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“TOOLS FOR SUCCESS”: THE TRIPS AGREEMENT AND THE HUMAN RIGHT TO ESSENTIAL MEDICINES

Melissa McClellan*

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Human rights are more than principles to guide the national and global response to AIDS: they are among the most powerful tools to ensure its success.¹

I. Introduction

Paying the Price,² a short film produced by Television Trust for the Environment to publicize the need for affordable AIDS medicine in Africa, begins masterfully. In documentary fashion, the cameras follow a Ugandan

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¹ See OFFICE OF THE UNITED NATIONS HIGH COMMISSIONER FOR HUMAN RIGHTS AND THE JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, HIV/AIDS AND HUMAN RIGHTS: INTERNATIONAL GUIDELINES (2002) (introducing new Guidelines for understanding human rights principles in the context of the HIV/AIDS epidemic).

² PAYING THE PRICE (Television Trust for the Environment, U.S. Release 2002). The transcript for the film is available at <http://www.tve.org/lifeonline/index.cfm?aid=1174>.

boy's visit to the doctor in Kampala. According to the video voice-over, Vincent is fourteen years old, but he looks younger. He is small for his age and severely underweight. His skin is stretched so tight and thin that his ribs threaten to break through. Vincent seems frightened—and with good reason. Viewers learn from the commentary that both his parents have died from AIDS, and now Vincent is suffering from AIDS-related meningitis because, "[t]he antiretroviral drugs that could save his life are too expensive for most people in Africa."³ In the West, antiretroviral drugs have "transformed AIDS from a death sentence to a chronic illness and saved thousands of lives," but even at the reduced price of \$300 per year, the drugs remain out of reach for the 25 million Sub-Saharan Africans suffering from HIV and AIDS.⁴

Paying the Price eventually pans from Vincent's story to focus on its target, the large pharmaceutical companies that control patents and prices for AIDS medication. The film concludes with the question, "Can the drug companies go on ignoring growing outrage from around the world—and still protect their patents and profits?"⁵ It is a potent message. One look at Vincent's frail body and frightened face and the audience is ready to say, "To hell with patents; get this boy some drugs."

However, activist groups do not have a monopoly on propaganda. GlaxoSmithKline (GSK), one of the world's larger multinational pharmaceutical companies, has launched its own campaign to educate Americans on the importance of drug patents and profits.⁶ In an advertisement aired on network television, a GSK scientist explains that developing the latest lifesaving heart-disease medicine took lots of time and lots of money.⁷ Where do the profits from the medicine go? According to the GSK scientist, the money goes "down the hall," where researchers are working toward a cure for Alzheimer's disease. The ad ends with the tagline, "Today's medicines finance tomorrow's miracles."⁸ The pharmaceutical company is not selling anything; rather it is trying to buy goodwill by

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ See Tracy Krisanits, *GSK Rolls Out Corporate Ad Campaigns*, 39 MED. MARKETING & MEDIA 9 (2004) (reporting on GlaxoSmithKline's campaign aimed to increase awareness of the pharmaceutical industry's research function).

⁷ This advertisement aired on network television stations in the spring of 2004. For more information about the advertisement campaign featuring GlaxoSmithKline scientists, see David Ranii, *GSK Aims to Soften Image: Two New Ads; One Stars Scientist*, NEWS & OBSERVER (Raleigh, N.C.), Mar. 14, 2004, at E1 (noting that the ad campaign was, in part, a response to negative publicity GSK had received for the prices it charged for AIDS medicine in Africa).

⁸ See Krisanits, *supra* note 6 (quoting the slogan from the advertisement's conclusion); Ranii, *supra* note 7 (same).

reminding the viewer why prescription drugs are exorbitantly expensive. Society wants a cure for Alzheimer's, right?

The juxtaposition of the film and the ad highlights the tension between patent rights, which play an important role in the research and development of new medical technology,⁹ and the urgent need for access to affordable drugs, especially in nations that are experiencing an AIDS crisis. However, like all good works of propaganda, both film and ad go too far. *Paying the Price* opens with the following claim from the Brazilian Minister of Health: "And what is our case? Simply that access to medicines is a basic human right."¹⁰ Clearly, his statement must be qualified—there will be no human rights crusade for free distribution of Viagra, or even for equal access to state-of-the-art cancer treatment. Equally far-fetched, however, is the notion that pharmaceutical companies must charge exorbitant prices and enjoy unlimited patent protection to continue research and development. Today's medicines may finance tomorrow's miracles, but they also fund generous salaries for the CEOs of pharmaceutical companies.¹¹ Furthermore, the GSK advertisement raises the question of whose "miracle" the profits are funding. Americans may be willing to fund research and development for a miracle pill that alleviates depression without sexual side effects, but there is considerably less financial incentive for providing the miracle of life without malaria or tuberculosis, diseases peculiar to developing nations.¹²

⁹ See WORLD HEALTH ORGANIZATION & WORLD TRADE ORGANIZATION, WTO AGREEMENTS AND PUBLIC HEALTH: A JOINT STUDY BY THE WHO AND THE WTO SECRETARIAT 92 (2002), available at http://www.wto.org/English/res_e/booksp_e/who_wto_e.pdf (noting studies have demonstrated that pharmaceutical patent protection are the most important factor for research and development decisions). Strong intellectual property protection is key to pharmaceutical companies because of the effectiveness of pharmaceutical patents, the high costs of research and development, and the fact that, in the absence of patents, generics can be produced at a very low cost—thus reducing the commercial benefits of research and development. *Id.*

¹⁰ See PAYING THE PRICE, *supra* note 2 (translating a statement from Jose Serra, Health Minister of Brazil).

¹¹ See Gardiner Harris, *Will the Pain Ever Let Up at Bristol-Myers*, N.Y. TIMES, May 18, 2003, at S3 (noting that in 2001 the chairman and chief executive officer of Bristol-Myers Squibb, Peter Dolan, "received a compensation package the company valued at \$12.9 million—including \$10.6 million in long-term incentives, mostly stock options..."); Bloomberg News, *World Business Briefing Europe: Britain: Drug Maker Names Chief*, N.Y. TIMES, May 27, 2004, at W1 (reporting that the newly appointed executive chairman of GlaxoSmithKline, Sir Christopher Gent, will be paid \$434,760 in cash for serving as deputy chairman, with additional compensation in the form of corporate shares and a significant raise when he becomes chairman); Melody Petersen, *Lifting the Curtain on the Real Costs of Making AIDS Drugs*, N.Y. TIMES, Apr. 24, 2001, at C2 (finding that GlaxoSmithKline and Bristol-Myers Squibb spent a significantly larger percentage of their revenue on advertising, marketing, and administrative costs than they did on research).

¹² But note that according to the company's website, GlaxoSmithKline is committed to researching and developing treatments for diseases that primarily affect developing nations. See GLAXOSMITHKLINE, DEVELOPING WORLD CHALLENGES: ACCESS TO HEALTHCARE (last updated Apr. 28, 2003), http://www.gsk.com/about/developing_world.htm (articulating the company's commitment to developing nations). The website makes the following declaration:

The truth lies somewhere in between. There is a general consensus that intellectual property rights must be tempered by health considerations,¹³ and the current regime of international law regulating patent rights attempts to balance the need for intellectual property rights with the need for access to affordable medicine.¹⁴ The question now is not whether intellectual property law should reflect health considerations, but rather how to define the relationship between intellectual property and human rights.

II. Overview of the International Law Concerning Intellectual Property and Public Health

Patent rights are a creation of domestic law.¹⁵ In 1994, the Member states of the newly formed World Trade Organization (WTO) adopted the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement to work toward global protection of intellectual property rights.¹⁶ From its inception, TRIPS has acknowledged the nexus of intellectual property rights and public health.¹⁷ In particular, TRIPS addressed the special needs of developing states in the area of pharmaceutical patents: although the Agreement entered into force with respect to developed Members in January

We strongly believe we are making an important contribution to the improvement of healthcare in the developing world. We will continue with these and other efforts, focusing on areas where we can make the most difference and helping to find imaginative ways of making our medicines available and accessible to developing countries, as part of a more holistic approach to care.

Id.

¹³ Even the United States, the most vocal and powerful proponent of strong intellectual property rights, has acknowledged the need for flexible patent laws in light of public health concerns. See Bebe Loff & Mark Heywood, *Patents of Drugs: Manufacturing Scarcity or Advancing Health?*, 30 J.L. MED. & ETHICS 621, 627 (2002) (discussing the demands for drugs to combat anthrax). In the face of the anthrax incidents following the September 11th terrorist attacks, the United States and Canada threatened to break the patent for Ciproflaxacin if Bayer did not agree to reduce the price of the drug. *Id.* As one commentator noted, "[t]he parallels with the demand for AIDS medicines were unavoidable." *Id.*

¹⁴ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, Legal INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81, art. 8 (1994), available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (last visited Oct. 5, 2005) [hereinafter TRIPS Agreement] (noting right of Member states to protect and promote public health).

¹⁵ In the United States, patent rights are contained in Title 35 of the United States Code. See 35 U.S.C.S. § 101 (2004) (defining patentable inventions). For a brief history of the development of patent law in the West and in developing nations, see Sridvidhya Ragavan, *Can't We All Get Along? The Case for a Workable Patent Model*, 35 ARIZ. ST. L.J. 117, 121–28 (2003) (tracing the history of patents from the fourteenth century to the present, and noting that "economic gains were the main motive for the development of patent policies").

¹⁶ See DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 27 (2003) (describing the adoption of the TRIPS Agreement).

¹⁷ See *id.* at 46 (noting that the TRIPS Agreement emphasized from the beginning that it "should not prevent WTO Members from taking measure to protect public health, and that the TRIPS Agreement should be interpreted in that manner").

1996, developing nations had until January 2005 to implement the provisions regarding pharmaceutical patents, and least-developed nations are not required to provide pharmaceutical patent protection until 2016.¹⁸

Furthermore, Article 8 of TRIPS, which applies to all Member states, addresses the need to balance patent rights and public health by permitting states to "adopt measures necessary to protect public health and nutrition," as long as "such measures are consistent with the provisions of this Agreement."¹⁹ Additionally, Article 30 states that Members may make limited exceptions to patent rights, "provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent."²⁰ Together, these provisions are intended to provide Member states the flexibility to draft patent laws that take public health considerations into account. The provisions are vaguely worded, however, and require that any measures taken to protect health remain subject to the other terms of TRIPS.²¹

Specifically, Article 31 allows governments to mandate manufacturing of generic pharmaceuticals if good-faith negotiations with the patent holder fail.²² The practice of government-mandated manufacturing without the authorization of the patent holder, commonly termed "compulsory licensing," has been the topic of recent controversy over pharmaceutical patents and access to medication.²³ Recent negotiations over

¹⁸ *Id.* at 47. The extension for least-developed Member states emerged from the Doha Ministerial Conference on TRIPS and Public Health in 2001. *Id.* at 27 n.2.

¹⁹ The full text of Article 8 of the TRIPS Agreement provides: "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." TRIPS Agreement, *supra* note 14, at art. 8.

²⁰ The full text of Article 30 states: "Members may 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." TRIPS Agreement, *supra* note 14, at art. 30.

²¹ See Loff & Heywood, *supra* note 13, at 623 (quoting a United Nations Commissioner on Human Rights report, which stated "The various links [in TRIPS] with the subject matter of human rights—the promotion of public health, nutrition, environment and development—are generally expressed in terms of exceptions to the rule rather than the guiding principles themselves and are made subject to the provisions of the Agreement").

²² See TRIPS Agreement, *supra* note 14, at art. 31 ("Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected. . . .").

²³ See Joint Communication from the African Group in the WTO, *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/35 (June 24, 2002), <http://docsonline.wto.org> [hereinafter Joint Communication] (noting the ineffectiveness of the compulsory licensing provisions and calling for a number of measures to solve the problem, including a moratorium on claims against Members that take action to alleviate public health crises in states without manufacturing capacities); Second Communication from the United States, *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/358, (July 9, 2002),

TRIPS focused on Article 31(f), which limits the distribution of drugs manufactured under compulsory licenses: "Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."²⁴ Because Article 31(f) restricts the exportation of medicines manufactured under compulsory licenses, TRIPS did not offer an effective solution for nations without the capability to manufacture drugs.²⁵ In other words, even though TRIPS did not require developing nations to extend patent protection to pharmaceuticals until 2005 or 2016, the exemption from patent law did not increase access to affordable medicine because Article 31(f) prohibited Member states from importing generic medicines from countries where the pharmaceuticals were patented.²⁶ For example, Brazil could legally obtain a compulsory license to manufacture generic AIDS medicine to alleviate its domestic epidemic, but exporting those same drugs to African nations would run afoul of the WTO laws.²⁷ Under this interpretation of Article 31(f), developing nations that lack the capacity to manufacture their own generic medicines could not take advantage of the compulsory licensing provision.²⁸

Recognizing the ineffectiveness of Article 31 and the public health problems facing developing and least-developed nations without manufacturing capability, the WTO addressed the compulsory licensing issue at its Ministerial Conference in Doha, Qatar in November 2001.²⁹ Paragraph

<http://docsonline.wto.org> [hereinafter Second Communication] (acknowledging that Member states without manufacturing capability cannot make effective use of compulsory licensing under trips, and suggesting a waiver or moratorium of Article 31(f) for those states only).

²⁴ TRIPS Agreement, *supra* note 14, at art. 31 (f).

²⁵ See Joint Communication *supra* note 23 (citing proposals on the compulsory licensing problem); see also World Trade Organization, Press Release, *Decision Removes Final Patent Obstacle to Cheap Drug Imports*, Aug. 30, 2003, http://www.wto.org/english/news_e/pres03_e.htm [hereinafter Press Release] (discussing the effect of Article 31(f) on countries that cannot produce pharmaceuticals domestically).

²⁶ *Id.*

²⁷ See Doug Alexander, *Canada's New Plan for Generic-Drug Sales*, CHRISTIAN SCIENCE MONITOR, Mar. 25, 2004, at 1 (discussing the practices of Brazil and India, "which have been exporting AIDS knock-off drugs to Africa, but in violation of WTO rules").

²⁸ I say "this interpretation of Article 31(f)" because in the negotiations following the Doha Ministerial Conference, some nations advocated reading "predominantly for the domestic market" to mean that 49.9% of the generics could be exported. See Joint Communication from the African Group in the WTO, *supra* note 23, at para. 6(d) ("Further, the requirement in Article 31(f) that the supply be predominantly for the domestic market of the Member issuing the compulsory license, [sic] should be interpreted to mean that up to 49.9 percent of the production can be exported."). While the suggested "49.9%" interpretation would allow for some exportation of drugs, it was not a satisfactory solution because it illogically made the supply of AIDS medicines for a nation without manufacturing capacity dependant on the need for AIDS medicines in the manufacturing countries.

²⁹ See World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001) para. 1 [hereinafter Doha Declaration] (recognizing the public health problems facing developing and least-developed nations, especially problems "resulting from HIV/AIDS, tuberculosis, malaria and other epidemics"); see *id.* at para. 6 (recognizing that Members with little or no manufacturing capacities cannot effectively use compulsory licensing under TRIPS).

Six of the Doha Declaration on TRIPS and Public Health, called for a solution to the compulsory licensing question by the end of 2002.³⁰ After lengthy negotiations that were heavily influenced by arguments from the African Group (comprising all African Member states), the WTO finally reached an agreement on August 30, 2003 to allow a waiver of Article 31(f) for nations that need to import generic drugs.³¹ The August 30 Agreement allows any Member state to export medicines made under compulsory licenses to any other Member state, subject to a number of conditions, including notification to the TRIPS Council, remuneration to the patent holder,³² and safeguards to ensure that the products produced under compulsory licenses are not diverted from the "public health purposes underlying their importation."³³ The agreement does not limit which states can take advantage of the waiver to Article 31(f), although many developed nations announced that they will not use the system to import drugs.³⁴ Furthermore, although it refers to "public health," the agreement never defines the permitted purposes for implementing the waiver.³⁵ The General Council Chairperson's statement issued along with the agreement, however, notes that "Members recognize that the system that will be established by the Decision should be used in good faith to protect public health."³⁶

³⁰ The Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 6 states:

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 and to report to the General Conference before the end of 2002.

Id. at para. 6.

³¹ See Press Release, *supra* note 25 (discussing the negotiations leading up to the agreement and its provisions).

³² See *infra* notes 72–78 and accompanying text (discussing remuneration to the patent holder).

³³ WORLD TRADE ORGANIZATION, IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH: DECISION OF THE GENERAL COUNCIL OF 30 AUGUST 2003, Sept. 1, 2003, WT/L/540, http://www.wto.org/English/tratop_e/trips_e/implement_para6_e.htm [hereinafter August 30 Agreement].

³⁴ See Press Release, *supra* note 25 (noting that 23 developed countries are on record stating they will not use the system to import; another eleven countries have announced that they will use the system only in emergencies).

³⁵ See August 30 Agreement, *supra* note 33 (defining "pharmaceutical product" as a patented product of "the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration").

³⁶ WORLD TRADE ORGANIZATION, *Intellectual Property: The General Council Chairperson's Statement*, Aug. 30, 2003, http://www.wto.org/English/news_e/news03_e/trips_stat_28aug03_e.htm [hereinafter General Council Chairperson's Statement].

A. Human Rights and Defining a Health Exception to Patent Rights

Although the new trade agreements are promising steps toward making access to AIDS medication a reality for developing nations, the WTO negotiations and agreements noticeably avoid any overt recognition of human rights. Instead, the debate has focused largely on the more general notion of "public health." Although public health considerations are crucial to the development of responsible patent laws, the public-health focus does not acknowledge what *Paying the Price* termed as "a basic human right to access to medicines."³⁷

Focusing on public health, to the exclusion of individual human rights, results in less effective laws to achieve access to AIDS medicines. The WTO's patent laws should include recognition of basic human rights to life and health, which in turn encompass a minimum and universal right to affordable essential medicines. The right to medicine must be defined in limited, justiciable terms that establish a practical standard or continuum of health.³⁸

Drafting and interpreting trade laws in light of a defined human right would avoid some of the problems currently surrounding the drug debacle. First, defining a minimum right to medicine would offer more guidance than the current "public health" language of the agreements, which leaves much to the discretion of Member states. Pharmaceutical companies have legitimate concerns under the recent waiver to TRIPS Article 31(f), because there are no effective limits on which states can use compulsory licenses or on the circumstances that trigger compulsory licensing.³⁹ The provisions are couched in terms of "good faith"⁴⁰ and are intended to be used by developing nations for the purpose of alleviating epidemics and assisting nations that

³⁷ Paragraph 4 of the Doha Declaration on TRIPS and Public Health does affirm "that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." Doha Declaration, *supra* note 29. While the affirmation speaks to promoting universal access to medicine, it recognizes only the state's right to promote access—not an individual right to demand access to medicine. *Id.*

³⁸ See *infra* notes 30–42 and accompanying text (defining the right to medicine).

³⁹ Indeed, before the waiver to Article 31(f) Member states had wide latitude to declare the need for compulsory licensing. See Doha Declaration, *supra* note 29, at para. 5(b) ("Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."). See also Ragavan, *supra* note 19, at 178 (noting that "[t]he wide definition of drugs in the Declaration diminishes the line between important and necessary drugs," and that the wide definition of "epidemics" will enable "developing nations to decide whether an epidemic is prevalent based on national standards"); GERVAIS, *supra* note 16, at 251 ("In light of the Doha Declaration on TRIPS and Public Health it seems that WTO Member are free, within reason, to determine what constitutes a national emergency.") (footnote omitted).

⁴⁰ See General Council Chairperson's Statement, *supra* note 36 (recognizing that the system should be "used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial objectives").

cannot manufacture their own medicines,⁴¹ but there are no legal qualifications to prevent abuse. A human rights definition could add clarity to the purpose and scope of the exceptions to patent rights. The definition would provide specific grounds for compulsory licensing and exportation that would both require more exceptions to patent rights when individual lives are at stake, and limit exceptions when only some vague notion of public health or public good is at stake.

Second, if the WTO law recognized a basic human right to medicine, states would have to respect the right as they implemented the provisions in domestic law.⁴² As states begin drafting and implementing patent laws that reflect the flexibilities of the new trade agreements, they will likely face opposition from pharmaceutical companies and, possibly, from the United States.⁴³ An unequivocal statement requiring that the TRIPS Agreement be interpreted in light of a basic right to medicine could lend greater legal certainty to the provisions regarding patent laws and health, and help curb legal challenges to generic-friendly patent laws.

Finally, a human rights emphasis would ensure that a person's right to medicine for a treatable disease would not be contingent on his ailment reaching epidemic proportions or threatening "public health." Far from adding confusion to the debate over patent rights, a well-articulated human right to medicine could help clarify the intent of the new patent agreements and rein in objections to their implementation.

⁴¹ See August 30 Agreement, *supra* note 33, at para. 4 (referring to the "public health purposes underlying their importation").

⁴² The agreements reached by the WTO Members have to be executed through national legislation; Canada has already begun the process. See Doug Alexander, *Canada's New Plan for Generic-Drug Sales*, CHRISTIAN SCIENCE MONITOR, Mar. 25, 2004, at 01 (discussing Canada's efforts to implement the WTO August 30, 2003 decision), available at <http://www.csmonitor.com/2004/0325/p01s04-woam.html> (Mar. 25, 2004).

⁴³ See WTO AGREEMENTS AND PUBLIC HEALTH: A JOINT STUDY BY THE WHO AND THE WTO SECRETARIAT 103 (2002), available at http://www.wto.org/English/res_e/booksp_e/who_wto_e.pdf [hereinafter Joint Study] (discussing concerns about the whether the public health safeguards in the TRIPS Agreement has enough legal certainty to protect it from challenges under other laws). Although the United States has expressed views that TRIPS does not adequately protect intellectual property rights, President Clinton issued an executive order in 2000 stating that his administration would refrain from actions negatively affecting intellectual property laws applying to HIV/AIDS drugs, as long as the laws were TRIPS-consistent. *Id.* President Bush reaffirmed the executive order when he took office in 2001. *Id.* The executive order is limited to laws or policies affecting AIDS drugs benefiting Sub-Saharan African countries, though, and does not apply to other medicines or developing nations; see *id.* at 104 (quoting Executive Order 13155).

B. Defining the Right to Medicine

We already have some models for defining a justiciable right to medicine.⁴⁴ Perhaps the most valuable tool available in the search for a justiciable definition of the right to medicine is the World Health Organization's (WHO) concept of essential medicines. The WHO defines "essential medicine" as "those that satisfy the priority health care needs of the population."⁴⁵ Public health systems must draw lines when supplying medicines, and the WHO developed the concept of essential medicines to help determine where the lines should be drawn.⁴⁶ Over 156 nations have adopted lists of essential medicines, and many use the lists when making decisions regarding "the procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations, and local medicine production."⁴⁷

The definition of essential medicines will vary nationally depending on local situations, but the WHO suggests the following criteria for formulating a list of essential medicines: sound and adequate evidence of the medicine's safety and efficacy in a variety of settings, the cost-effectiveness of the medicine (compared to other medicines within the same category), the availability of the medicine, and the capacity to store it in a stable condition.⁴⁸ Additionally, the WHO notes that most essential medicines should be single compounds, with exceptions for AIDS, malaria, and tuberculosis treatments.⁴⁹ The list should also be reviewed and updated often.⁵⁰

While the WHO definition of essential medicines is not a "rights definition," the WHO criteria could be used to develop a flexible standard for a right, determined on a drug-by-drug basis. Because trade and patent laws have a profound impact on access to medicine, perhaps the WTO should explicitly defer to the WHO to define the parameters of TRIPS and the right to essential medicines instead of referring to "public health." The WTO could draft and interpret the TRIPS Agreement to fulfill the basic rights to life and health, which include a right of access to essential medicines as defined by standards established by the WHO. A statement of this type

⁴⁴ One of the most well-developed legal definitions has been advanced by the Constitutional Court of Colombia. See Alicia Ely Yamin, *Not Just a Tragedy: Access to Medications as a Right under International Law*, 21 B.U. INT'L L.J. 325, 340-41 (2003) (citing *Alvarez v. Estado Colombiano*, SU.819/99, Corte Constitucional de Colombia (1999)).

⁴⁵ WHO Policy Perspectives on Medicines: The Selection of Essential Medicines 1 (2002), http://www.who.int/medicines/library/edm_general/6paggers/ppm04eng.pdf.

⁴⁶ *Id.*

⁴⁷ *Id.* at 2.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

would be more effective than the vague language in TRIPS Article 8 that subordinates public health to other provisions of the Agreement,⁵¹ or the affirmation in the Doha Declaration, which recognizes only the states' rights to "promote" universal access to medicine.⁵²

The WTO and WHO have already recognized the need to coordinate their activities at the international level, as demonstrated in the regulation of food safety.⁵³ The WTO Sanitary and Phytosanitary Measures (SPS) Agreement specifically incorporates the standards and recommendations promulgated by the WHO Codex.⁵⁴ The link between the two organizations makes perfect sense: the WTO is not equipped to establish scientific or health standards, while the WHO has useful expertise to lend to health-related trade decisions.⁵⁵ In fact, the WHO has already advised countries on options for integrating public health considerations into national patent laws and on how to use the flexibilities of TRIPS to promote access to essential medicine.⁵⁶ The WHO also has "observer status" in the TRIPS Councils and WTO Ministerial Meetings.⁵⁷ By establishing a more formal connection between the TRIPS patent regulations and the WHO recommendations for essential medicines, the WTO could create a clear, scientific standard to guide Member states as they implement the provisions of TRIPS and its progeny.

The WHO could improve its definition of essential medicines by fine-tuning the "cost-effectiveness" requirement. Patents affect the cost-effectiveness of drugs,⁵⁸ and patent status should not determine whether a drug makes the essential medicine list. Also, the WHO should elaborate on the concept of "priority health care" to ensure that it includes, in addition to lifesaving medicines, medicines that substantially alleviate profound impairments affecting normal health functions. This definition would

⁵¹ See TRIPS Agreement, *supra* note 14, at art. 8 (allowing Members to take measures to "protect public health" as long as the measures "are consistent with the provisions of this Agreement").

⁵² See Doha Declaration, *supra* note 29, at para. 4 (affirming that the TRIPS Agreement should be interpreted to support of each Member's right to "promote access to medicines for all").

⁵³ See JOINT STUDY, *supra* note 43, at 142 (discussing WTO and WHO collaboration in regulating trade and food safety).

⁵⁴ See *id.* at 142-43 (noting that "[t]he WHO's active presence at SPS meetings has allowed WHO staff to provide advice on health matters relevant to trade. Examples are WHO's input on the risks of mad cow disease . . . to human health, and on the health effects of genetically-modified organisms in food").

⁵⁵ See *id.* at 143 (stating that "the WTO is not a scientific body and does not develop standards").

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ See generally Loff & Heywood, *supra* note 13 (arguing that patents are the major determinate of the price of medicine); see also COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 37-38 (2002), available at http://www.iprcommission.org/papers/pdfs/final_report/Ch2final.pdf (discussing the correlation between patents and prices in developed and developing nations).

encompass not only medicines that treat life-threatening diseases such as HIV/AIDS and tuberculosis, but also treatments for chronic diseases such as asthma and diabetes.⁵⁹ The WHO has the knowledge and resources to develop a justiciable, scientific standard that would help ensure that WTO patent agreements are responsive to basic human rights:

C. Enforcing the Right

In addition to defining a justiciable right to medicine, it is important to locate the right within a recognized fundamental human right. Most, if not all, of the Member States of the WTO already have obligations under international, regional, and national laws to recognize a basic human right to life. International institutions and national constitutional courts are increasingly interpreting the right to life to encompass a right to conditions that sustain life, including a right to minimum standards of health.⁶⁰ If the right to medicine can be located within an established universal human right, the Member states of the WTO would have a duty to ensure that trade laws do not violate or impede the fulfillment of the right.

The United Nations Charter, a legally binding treaty, affirmed respect for "fundamental human rights" in its preamble, and Articles 1, 55, and 56 refer to the U.N.'s purpose of promoting "human rights and fundamental freedoms for all."⁶¹ In 1948, the U.N. General Assembly adopted the Universal Declaration on Human Rights, which set forth a spectrum of human rights ranging from the basic right to life,⁶² to the more esoteric right to the "free development" of one's personality.⁶³ Article 25 of the Universal Declaration expressly addressed the right to medicine, stating that "[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing,

⁵⁹ See World Health Organization, *Chronic Conditions are Escalating* (2004), http://www.who.int/chronic_conditions/conditions/en/print.html (discussing the lack of attention paid to chronic illnesses in low income settings).

⁶⁰ See Yamin, *supra* note 44, at 331 ("The right to life has generally been recognized to encompass more than not dying as a result of actions directly attributable to the state, to extend to conditions that permit, at a minimum, survival and, more broadly, to those that are conducive to dignity and well-being.")

⁶¹ See U.N. CHARTER PREAMBLE. ("We the peoples of the United Nations determined . . . to reaffirm faith in fundamental human rights, in the dignity and worth of the human person. . . ."); *Id.* at arts. 1, 55 & 56; see also LAWRENCE O. GOSTIN & ZITA LAZZARINI, HUMAN RIGHTS AND PUBLIC HEALTH IN THE AIDS PANDEMIC 2 (1997) (noting that the U.N. Charter, a binding treaty, pledges its parties to promote health and higher standards of living).

⁶² UNIVERSAL DECLARATION OF HUMAN RIGHTS (1948), G.A. Res. 217A (III) art. 3 (stating that "[e]veryone has the right to life, liberty and the security of person").

⁶³ See *id.* at art. 22 (declaring that everyone is "entitled to realization . . . of the economic, social and cultural rights indispensable for his dignity and the free development of his personality").

housing and medical care. . . ."⁶⁴ Although the language of the right to medical care is unequivocal, the legal significance of Article 25 is debatable. The Universal Declaration was initially adopted in the form of a General Assembly resolution, which is not legally binding.⁶⁵ In subsequent years, however, the Universal Declaration has been cited countless times as constituting a binding obligation on nations.⁶⁶ In a 1980 human rights case, the United States Court of Appeals for the Second Circuit noted that "several commentators have concluded that the Universal Declaration has become, *in toto*, a part of binding customary international law."⁶⁷ That case, however, dealt specifically with the Universal Declaration's prohibition against torture.⁶⁸ It seems more accurate to say that *some* provisions of the Universal Declaration on Human Rights have become part of customary law: the provision protecting the right to health care has not attained the same status in international law as the provision prohibiting torture.⁶⁹ Without other documents to reinforce the status of the rights contained in its articles, the Universal Declaration of Human Rights—on its own—probably does not create a legally binding right to medicine, although the Declaration does carry great moral and political significance.⁷⁰

Most of the provisions in the Universal Declaration are also embodied in the two paramount U.N. covenants on human rights, the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR).⁷¹ Unlike the Universal Declaration, the Covenants are both legally binding treaties,⁷² although their enforcement mechanisms differ.

⁶⁴ *Id.* at art. 25.

⁶⁵ Indeed, at the time of the adoption of the Universal Declaration, Eleanor Roosevelt, the Chairperson of the Commission on Human Rights, stated that "In giving our approval to the declaration today, it is of primary importance that we keep clearly in mind the basic character of the document. It is not a treaty; it is not an international agreement. It is not and does not purport to be a statement of law or of legal obligation." 19 DEPT. STATE BULL. 751 (1948) (quoted in Frederic L. Kirgis, *Current International Law* 397 (2003)).

⁶⁶ See GOSTIN & LAZZARINI, *supra* note 61, at 4 ("Although [the Universal Declaration] was not promulgated to legally bind member states, its key provision have so often been applied and accepted that they are now widely considered to have attained the status of customary international law.").

⁶⁷ *Filartiga v. Pena-Irala*, 630 F.2d 876, 883 (2d Cir. 1980) (finding that torture violated the "law of nations" for purposes of the Alien Tort Statute).

⁶⁸ *Id.*

⁶⁹ See *Sosa v. Alvarez-Machain*, 542 U.S. 692, 755 (citing *Filartiga* and acknowledging that the prohibition of torture has achieved the status of an international norm, while denying that status to the offense of arbitrary arrest).

⁷⁰ See *id.* (stating that the Universal Declaration of Human Rights "does not of its own force impose obligations as a matter of international law").

⁷¹ See PAUL SIEGHART, *THE INTERNATIONAL LAW OF HUMAN RIGHTS* 25 (1983) (finding that the "single [Universal Declaration] catalogue" of rights was divided between the ICCPR and the ICESCR).

⁷² See *id.* (noting that, unlike the Universal Declaration, the ICCPR and ICESCR were designed to legally bind the states).

The ICCPR, signed by more than 150 nations including the United States, recognizes an inherent right to life.⁷³ The Human Rights Committee of the U.N., the body that monitors the implementation of the ICCPR, has interpreted the right to life to encompass obligations on the part of the state to *protect* human life, including obligations to increase life expectancy and to eliminate malnutrition and epidemics.⁷⁴ While an argument for the right to medicine could be made under the ICCPR right to life, the enforcement mechanism provided by the treaty does not offer much practical assistance to individuals demanding fulfillment of the right. The Human Rights Commission oversees state party compliance with the treaty by investigating claims brought by one state party declaring that another state party is not complying with the terms of the Covenant.⁷⁵ The ICCPR does not provide individuals with standing to bring complaints under the treaty. The First Optional Protocol to the ICCPR does provide standing for individuals to file complaints with the HRC, but standing is only available to the citizens of states that are parties to the Protocol—104 of the 153 parties to the ICCPR.⁷⁶ For individuals who are able to bring complaints, the remedy is not necessarily satisfactory: the HRC will consider the claims and issue its views to the state concerned and to the individual, but the HRC has no further enforcement power.⁷⁷

⁷³ See International Covenant on Civil and Political Rights, G.A. Res. 2200A (XXI), U.N. Doc. AA/6316/art. 6(1) (1966) [hereinafter ICCPR] ("Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.").

⁷⁴ See Yamin, *supra* note 44, at 331 ("Specifically, the Human Rights Committee has defined the role of the state in protecting human life to include obligations to reduce infant mortality, to increase life expectancy, and to eliminate malnutrition and disease.").

⁷⁵ See ICCPR, *supra* note 59, at art. 41 (explaining the procedure for bringing a complaint before the Human Rights Committee). The Human Rights Committee will not receive claims against any State Party unless that state has made a declaration recognizing the Committee's competence. *Id.* In addition, the Human Rights Committee will not investigate a complaint until satisfied that the party has exhausted domestic remedies. *Id.*

⁷⁶ See OFFICE OF THE UNITED NATIONS HIGH COMMISSIONER ON HUMAN RIGHTS, OPTIONAL PROTOCOL TO THE INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS, art. 1 (1966) [hereinafter Optional Protocol], http://www.unhcr.ch/html/menu3/b/a_opt.htm (declaring that a state party to the Protocol recognizes the Human Rights Committee's competence to hear communications from individuals within the state's jurisdiction "who claim to be victims of a violation by that State Party of any of the rights set forth in the Covenant"). Article 1 also notes that "[n]o communication shall be received by the Committee if it concerns a State Party to the Covenant which is not a Party to the present Protocol." *Id.* There are 153 state parties to the ICCPR. See OFFICE OF THE UNITED NATIONS HIGH COMMISSIONER ON HUMAN RIGHTS, 4. *International Covenant on Civil and Political Rights New York, 16 December 1966*, <http://www.ohchr.org/english/countries/ratification/4.htm> (last visited Sept. 16, 2005) (listing the state parties to the ICCPR). There are 104 state parties to the Optional Protocol allowing individuals to bring complaints before the Human Rights Committee. See OFFICE OF THE UNITED NATIONS HIGH COMMISSIONER ON HUMAN RIGHTS, 5. *Optional Protocol to the International Covenant on Civil and Political Rights New York, 16 December 1966*, <http://www.ohchr.org/english/countries/ratification/5.htm#N3> (last visited Sept. 16, 2005) (listing the state parties to the Optional Protocol). Neither the United States nor the United Kingdom has become a party to the Optional Protocol. *Id.*

⁷⁷ See Optional Protocol, *supra* note 76, at art. 5 (outlining HRC's response to communications received under the ICCPR).

The ICCPR's counterpart, the International Covenant on Economic, Social and Cultural Rights, provides more explicit recognition of the right to health.⁷⁸ Article 12 of the treaty requires parties to take steps to meet "the right of everyone to the highest attainable standard of physical and mental health."⁷⁹ The Economic, Social and Cultural Rights Committee further defined this right in General Comment 14, which established that all health care services and medications should be available in sufficient quantity, as well as physically and economically accessible to everyone without discrimination.⁸⁰ General Comment 14 also established that the provision of essential medicines, as defined by the WHO, is one of a state's minimum core duties under the ICESCR.⁸¹ Therefore, it seems that the ICESCR already embodies the right to essential medicines, and that the more than 140 state parties to the Covenant are legally obligated to ensure that their other obligations—including trading practices—do not violate the right to essential medicine.

The problem with the ICESCR, however, is its weak enforcement mechanism. The ICESCR relies on states reporting their progress regarding human rights to the U.N. Economic and Social Council and does not provide individuals standing to bring complaints.⁸² Although it is a legally binding treaty, the ICESCR depends on political pressure, rather than legal obligations, to advance and protect human rights.

Many citizens of the world do not have to look to international law to find a legal right to health, however. More than sixty nations include some form of a right to healthcare in their constitutions.⁸³ National courts in Costa Rica, India, Colombia, Argentina, and South Africa, among others, have determined that the state has an obligation to provide drugs for citizens suffering from HIV/AIDS and other diseases.⁸⁴ Some national courts find the right to health in their own laws, while some courts are willing to apply

⁷⁸ See International Covenant on Economic, Social and Cultural Rights, G.A. Res. 220 A (XXI), U.N. Doc. A/6316/art. 12 (Dec. 16, 1966) (recognizing the universal right to "the enjoyment of the highest attainable standard of physical and mental health").

⁷⁹ *Id.*

⁸⁰ See The Right to the Highest Attainable Standard of Health, General Comment No. 14, U.N. CESCR, 22nd Sess., Agenda item 3, E/C.12/2000/4 para. 12 (2000), [http://www.unhchr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En?OpenDocument](http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument) (last visited Oct. 13, 2005) [hereinafter General Comment 14] (declaring that the right to health must address availability and the "four overlapping dimensions" of accessibility: nondiscrimination and physical, economic, and information accessibility).

⁸¹ *Id.* at para. 43(d).

⁸² See GOSTIN & LAZZARINI, *supra* note 61, at 8 ("Beyond reporting, few mechanisms exist to monitor or enforce the ICESCR's provisions.").

⁸³ See Yamin, *supra* note 44, at 339 (noting that the right to health or healthcare is "enshrined in over sixty national constitutions").

⁸⁴ *Id.* at 340.

international law domestically.⁸⁵ No matter where the courts derive the right, these national decisions are especially promising for the enforcement of the right to medicine because (1) local courts can often provide more efficient relief to citizens, and (2) international law usually requires the exhaustion of domestic remedies before hearing complaints.⁸⁶

International law and the national laws of some states form a basis for a legally recognized human right to medicine. Even without a specific reference to human rights in the World Trade Organization Agreements, the WTO may already recognize a Member State's duty to implement patent laws in a way that would allow the State to fulfill the human rights of its citizens. In a 1996 decision settling a dispute between the United States and Venezuela, the Appellate Body of the WTO found that the WTO Agreement, which would include TRIPS, "is not to be read in clinical isolation from public international law."⁸⁷ In other decisions, the Appellate Body cited the case law of international human rights tribunals when interpreting the provisions of the WTO Agreement.⁸⁸ Thus, if a Member State was in a position to argue that it had the authority to break patents to make AIDS medicine affordable for its citizens, the TRIPS Council might be willing to look to other human rights documents to interpret the TRIPS Agreement—perhaps finding that Article 8's permission to formulate laws to "protect public health" and to "promote the public interest in sectors of vital importance to their socio-economic . . . development" includes permission to fulfill the rights recognized in international human rights documents. This argument seems unlikely to succeed, however, especially since the discussions in the WTO leading up to the Agreements centered more on public health emergencies than individual human rights.⁸⁹ Therefore, international human rights documents cannot serve as a substitute for an explicit recognition of the right to medicine in the TRIPS Agreement. By embodying the right in the TRIPS Agreement, the WTO would help secure the right to medicine by supplying Member States with a legal justification for implementing patent laws that do not impede access to essential medicines.

⁸⁵ *Id.*

⁸⁶ See GOSTIN & LAZZARINI, *supra* note 61, at 8 (noting that individuals have a better chance at effecting change in their own countries, where they are familiar with the domestic legal and political processes, and that international law often requires claimants to exhaust domestic remedies as a prerequisite to relief).

⁸⁷ WTO Appellate Body, *United States—Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R (Apr. 29, 1996), http://www.wto.org/english/tratop_e/envir_e/gas1_e.htm.

⁸⁸ See GERVAIS, *supra* note 16, at 343 (discussing the TRIPS dispute settlement mechanisms).

⁸⁹ See *supra* notes 37–43 and accompanying text (discussing the need for a human rights focus).

III. Moral Justifications for the Right to Essential Medicine

Although international and domestic law may not yet recognize a universal, legally enforceable right to medicine, individuals still have a strong moral justification for demanding access to certain medicines. It is important not to underestimate the power of moral rights, which are often precursors to legally enforceable rights and may at times be more effective or efficient in producing the substance of a right than a legal right would be.⁹⁰

Henry Shue provides a useful framework for analyzing moral rights in his *Basic Rights: Subsistence, Affluence and U.S. Foreign Policy*.⁹¹ According to Shue, a basic moral right provides a person with a justified demand to enjoy the substance of the right, which is socially protected against "standard threats."⁹² To apply this definition to the pharmaceutical patent context, we must start with the premise that a person has a basic right to life.⁹³ For a person to enjoy the substance of this right, he must be able to demand that the right be protected against the "typical major threats" to life.⁹⁴ The concept of standard threats is fluid, but it seems reasonable to suggest that treatable diseases pose a standard threat to the enjoyment of the right to life.

Returning to Vincent's story in *Paying the Price*, we can see that Sub-Saharan Africa offers an easy case for viewing HIV/AIDS as a typical threat to life.⁹⁵ Despite the sheer number of people suffering from the disease in the region, however, the threat would not be "standard," in terms of a moral right, if there were no practical treatment available. Shue describes the shifting measure of standard threats:

What is . . . eradicable changes, of course, over time. Today, we have very little excuse for allowing so many poor people to die of malaria and more excuse probably for allowing people to die of cancer. Later perhaps we will have equally little excuse to allow deaths by many kinds of cancer, or perhaps not. In any case, the

⁹⁰ For example, in April 2001, public pressure caused a group of almost forty pharmaceutical companies to withdraw its suit against the South African government. See JOINT STUDY, *supra* note 43, at 106 (describing the history of the case). The pharmaceutical companies had raised a challenge under the South African Constitution to the state's Medicines and Related Substances Control Amendment Act of 1997, designed to increase the supply of cost-effective drugs by importing generic patented drugs. *Id.*

⁹¹ See generally HENRY SHUE, *BASIC RIGHTS: SUBSISTENCE, AFFLUENCE, AND U.S. FOREIGN POLICY* (2d ed. 1996).

⁹² *Id.* at 13.

⁹³ The right to life can be located in natural law, or in religion, or in international or national law; the origin of the right to life does not matter, as long as one concedes that it exists.

⁹⁴ SHUE, *supra* note 91, at 33.

⁹⁵ See *supra* notes 1–4 and accompanying text (discussing the AIDS crisis in Africa).

measure is a realistic, not a utopian, one, and what is realistic can change.⁹⁶

In other words, AIDS would not have been characterized as a "standard threat" a few decades ago when a diagnosis would have constituted a death sentence for any person, whether she lived in an affluent nation or a least-developed country. Fortunately, the reality of HIV/AIDS has changed. Twelve antiretroviral medicines for the prevention and treatment of HIV/AIDS now appear on WHO's Essential Medicine list, which by definition contains only safe and effective medical treatments.⁹⁷ In light of the development of antiretroviral drugs (ARVs) to treat HIV/AIDS, the disease fits Shue's definition of a standard threat to the enjoyment of the right to life. Therefore, people now have a moral justification to demand access to ARVs to protect their fundamental right to life.

In order to fulfill basic rights, Shue argues that there is a duty to make arrangements that serve three functions: to avoid depriving people of the substance of their rights, to protect people against deprivation, and to aid them when they are deprived of their rights.⁹⁸ Of course, discussions about fulfilling basic rights tend to be framed as passive sentences, without identifying who (or what) will be guaranteeing the right. Governments, private actors, and non-government organizations are all candidates for bearing the burden of fulfilling rights, but this paper focuses on the role that the WTO can and should play in fulfilling the basic right to essential medicine, specifically ARVs to treat HIV/AIDS.

The WTO, as an international institution, is in a position to fulfill the first two duties that Shue sets forth. At the very least, the WTO has an obligation not to deprive people of their right to certain basic medicines by establishing patent laws that impede access. If, for example, the WTO agreements allow nations to draft patent laws that increase the cost of ARVs or prevent the exportation of generics drugs to poor countries, the WTO is in effect depriving people of their right to medicine.⁹⁹ The WTO also has the obligation to protect people from being deprived of their right to essential medicine. It is within the scope of the WTO's authority to take a firm stance on human rights—to recognize a right to life that cannot be derogated by patents. If the WTO made such a statement, the Member States would have to respect human rights principles when implementing the WTO agreement

⁹⁶ *Id.* at 33.

⁹⁷ WORLD HEALTH ORGANIZATION, *Essential Medicines* (last visited Oct. 11, 2005), http://www.who.int/medicines/services/essmedicines_def/en/index.html, [hereinafter *Essential Medicines*]; WORLD HEALTH ORGANIZATION, *The WHO List of Essential Medicines* (last updated Mar. 2005), <http://www.who.int/medicines/publications/essentialmedicines/en/>.

⁹⁸ SHUE, *supra* note 91, at 17.

⁹⁹ *See supra* note 58 (citing sources finding that patents affect drug prices).

provisions into domestic legislation. These domestic laws would, in turn, create the legal framework that controls the pharmaceutical industry.

While many arguments for affordable drugs—including *Paying the Price*—target pharmaceutical companies as the primary actors affecting access to medicine, the focus is misplaced, or at least myopic. Of course, a strong moral argument can be made for why rich drug companies owe a duty to fulfill the needs of people suffering from treatable diseases. And, currently, the pharmaceutical industry does make voluntary efforts to increase access to affordable medicine.¹⁰⁰ But focusing on the private companies, rather than on public institutions like the WTO, is not the best route for guaranteeing people the right to medicine. The voluntary efforts of pharmaceutical corporations are just that—voluntary.¹⁰¹ As Shue illustrates clearly in *Basic Rights*, benevolence does not provide any guarantees to the right holder.¹⁰² If the pharmaceutical industry decides that the rewards for philanthropy are not worth the cost, they may not continue to offer drugs at reduced prices to poor nations. Public pressure may persuade pharmaceutical companies to act benevolently for a time, but as Shue notes, "to enjoy something only at the discretion of someone else . . . is precisely *not* to enjoy a *right* to it."¹⁰³ The better approach, then, is to focus on the legal institutions and public international organizations that can guarantee rights, thereby relieving pharmaceutical companies of the "benevolent or malevolent discretion . . . to decide what counts as benevolent."¹⁰⁴

¹⁰⁰ See *supra* note 12 (citing GlaxoSmithKline's statement of commitment to making medicine accessible to the developing world); see also International Federal of Pharmaceutical Manufacturers Association, *Vatican Statement on AIDS Demonstrates a Lack of Information on Industry's Actions to Improve Access to AIDS Medicines* (Jan. 29, 2004), available at <http://www.ifpma.org> (describing voluntary efforts of pharmaceutical industry to improve access to AIDS drugs).

¹⁰¹ But see Lissett Ferreira, Note, *Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations*, 71 *FORDHAM L. REV.* 1133, 1166–73 (2002) (arguing that transnational pharmaceutical companies have "soft law" obligations to respect the human rights of HIV/AIDS patients in developing countries, and that pharmaceutical companies violate these obligations when they oppose countries trying to promote access to AIDS medicine).

¹⁰² SHUE, *supra* note 91, at 78.

¹⁰³ *Id.*

¹⁰⁴ See *id.* (describing the need for participatory institutions to guarantee rights); see also CIPR Report, *supra* note 58, at 41 (noting that while voluntary differential pricing schemes "are welcome contributions to improving access to medicines in developing countries . . . there is also the need to seek more broad-based solutions, which are also sustainable, to the serious public health problems that are being addressed"); WTO AGREEMENTS AND PUBLIC HEALTH: A JOINT STUDY BY THE WHO & THE WTO SECRETARIAT 101 (2002) (emphasizing that "donations are not considered to be a long-term solution to the affordability problem because of their time-limited nature"), available at http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf (Aug. 20, 2002).

IV. *Evaluating the Current WTO Intellectual Property Regime in Light of Human Rights*

In light of the moral, and possibly legal, obligations of the WTO member states to help fulfill the right to essential medicine, do the WTO agreements regarding TRIPS and public health go far enough? Commentators have found several reasons to criticize the current state of the law governing compulsory licensing. One potential problem with the August 30 Agreement is that it requires that someone compensate the patent holder when a compulsory license is issued.¹⁰⁵ Paragraph Four of the Agreement states that "adequate remuneration" should be paid, "taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member."¹⁰⁶ This less-than-lucid definition leaves states the task of calculating compensation. Malaysia, the first nation to issue a compulsory license to import generic antiretroviral drugs, decided to base its rate of remuneration on the per capita income of Malaysians and "the value of each life which would have been lost had the drugs not been available."¹⁰⁷ If the patent holders, Bristol-Myers Squibb and GlaxoSmithKline, do not agree with the level of compensation Malaysia offers, they may bring a complaint before the TRIPS Council.¹⁰⁸ Whether the remuneration requirement will turn into a stumbling block for poor nations remains to be seen, but the Malaysian government's compulsory license should, in the words of Indian Pharmaceuticals Alliance secretary general Dilip G. Shah, "provide an interesting test case to assess whether the August 30 decision is workable or needs modification."¹⁰⁹

A human-rights focus could help clarify the remuneration requirement. Suppose, for example, that Bristol-Myers Squibb and GSK decide to challenge Malaysia's rate of compensation. If the TRIPS Agreement recognized a basic right to essential medicine, the TRIPS Council would have to interpret "adequate remuneration" in light of that right and find that the rate of remuneration could not exceed the available resources of the importing state. Of course, the TRIPS Council could make that same determination from the current language of the August 30 Agreement, but

¹⁰⁵ August 30 Agreement, *supra* note 33, at 4.

¹⁰⁶ *Id.*

¹⁰⁷ See Gustav Ando, *World's First Compulsory License Issued in Malaysia for Generic HIV/AIDS Drug*, WORLD MARKET ANALYSIS, Feb. 26, 2004 (reporting that the exact calculation for compensation has not been determined). The Malaysian government has made a contract to import four ARVs from the Indian generic drug manufacturer Cipla. *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

the wording of the provision is too vague to meaningfully guarantee affordable medicine.¹¹⁰

Public health groups have also argued that the new agreements require so much red tape that nations will not be able to implement the compulsory licensing system.¹¹¹ The August 30 Agreement does require importing Members to make three notifications to the TRIPS Council when importing drugs under compulsory licenses.¹¹² First, the importing Member must specify the name and expected quantity of the medicine it will be importing.¹¹³ Second, if the Member is not a "least-developed country" it must establish that it lacks the manufacturing capacity to produce a sufficient supply of the medicine it will be importing under the system.¹¹⁴ Third, the importing Member must confirm that it has granted or intends to grant a compulsory license in accordance with TRIP Article 31 and the modifications of the August 30 decision.¹¹⁵ The exporting Members actually bear more of the administrative burden under the system, however. In addition to notifying the TRIPS Council of the quantities, names, and destinations of the drugs it will be producing under compulsory licensing, the exporting Member must make sure that the products are clearly identified to reduce the risk that they will be diverted from their intended market.¹¹⁶ The Agreement states, "Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction does not have a significant impact on price. . . ."¹¹⁷

The conditions on compulsory licensing are somewhat burdensome, but they are necessary to prevent abuse of the system. The WTO has dedicated a webpage to notifications, so the importing and exporting states can easily fulfill the reporting requirements online.¹¹⁸ The accountability required by the system seems no more tedious than necessary in order to ensure that compulsory licensing fulfills its purpose of helping nations

¹¹⁰ See *supra* notes 39–40 and accompanying text (discussing the vague wording of the August 30 Agreement).

¹¹¹ See Elizabeth Becker, *Poor Nations Can Purchase Cheap Drugs Under Accord*, N.Y. TIMES, Aug. 31, 2003, at 14 (quoting Doctors Without Borders representative Ellen 't Hoen, who stated that the August 30 decision "was designed to offer comfort to the U.S. and the Western pharmaceutical industry Global patent rules will continue to drive up the price of medicines.").

¹¹² August 30 Agreement, *supra* note 33, at para. 2(a).

¹¹³ *Id.* at para. 2(a)(i).

¹¹⁴ *Id.* at para. 2(a)(ii).

¹¹⁵ *Id.* at para. 2(a)(iii).

¹¹⁶ *Id.* at para. 2(b)(ii).

¹¹⁷ *Id.*

¹¹⁸ The WTO webpage dedicated to public health notifications can be accessed at http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm (last visited Oct. 6, 2005).

without manufacturing capability increase their supply of affordable medicine.

A human-rights focus could also help in this area, though, by guaranteeing that the system does not become so expensive that it impedes access to drugs. Specifically, a human rights requirement could be helpful in determining whether making the drugs identifiable would be "feasible"¹¹⁹—if the cost of distinguishing the product could prevent people from being able to afford the drug, then it would be impermissible under a rights analysis. As with the remuneration requirement, the TRIPS Council could interpret the current language of the Agreement—which states that the special packaging must "not have a significant impact on the price"¹²⁰—to mean that the cost must not affect the availability of the drug. But absent a more explicit statement in the Agreement, the provisions could become too burdensome for states, thereby allowing patents to prevent access to medicine.

V. Conclusion

Of course, patents are not the only, or even the primary, roadblocks to accessible medicine in developing nations. Over one-third of the world's population lacks access to the drugs on the WHO list of Essential Medicines, the great majority of which are not protected by patents in any country.¹²¹ As noted in a joint study by the WHO and WTO, "[t]he fact that billions of people lack access to essential drugs, most of which are not protected by patents, underscores the other problems contributing to inadequate access."¹²² The study identifies possible contributing factors to include insufficient distribution systems, poor financing, lack of capacity to import drugs, and the affordability of generic drugs for people in poor countries.¹²³

Many critics of compulsory licensing are also quick to point out that the lack of health-care infrastructure in developing nations "may mean that even inexpensive medicines are not used, or that they may be misused and contribute to the emergence of drug resistant pathogens or a virus."¹²⁴ In fact, one nation has used its own lack of infrastructure as an excuse for not providing publicly funded AIDS medication. Although the South African government triumphed over the pharmaceutical companies when it decided

¹¹⁹ August 30 Agreement, *supra* note 33, at para. 2(b)(ii).

¹²⁰ *Id.*

¹²¹ See Essential Medicines, *supra* note 97 (citing statistics for access to essential medicines); JOINT STUDY, *supra* note 58, at 96 (noting that the "vast majority of the 300 or so drugs on WHO's Model List of Essential Drugs are not under patent protection in any country").

¹²² JOINT STUDY, *supra* note 58, at 96.

¹²³ *Id.*

¹²⁴ See CIPR Report, *supra* note 58, at 31 (commenting on the problem of inadequate infrastructures in developing countries).

to break patents to manufacture and import generic drugs to help alleviate the nation's AIDS epidemic,¹²⁵ the government eventually announced that it would *not* provide ARV drugs through the public health system because it lacked the infrastructure to administer the drugs.¹²⁶

It does not follow, however, that because additional factors affect access to drugs the Members of the WTO should not attempt to make intellectual property laws socially responsible and responsive to human rights. In the negotiations preceding the August 30 Agreement, the African Group directly addressed arguments that the access problem involves more than patents:

Care should be exercised not to use the existence of other categories of problems as an argument against finding an expeditious solution [to the compulsory licensing problem]. [T]he expeditious solution under paragraph 6 [of the Doha Declaration] should relate to the lack of or insufficiency of local manufacturing capacity in the pharmaceutical sector, rather than the inadequacy of infrastructure or even poverty.¹²⁷

Undoubtedly, other agents—both public and private—must also contribute to a comprehensive, effective program to deliver needed medicines to people in poor countries. The necessity of other actors, however, does not detract from the role that the World Trade Organization should play in fulfilling the basic rights to life and health. By shifting its focus from "public health" to individual human rights, the WTO could improve the clarity and effectiveness of the measures it has already taken to increase access to essential medicine.

¹²⁵ See *infra* note 61 (discussing the pharmaceutical companies' decision to withdraw their legal challenge to the South African government's position on patents and AIDS drugs).

¹²⁶ See PAYING THE PRICE, *supra* note 2 ("[T]he South African government shocked the world by announcing that it would NOT start using ARV drugs. It claimed the cost was still beyond the reach of the public health system which simply did not have the infrastructure to administer the drugs."). Despite the government's claims, it is important to note that South Africa has greater resources at its disposal than other African nations that are attempting to supply ARVs through public health programs. *Id.* This may be due to the reluctance of the South African government to acknowledge the link between HIV and AIDS. *Id.* (quoting a South African man, who refused to accept that he had HIV until he developed full-blown AIDS, saying "Here in South Africa we always said there is no such thing you know—this disease is from the other countries like America you know").

¹²⁷ Joint Communication, *supra* note 23.

