeconomic consequence, and the effect on the rights of development and self determination. Third, a subject matter constitutional rela-
tionship between nations also increases the duty to enforce the positive obligations that have been accepted by members of that community. Some of those duties are admittedly tenuous in their legal effect, being based upon promises to 'promote' or to 'cooperate' in the realization of human rights. In contrast, others are quite tangible in character, and establish enforceable duties regarding technology transfer, incentives for development, equality, non-discrimination, trade preferences, and the maintenance of international peace and security. In each of these instances, the global community has been accepting increasing responsibility for raising the capacity of all nations to meet their constitutional duties and to 'obey' the norms of international law.

Finally, the existence of a constitutional community, even when limited to the subject matter of human rights, fundamentally alters the dynamics among the domestic and international members of that community. In a constitutional entity, not only do the actions of the majority bind all members, but the more elusive duties of promotion, cooperation, and interference tend to gain additional credence. Constitutionalism also removes a substantial degree of discretion from governmental regimes as constitutional rights serve to preempt other governmental priorities of a non-constitutional nature. While not intending to degrade any particular policy, it must be admitted that there are no constitutional rights or duties surrounding most governmental programs, expenditures, or subsidies and there is certainly no constitutional foundation in regard to excessive spending, patronage, or profitmaking by governmental officials.

In contrast, the right to the highest attainable standard of health imposes a constitutional duty to dedicate economic and policymaking resources to achieve the progressive realization of that right. While methods of implementation will always be subject to policy judgments, the priority of constitutional rights over non-constitutional rights cannot be open to debate.

This Article does not pretend to impose particular policy decisions on domestic governments or international regimes. The manner in which a duty is carried out will vary widely and governments must enjoy the necessary flexibility to address their own social and economic condition. Nevertheless, it must be reiterated that the HIV/AIDS epidemic is posing the most serious public
health crisis in more than 600 years. Under such a circumstance, it would seem quite logical to argue that domestic and international constitutional communities are in fact bound to place substantial emphasis on the HIV/AIDS epidemic in fulfilling their duties of progressive realization. With almost twenty-eight million fatalities and another forty million living with the infection, governmental policies that are either retrogressive or merely passive in nature must be viewed with substantial suspicion.

As a result, this Article suggests that nations experiencing the HIV/AIDS crisis must (as a matter of law) invoke the compulsory licensing provisions of Article 31 of the TRIPS Agreement. Where domestic production capacity is lacking, those nations must instead invoke the compulsory licensing scheme provided by the Implementing Decision of the Declaration on TRIPS. In the further event that compulsory licensing proves to be inadequate or overly burdensome—whether economically, politically, or bureaucratically—nations must exercise their rights under the security exception of Article 73 of the TRIPS Agreement and acquire pharmaceuticals from producers capable of selling at the lowest possible price. Similarly, in meeting their responsibilities toward other communal States, drug-producing nations are under the duty (even if only phrased in terms of promotion and cooperation) to exercise their rights under the security exception and the Decision on TRIPS to export pharmaceuticals to populations in need. While governments of exporting nations inherently possess more legal discretion than those of HIV/AIDS stricken States, duties to export may certainly be based upon enumerable promises to aid in global development, to promote human rights and self-determination, to respect the right to health in other countries, to facilitate access to pharmaceuticals, and to take action for the maintenance of international peace and security. Additionally, the duty to export can be supplemented by the fact that exporting nations have the duty to protect their own citizens from possible invasion of the epidemic and to take preventive measures in such a regard.

969 See supra note 32 and accompanying text (describing HIV/AIDS as the most lethal epidemic since the Black Death 650 years ago).

970 See supra notes 33-41 and accompanying text (discussing the large numbers of people infected with HIV/AIDS and the signs that the epidemic is only in its early stages).

971 See, e.g., Substantive Issues, supra note 3, para. 39 (describing the international obligations of States).
This Article also suggests that, in addition to statutory revision in such areas as discrimination and the right to privacy, nations have the legal duty to consider (and to implement whenever appropriate) a variety of intellectual property policy alternatives. Nations must consider, for example, the relative merits of creating statutory protection in regard to the use of traditional knowledge and the appropriation of genetic resources. They must also consider the effects of establishing both a royalty system that reflects the level of those contributions and a system of taxation on intellectual property that recoups those contributions later in the commercialization chain. Either of these systems, assuming they do not violate anti-discrimination or national treatment provisions, can be targeted at specific products and tailored to meet a particular domestic health crisis.

On the other hand, all nations benefit from advances in medical science and from the development of life-saving pharmaceuticals, both of which can be initially dependent upon the resources of less-developed countries. As a result, royalty and taxation systems can also be approached from a more universal perspective. This Article argues that the progression toward a human rights constitutional community increasingly transforms individual States into citizens of a higher polity with rights progressively emanating from (and duties progressively owed to) that common entity. Within such a dynamic, a system of royalties or ‘fees’ that would be federative in character could, at least conceivably, be envisioned. Under such a system, each State-citizen would be required to contribute to a global public health fund in proportion to an established index. While contributors could be given credits upon which to draw, the resources generated would be available for addressing any public health crisis irrespective of geographic location or level of contribution. Parenthetically, it should be emphasized that mandated contributions may be more than offset not only by future savings in health care costs, but by reductions in such expenditures as those surrounding military responses to civil unrest and regional destabilization.

Simultaneously, the progressive realization of the right to the highest attainable standard of health also requires that all nations protect the viability of the pharmaceutical industry and to ensure

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972 In regard to the potential taxation of IPR, see supra notes 425-28 and accompanying text (discussing Abbott).
the continuing process of R&D. Much like individual nations provide incentives and support to domestic drug companies, a constitutional dynamic would require the international community to provide a federative foundation for the 'global drug industry.' Differential pricing, for example, would be strongly encouraged and strict standards would be imposed for the prevention of diversion. Safety and purity standards could be uniformly enforced and suppliers of fraudulent or worthless medications could be held accountable. Economies of scale could be established in terms of purchasing power, distribution, and administration. Financial incentives could be offered for innovation, and supplemental R&D support could be made available, pursuant to similar international funds generated by mandated royalty/fee contributions.

While discussions regarding the creation of federal relationships and the mandating of financial contributions may appear utopian, the progression toward a global constitutionalization of human rights and public health is far from the theoretical. To the contrary, nations that view the issue of public health as territorial in nature or that attempt to compartmentalize human rights on the basis of geography, economic or political status, or artificial classifications are only promoting parochial fantasy. To ignore the effects of the HIV/AIDS epidemic on the world's economy, on its political stability, and on its ultimate peace and security is not only a denial of the progression toward constitutionalism, it is the imposition of a delusional, unsustainable, and repressive form of isolationism.

With fourteen thousand individuals being infected each day, the HIV/AIDS crisis has served to highlight the frailty of mankind. That frailty, however, also defines a fundamental commonality among all people that is proving to be more sustainable than the traditional policies of individual governments or the proprietary claims of powerful interest groups. Despite economic, social, and political differences, it is the individual who is the fundamental unit of the global human rights society and it is the individual who will stimulate both the domestic and international constitutional process. While particular governmental regimes may attempt to impose different sets of values, the desire for inherent dignity, equality, and the rights to life and health is truly shared by most individuals. As a result, this Article argues that not only have re-

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cent public and private actions signaled a progression toward global constitutionalism in the area of human rights and public health, but that common values, needs, and demands of individuals are in fact at the basis of that progression. While the pace of this movement will continue to be influenced by the realities of mistrust, animosity, and conflict, its evolution will remain inevitable. In light of that inevitability, and in light of the very troubling nature of the alternative, the international community would be well served to take an increasingly constitutional approach to the HIV/AIDS crisis and to actually embrace the broader context and the boundless potential of progressive constitutionalism.