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## Amending TRIPS: A New Hope for Increased Access to Essential Medicines

Tina S. Bhatt

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# AMENDING TRIPS: A NEW HOPE FOR INCREASED ACCESS TO ESSENTIAL MEDICINES

## INTRODUCTION

Global health has been a central concern of the international community since the creation of the United Nations.<sup>1</sup> Despite focused efforts by governments, regional and international alliances, and non-governmental organizations (“NGOs”),<sup>2</sup> a variety of obstacles continue to thwart the attainment of acceptable health standards across the globe.<sup>3</sup>

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1. For example, in 1948, the United Nations created a special agency, the World Health Organization (“WHO”), devoted to working towards attaining the highest possible standard of health for all peoples in the world. Over 190 countries participate in setting international health policy and implementing programs aimed at achieving the WHO mandate. WHO, Governance of WHO, <http://www.who.int/about/governance/en/index.html> (last visited Jan. 18, 2008). Since the creation of the WHO, the international community has continually reiterated its commitment to world health by creating other organizations and programs to deal with health issues on a global scale, such as the United Nations Children’s Fund (“UNICEF”), the United Nations Population Fund (“UNFPA”), and the Joint United Nations Program on HIV/AIDS (“UNAIDS”). YVES BEIGBEDER, INTERNATIONAL PUBLIC HEALTH 3 (2004). International commitment to world health is further illustrated by the fact that non-health related entities such as the World Bank and the World Trade Organization (“WTO”) now play a major role in financing and formulating health policy. *Id.* at 4–5.

2. For example, in 2003, the administration of United States President George W. Bush launched the President’s Emergency Plan for AIDS Relief (“PEPFAR”), “a five-year, \$15 billion, multifaceted approach to combating the disease around the world.” See The Office of the U.S. Global AIDS Coordinator, About PEPFAR, <http://www.pepfar.gov/about/> (last visited Feb. 24, 2008). In 2001, various Caribbean heads of state created The Pan Caribbean Partnership on HIV/AIDS (“PANCAP”), a coalition of public and private national, regional, and international organizations charged with scaling up national and regional responses to HIV/AIDS in the Caribbean. See PANCAP, <http://www.pancap.org/index.php> (last visited Jan. 18, 2008). In 1972, a coalition of “NGOs, foundations, corporations, government agencies and academic institutions” joined together and formed the Global Health Council, whose mission is “to ensure that all who strive for improvement and equity in global health have the information and resources they need to succeed.” See Global Health Council, Who we Are, [http://www.globalhealth.org/view\\_top.php3?id=25](http://www.globalhealth.org/view_top.php3?id=25) (last visited Feb. 24, 2008).

3. These include structural and societal challenges such as severe shortages of health workers in poor countries. See generally World Health Organization, *The World Health Report 2006—Working Together for Health* (2006), available at [http://www.who.int/whr/2006/whr06\\_en.pdf](http://www.who.int/whr/2006/whr06_en.pdf). On lack of access to basic sanitation and safe drinking water, see generally World Health Organization, *Meeting the MDG Drinking-water and Sanitation Target* (2006), available at [http://www.who.int/water\\_sanitation\\_health/monitoring/jmp/final.pdf](http://www.who.int/water_sanitation_health/monitoring/jmp/final.pdf). Regarding inadequate research into certain diseases that are prominent but for which there is no commercial market, see Special Rapporteur of the Commission on Human Rights on the Right of Everyone to the Enjoyment of the Highest Attainable Stan-

One such obstacle in the fight against HIV/AIDS<sup>4</sup> is inadequate access to essential medicines<sup>5</sup> in low- and middle-income countries.<sup>6</sup> According to a recent World Health Organization (“WHO”) study, eighty percent of HIV/AIDS patients that live in low- and middle-income countries and are in need of essential antiretroviral drug therapies<sup>7</sup> do not have access to

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dard of Physical and Mental Health, *Mission to the World Trade Organization*, ¶ 44, U.N. Doc E/CN.4/2004/49/Add.1 (Mar. 1, 2004) [hereinafter *Special Rapporteur's Mission to the WTO*]. There are also cultural challenges such as the stigma and violence faced by HIV positive persons that prevent many from getting tested or admitting that they are positive. See Tina Rosenberg, *When a Pill Is Not Enough*, N.Y. TIMES, Aug. 6, 2006, § 6 (Magazine), at 41 (describing some cultural obstacles to AIDS prevention in Africa). In 2003, the Bill and Melinda Gates Foundation, in collaboration with others, compiled a list of scientific and technological “grand challenges in global health” that included improving nutrition, insect, control, and vaccine delivery systems. See H. Varmus et al., *Grand Challenges in Global Health*, 302 SCIENCE 398, 399 (2003).

4. HIV, which stands for human immunodeficiency virus, is a human retrovirus that impairs the immune system over time as it replicates itself in the body. Pablo Tebas & Mary Horgan, *The Immuno-Compromised Host*, in THE WASHINGTON MANUAL OF MEDICAL THERAPEUTICS 288–89 (Charles F. Carey et al. eds., 29th ed. 1998). Eventually, the condition leads to AIDS, the acquired immune deficiency syndrome. *Id.* In the final stage of AIDS, known as full blown AIDS, “immune defenses break down completely and secondary (opportunistic) diseases attack the body. . . . Death usually follows a few years later.” AM. JUR., PROOF OF FACTS: ATTORNEY’S ILLUSTRATED MEDICAL DICTIONARY at A22 (3d series, 2002). In 2006, a total of 39.5 million people were living with HIV globally and there were 2.9 million AIDS-related deaths. Joint United Nations Programme on HIV/AIDS [UNAIDS] & World Health Organization [WHO], *AIDS Epidemic Update*, at 3, U.N. Doc. UNAIDS/06.29E (Dec. 2006), available at [http://www.who.int/hiv/mediacentre/2006\\_EpiUpdate\\_en.pdf](http://www.who.int/hiv/mediacentre/2006_EpiUpdate_en.pdf). Sixty-three percent of the world’s HIV positive population lives in sub-Saharan Africa and thirty-four percent of the 2006 AIDS-related deaths occurred in southern Africa. *Id.*

5. Essential medicines are those that, according to the WHO, “satisfy the priority health care needs of the population. They are selected [by the WHO] with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.” Essential Medicines, [http://www.who.int/topics/essential\\_medicines/en/](http://www.who.int/topics/essential_medicines/en/) (last visited Jan. 18, 2008). The updated WHO essential medicines list is available at [http://www.who.int/medicines/publications/08\\_ENGLISH\\_indexFINAL\\_EML15.pdf](http://www.who.int/medicines/publications/08_ENGLISH_indexFINAL_EML15.pdf) (last visited Jan. 18, 2008).

6. See generally WHO, *Progress on Global Access to HIV Antiretroviral Therapy: A Report on “3 by 5” and Beyond* (March 2006) [hereinafter *3 by 5 Report*], available at [whqlibdoc.who.int/publications/2006/9241594136\\_eng.pdf](http://whqlibdoc.who.int/publications/2006/9241594136_eng.pdf) (reporting that the goal of a joint WHO and UNAIDS initiative aimed at providing treatment to 3 million AIDS patients by 2005 had not been met and that treatment levels continue to be a major concern). See also *infra* Part I.A.

7. Antiretroviral treatments “temporarily suppress viral replication and improve symptoms” in HIV patients. WHO, *Essential Medicines*, § 6.4.2 (14th ed. Mar. 2005), available at [http://whqlibdoc.who.int/hq/2005/a87017\\_eng.pdf](http://whqlibdoc.who.int/hq/2005/a87017_eng.pdf). When used in the appropriate combination, they are the most effective means of suppressing HIV replication,

them.<sup>8</sup> There are a number of factors responsible for the staggeringly low rate of access.<sup>9</sup> One major culprit is drug prices.<sup>10</sup> The simple fact is that millions across the globe continue to suffer despite the existence of medical technology to improve their lives because they or their governments cannot afford to pay for treatment.<sup>11</sup>

Drug prices are set by the pharmaceutical companies that have invested time and money into the research and development that leads to medical discoveries.<sup>12</sup> In order to make the investment worthwhile and recoup their expenses, these companies patent their ideas. The patents give them the power to exclude others, namely generic manufacturers, from cheaply producing and profiting from their inventions.<sup>13</sup> Recognizing that without the ability to patent, and therefore profit from, their intellectual property, companies would cease the research necessary to discover medical technology, international trade regimes seek to ensure that pharmaceutical patents are honored across the globe rather than only in the companies' home countries.<sup>14</sup> The primary instrument for enforcing global patent protection is the Agreement on Trade-Related Aspects of

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Tebas & Horgan, *supra* note 4, at 290, and they are considered an essential component of HIV/AIDS treatment, *Essential Medicines, supra*. Their critical importance in combating the HIV/AIDS epidemic was underscored in 2003 when the United Nations launched a massive initiative called "3 by 5" to scale up global access to antiretroviral treatment. *See supra* note 6.

8. *See* World Health Organization, *World Health Statistics 2006*, at 18 (2006) [hereinafter *WHO Health Statistics*], available at <http://www.who.int/whosis/whostat2006/en/index.html>.

9. These include challenges associated with "partnerships, alignment, and harmonization; sustainable financing; drugs and other commodities; constraints in health systems, including human resources; ensuring equitable access; and monitoring, evaluation and research." *3 by 5 Report, supra* note 6, at 55.

10. *See, e.g., Special Rapporteur's Mission to the WTO, supra* note 3, at 12.

11. *See, e.g., id.*

12. *Cf.* ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 119 (3d ed. 2003) (explaining that under the "economic incentive" theory of patent law, "absent patent protection, inventors will not have sufficient incentive to invest in creating, developing, and marketing new products" and that patent protection allows "the inventor to appropriate the full economic rewards of her invention").

13. *Cf. id.* at 113 ("A patent confers the right to exclude others from making, using, selling, offering for sale, or importing the claimed invention for a specific term of years."). For a brief overview of the patent system, see Craig J. Madson, *Patents, in THE INTELLECTUAL PROPERTY HANDBOOK* 229–60 (William A. Finkelstein & James R. Simms III eds., 2005).

14. *See, e.g.,* Agreement on Trade-Related Aspects of Intellectual Property Rights § 5, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

Intellectual Property (“TRIPS”),<sup>15</sup> which was promulgated by the World Trade Organization (“WTO”)<sup>16</sup> in 1994 and has been ratified by all 193 current member states.<sup>17</sup>

International policymakers, however, have not been insensitive to the needs of sick, poor people in developing nations. TRIPS and subsequent WTO policy resolutions do allow countries to break patents under certain specified conditions when necessary to respond to emergencies such as a public health crisis.<sup>18</sup> However, these provisions, which are commonly referred to as “flexibilities,”<sup>19</sup> have not been successful in decreasing drug prices and thereby increasing access to essential medicines.<sup>20</sup> This failure is due in large part to the fact that patent flexibilities set by the WTO have been undermined by bilateral and multilateral free trade agreements (“FTAs”), most prominently by those negotiated between the United States and developing nations.<sup>21</sup>

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15. *Id.*

16. The WTO was created in 1995 to serve as an international institution that would carry out and promote the goals of the General Agreement on Trade and Tariffs (“GATT”). The GATT was originally negotiated in 1948 and served as both a provisional agreement and a provisional organization designed to promote international commerce by establishing a liberal world trade regime. Between 1948 and 1994, this was done primarily through a series of negotiations known as trade rounds. The final trade round was the Uruguay Round, which lasted seven and one half years and included 123 countries. The Uruguay Round replaced GATT the organization with the WTO but maintained an updated version of GATT the agreement as the main governing document. It also adopted a number of other agreements that established additional trade rules. These agreements are continually revised and renegotiated at ministerial conferences. *See* WTO, *Understanding the WTO*, 9, 14–22 (3d ed. 2005), available at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/understanding\\_e.pdf](http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf).

17. Margó A. Bagley, *Legal Movements in Intellectual Property: TRIPS, Unilateral Action, Bilateral Agreements, and HIV/AIDS*, 17 EMORY INT’L L. REV. 781, 782 (2003).

18. *See* TRIPS, *supra* note 14, art. 31; *see also* WTO, Doha Ministerial 2001: Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (May 2002) [hereinafter Doha Public Health Declaration], available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) (explicitly asserting that TRIPS “does not and should not prevent Members from taking measures to protect public health” and clarifying the exceptions to the patent rules that governments may make for legitimate public health concerns).

19. WTO, Fact Sheet: TRIPS and Pharmaceutical Patents, [http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm) (last visited Feb. 14, 2008).

20. *See* Bagley, *supra* note 17, at 791 (explaining that TRIPS flexibilities have been ineffective because they are rarely used).

21. *See id.* at 791–93; *see also* Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2871 (2006); Maria Julia Oliva, *Intellectual Property in the FTAA: Little Opportunity and Much Risk*, 19 AM. U. INT’L L. REV. 45, 53 (2003); *cf.* Michael D. Birnhack, *Global Copyright, Local Speech*, 24 CARDOZO ARTS &

Thus, lack of access to essential HIV/AIDS medicines because of unaffordable drug prices continues to be a world health problem. However, this situation is more than a social tragedy; it also poses a legal dilemma. Access to medicine is a fundamental aspect of the right to health, secured for every person by the International Bill of Human Rights.<sup>22</sup> On the other hand, not only do pharmaceutical companies also have intellectual property rights that must be protected,<sup>23</sup> patent protection is necessary for the continued availability of drugs.<sup>24</sup> The WTO has acknowledged these competing interests and has made significant progress towards reaching an appropriate balance.<sup>25</sup> However, U.S. policy, as expressed in the pharmaceutical patent provisions of bilateral and multilateral FTAs, fails to adequately take the right to health into account. It secures significantly more stringent patent protection for pharmaceuticals than provided for in TRIPS without incorporating the necessary flexibilities that would enable increased access to medicines for health crisis situations.<sup>26</sup> As such, it not only violates human rights norms, but also contradicts the WTO position. Thus, American policy must be changed.

This Note attempts to contribute toward effecting such change by exploring mechanisms within the human rights and international trade realms for challenging patent provisions in U.S. FTAs. Part I establishes the practical need for change by describing the current lack of access to essential medicines in developing nations and the legal ramifications of inadequate access in the context of the international human right to health. Part II discusses the impact of WTO and American trade and intellectual property policies on the accessibility of essential medicines. Part III argues that the WTO's recent decision to amend TRIPS has two consequences that invalidate U.S. pharmaceutical patent policy. First, it

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ENT. L.J. 491, 513–14 (2006) (describing TRIPS-plus provision in U.S. and European multilateral agreements in the context of literary and artistic work).

22. See U.N. Econ. & Soc. Council (“ECOSOC”), Comm. On Econ., Soc., & Cul. Rts (“CESCR”), *Substantive Issues Arising in the Implementation of the International Covenant On Economic, Social and Cultural Rights (General Comment No. 14)*, ¶ 2, U.N. Doc. E/C.12/2000/4 (May 12, 2000) [hereinafter *CESCR Gen. Comment 14*], available at [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); see also *infra* part I.B.

23. See TRIPS, *supra* note 14; see also *infra* part I.C.

24. See *supra* notes 13–14. But see *Special Rapporteur's Mission to the WTO*, *supra* note 3, ¶ 44 (pointing out that patent protection fails to incentivize medical research into diseases that only affect poor countries, such as river blindness and sleeping sickness, since the people that need such research would not be able to pay for it).

25. See *supra* note 18; see also *Special Rapporteur's Mission to the WTO*, *supra* note 3, ¶ 43; see also *infra* part II.A.

26. See *supra* note 21.

argues that the decision to amend, taken together with other historical developments, elevates the access to essential medicines component of the right to health to the status of customary international law. It then explores whether the amendment will invalidate U.S. policy as a violation of the General Agreement on Trades and Tariffs ("GATT"). Finally, The Note concludes with an assessment of the implications of these developments.

## I. THE NEED FOR CHANGE

### A. *The Current Lack of Access*

Eighty percent of people in low- and middle-income countries that need antiretroviral therapy ("ART") to treat HIV/AIDS do not have access to it.<sup>27</sup> Eighty-three percent of sub-Saharan Africans and ninety-five percent of northern Africans and Middle Easterners do not receive needed medicines.<sup>28</sup> In East, South, and Southeast Asia, eighty-four percent of those requiring ART do not receive it. In low- and middle-income countries in Europe and Central Asia, eighty-seven percent do not receive ART.<sup>29</sup> In Latin America and the Caribbean, ART coverage is better but still inadequate at sixty-eight percent.<sup>30</sup>

While these statistics represent the situation in a substantial part of the world, they do not represent what the standard of care can be, especially considering that ART coverage in high-income countries, such as the United States, the United Kingdom, and France reaches above seventy-five percent.<sup>31</sup> Also disconcerting is the fact that access to treatment is uneven between similarly situated countries. For example, Thailand's coverage reaches up to sixty percent<sup>32</sup> while in India, ART is accessible to a mere seven percent of those that need it.<sup>33</sup> Botswana and Uganda have over fifty percent coverage while coverage in other sub-Saharan countries is well below ten percent.<sup>34</sup>

One reason why essential medicines are not reaching all who need them is their high price.<sup>35</sup> Though prices have dropped over the last few

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27. *3 by 5 Report*, *supra* note 6, at 19.

28. *Id.*

29. *Id.*

30. *Id.*

31. *WHO Health Statistics*, *supra* note 8, at 37, 41.

32. *Id.* at 41.

33. *Id.* at 37.

34. *3 by 5 Report*, *supra* note 6, at 7.

35. *Id.* at 29–30 (discussing drug prices in the context of access to HIV treatment and reporting statistics establishing an inverse correlation between treatment costs and num-

years in some low-income countries, they remain “unacceptably high in some countries” and have remained “almost stable” in middle-income countries.<sup>36</sup> Additionally, drugs that have decreased in price represent mostly first-line treatment<sup>37</sup> while second-line treatment (used after patients develop immunities to first-line drugs<sup>38</sup>) costs are “prohibitive” in most countries<sup>39</sup> and vary greatly amongst countries of similar income level.<sup>40</sup>

Brazil, where ART coverage is at eighty-three percent,<sup>41</sup> presents a prime example of the dramatic effect drug prices have on access to treatment. Brazil was the first developing nation to provide universal free AIDS treatment and has “the best anti-AIDS program of any developing country.”<sup>42</sup> It has been able to afford this by manufacturing generic versions of brand name drugs, thus reducing costs by up to almost half.<sup>43</sup>

Generic manufacturers have been identified favorably as contributing to the price drops that have occurred within the last few years.<sup>44</sup> Moreover, in addition to making cheaper and therefore more accessible drugs, generic manufacturers are better able to serve the treatment needs of individuals in middle- and low-income countries because they provide

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ber of people treated in 2003, 2004, and 2005); *Special Rapporteur's Mission to the WTO*, *supra* note 3, ¶ 43.

36. *3 by 5 Report*, *supra* note 6, at 8.

37. *Id.* at 8–9 (reporting that in low-income countries the average cost per person per year of two particular types of first-line treatment ranged from \$148 to \$549 whereas a particular second-line regime cost an average of \$1888).

38. First line treatment refers to a “preferred, standard, or first choice” drug or procedure. Merriam-Webster Online Dictionary, <http://www.merriam-webster.com/dictionary/first-line> (last visited Feb. 28, 2008).

39. *3 by 5 Report*, *supra* note 6, at 12.

40. *Id.* at 8–9 (reporting the cost of the same second-line treatment in the middle-income Ivory Coast was \$1700 but \$6788 in its fellow middle-income country of El Salvador).

41. *Id.* at 71.

42. Editorial, *Brazil's Right to Save Lives*, N.Y. TIMES, June 23, 2005, at A18.

43. Brazil makes “copycat versions of expensive brand-name drugs” that were “commercialized before 1997, when the country began to respect patents on medicines, a requirement for joining the World Trade Organization.” *Id.* The system worked so well that in June 2005, Brazil became the first country to break the patent for a previously protected antiretroviral medicine when it announced that it would manufacture generic Kaletra. Todd Benson, *Brazil to Copy AIDS Drug Made by Abbott*, N.Y. TIMES, June 25, 2005, at C12. Though WTO rules required Brazil to pay the patent holder, Abbott Laboratories, a royalty on the generic version, the Brazilian government estimated that it would save \$55 million per year. *Id.*

44. *3 by 5 Report*, *supra* note 6, at 8.

drugs in therapy combinations not supplied by brand-name manufacturers.<sup>45</sup>

*B. The Right to Health: Legal Ramifications of Inadequate Access*

That treatments for HIV/AIDS are available yet so many cannot access them is a great social tragedy. However, it is also a legal dilemma. On December 12, 1948, the General Assembly of the United Nations adopted the Universal Declaration of Human Rights ("UDHR").<sup>46</sup> From this list of principles emerged two binding treaties: the International Covenant on Civil and Political Rights ("ICCPR")<sup>47</sup> and the International Covenant on Economic, Social and Cultural Rights ("ICESCR").<sup>48</sup> These three documents together constitute the International Bill of Human Rights and have enabled the modern day human rights movement.<sup>49</sup> They

45. *3 by 5 Report*, *supra* note 6, at 60.

46. Universal Declaration of Human Rights, G.A. Res. 217A, at 71, U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc A/810 (Dec. 10, 1948) [hereinafter UDHR], available at <http://www.unhcr.ch/udhr/lang/eng.pdf>. As a declaration, the UDHR was intended to be "a moral and political influence on states rather than constitute a legally binding instrument." HENRY J. STEINER & PHILIP ALSTON, HUMAN RIGHTS IN CONTEXT 138 (2000). Nonetheless, it has had a tremendous impact on the development of international law:

[I]t has retained a place of honor in the human rights movement. No other document has so caught the historical moment, achieved the same moral and rhetorical force, or exerted as much influence on the movement as a whole. . . . It proceeded to work its subversive path through many rooted doctrines of international law, forever changing the discourse of international relations on issues vital to human decency and peace.

*Id.* at 139 (internal citation and quotation marks omitted). The UDHR was originally intended to give rise to a single binding convention. *Id.* However, due to ideological differences, two covenants, one for civil and political rights and another for social, economic, and cultural rights were created, *id.* at 242–45, even though the UDHR "included both categories without any sense of separateness or priority." *Id.* at 247.

47. International Covenant on Civil and Political Rights, Dec. 16, 1966, 999 U.N.T.S. 171, [hereinafter ICCPR], available at <http://www.ohchr.org/english/law/pdf/ccpr.pdf>. The rights secured by the ICCPR can be loosely classified into the following five: (1) protection of the individual's physical integrity (e.g., prohibitions on torture and arbitrary deprivations of life); (2) procedural due process; (3) equal protection; (4) freedoms of belief, speech, and association; and (5) the right to political participation. STEINER & ALSTON, *supra* note 46, at 145. There are currently 160 state parties to the ICCPR. U.N. High Comm. On Hum. Rts., Status of Ratification: ICCPR, <http://www2.ohchr.org/english/bodies/ratification/4.htm> (last visited Feb. 14, 2008).

48. International Covenant on Economic, Social, and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3, [hereinafter ICESCR], available at <http://www.ohchr.org/english/law/pdf/cescr.pdf>.

49. STEINER & ALSTON, *supra* note 46, at 136.

also officially established every individual's right to health, thus making access to treatment for medical illness a human rights and international law issue.

Article 25.1 of the UDHR proclaims 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, housing and medical care and necessary social services."<sup>50</sup> This concept is comprehensively enshrined in and given binding effect by article 12 of the ICESCR. Section 1 of the article defines the right and section 2 lays out the correlative governmental obligations to protect the right by providing an "illustrative, non-exhaustive" list of examples.<sup>51</sup> Article 12 reads in relevant part:

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.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
  - ...
  - (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
  - (d) The creation of conditions, which would assure to all medical service and medical attention in the event of sickness.<sup>52</sup>

The right to health is also recognized in various other international and regional agreements.<sup>53</sup> None of these documents explicitly grant a right of "access to pharmaceuticals," however, the language of the provisions

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50. UDHR, *supra* note 46, art. 25.1.

51. *ICESCR Gen. Comment 14*, *supra* note 22, ¶ 7.

52. ICESCR, *supra* note 48, art. 12.

53. See International Convention on the Elimination of All Forms of Racial Discrimination, Art. 5(e)(iv), *opened for signature* Mar. 7, 1966, 660 U.N.T.S. 212; Convention on the Elimination of All Forms of Discrimination against Women, art. 11.1(f), 12, Dec. 18, 1979, 1249 U.N.T.S. 14; Convention on the Rights of the Child, art. 24, *adopted* Nov. 20, 1989, 144 U.N.T.S. 123; The European Social Charter, art. 11, Oct. 13, 1961, 529 U.N.T.S. 89; African Charter on Human and Peoples' Rights, art. 16, Jan. 27, 1981, 21 I.L.M. 58. For a collection of the basic international right to health documents, see generally FRANCIOS-XAVIER BAGNOUD CTR. FOR HEALTH AND HUM. RTS., HARV. SCH. OF PUB. HEALTH, HEALTH AND HUMAN RIGHTS: BASIC INTERNATIONAL DOCUMENTS (Stephen P. Parks ed., 2004). For a more comprehensive collection, see THE RAOUL WALLENBERG INSTITUTE OF HUMAN RIGHTS AND HUMANITARIAN LAW, A THEMATIC GUIDE TO DOCUMENTS ON HEALTH AND HUMAN RIGHTS (Gudmundur Alfredsson & Katrina Tomaševski eds., 1999).

clearly contemplates access to essential medicines and article 25 has been interpreted to include such a right.<sup>54</sup> Moreover, other rights also imply a right of access to pharmaceuticals. The UDHR states that everyone has the right to “share in scientific advancement and its benefits.”<sup>55</sup> The ICESCR confers on everyone “the right to enjoy the benefits of scientific progress and its applications.”<sup>56</sup> There is also the right to life itself,<sup>57</sup> to which the right to health is regarded as “closely related” and “dependent upon.”<sup>58</sup>

Finally, access to essential medicines is acknowledged as a legitimate and important concern in non-human rights contexts as well. The WTO has most prominently addressed the issue.<sup>59</sup> The World Bank has issued statements recognizing its importance.<sup>60</sup> Even the World Intellectual Property Organization (“WIPO”),<sup>61</sup> which downplays both the impact of patent protection on drug prices and the impact of drug prices on access to drugs, acknowledges the importance of striking a balance between

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54. See *CESCR Gen. Comment 14*, *supra* note 22, ¶ 11–12 (identifying access to essential medicines as defined by the WTO as a core obligation of states under right to health and explaining that the right to health is “an inclusive right extending not only to the timely and appropriate health care but also to the underlying determinants of health” and requires states parties to ensure that health facilities, goods, and services “whether privately or publicly provided, are affordable for all, including socially disadvantaged groups”); see also *Special Rapporteur’s Mission to the WTO*, *supra* note 3, ¶ 43 (explaining that because the right to health includes access to essential medicines, patent protection can infringe upon the right).

55. UDHR, *supra* note 46, art. 27(1).

56. ICESCR, *supra* note 48, art. 15(1)(b).

57. UDHR, *supra* note 46, art. 3 (“Everyone has the right to life, liberty and security of person.”); ICCPR, *supra* note 47, art. 6(1) (“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.”).

58. See *CESCR Gen. Comment 14*, *supra* note 22, ¶ 3.

59. See *infra* Part II.A.

60. See Juan Rovira, *Trade Agreements, Intellectual Property, and the Role of the World Bank in Improving Access to Medicines in Developing Countries*, 4 *YALE J. HEALTH POL’Y L. & ETHICS* 401 (2004), 410–411 (describing the World Bank’s position encouraging the use of patent flexibilities and the production of generics to increase access to antiretroviral AIDS drugs).

61. WIPO is a specialized United Nations agency with a mandate “to promote the protection of IP throughout the world through cooperation among states and in collaboration with other international organizations.” WIPO, *What is WIPO?*, [http://www.wipo.int/about-wipo/en/what\\_is\\_wipo.html](http://www.wipo.int/about-wipo/en/what_is_wipo.html) (last visited Feb. 14, 2008). For a brief overview of WIPO’s history and the WIPO framework, see Elaine Gin, *International Copyright Law: Beyond the WIPO & TRIPS Debate*, 86 *J. PAT. & TRADEMARK OFF. SOC’Y* 763 (2004), 779–781.

health concerns such as access to medicine and the benefits of a robust patent regime.<sup>62</sup>

Despite the fact that the concept has been a part of the human rights movement for quite some time and is recognized in a number of instruments, the right to health does not enjoy the same legal force as rights that are considered “fundamental,” such as rights protecting against torture and genocide. There are a number of reasons for this. First, the right to health suffers from a degree of “conceptual unclarity.”<sup>63</sup> Although certain core concepts, including access to essential medicine, have emerged over the years,<sup>64</sup> “[i]t is difficult to pinpoint exactly what the right to health contains. Health is a very broad and subjective concept . . . [and] there exists a certain normative overlap with other human rights . . . .”<sup>65</sup>

Second, the right to health is different from other human rights in that it is subject to progressive realization over time.<sup>66</sup> However, “[r]ecognition of core content underlines the fact that some elements are not subject to progressive realization and should be realized immediately, a notion which makes the right to health more tangible.”<sup>67</sup> Additionally, the right to health does impose an immediate obligation to take meaningful steps towards its fulfillment.<sup>68</sup> Finally, there is a presumption that the

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62. See WIPO, *Striking a Balance: The Patent System and Access to Drugs and Health Care*, [http://www.wipo.int/freepublications/en/patents/491/wipo\\_pub\\_491.pdf](http://www.wipo.int/freepublications/en/patents/491/wipo_pub_491.pdf) (last visited Feb. 14, 2008) (describing the WIPO’s efforts to strike the appropriate balance between public health concerns relating to access to medicine and the interests of patent owners).

63. Brigit Toebes, *The Right to Health*, in *ECONOMIC, SOCIAL, AND CULTURAL RIGHTS* 175 (Asbjørn Eide, Catarina Krause & Allan Rosas eds., 2d rev. ed. 2001).

64. *Id.* at 176–177. Core concepts are primarily derived from the WHO Health for All strategy and include maternal and child healthcare, family planning, immunization against the major infectious diseases, appropriate treatment of common diseases and injuries, education concerning prevention and control of major health problems, promotion of food supply and proper nutrition, and adequate supply of safe water and basic sanitation. *Id.*

65. *Id.* at 174–175. See also John D. Blum, *Is Justice for One Justice for All? The Dilemma of Public Health Enforcement in an Interconnected World*, 36 *LOY. U. CHI. L.J.* 349 (2004) (describing the difficulty of achieving an international agreement on what the right to health means as a function of the “conceptual split over health, and the commensurate legal right to health, between the developed and the developing world”).

66. See *CESCR Gen. Comment 14*, *supra* note 22, ¶ 31 (“[P]rogressive realization means that States parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of article 12.”).

67. Toebes, *supra* note 63, at 176.

68. *CESCR Gen. Comment 14*, *supra* note 22, ¶ 30 (“States parties have immediate obligations in relations to the right to health, such as the guarantee that the right will be exercised without discrimination of any kind (art. 2.2) and the obligation to take steps

right prohibits states from taking steps that would undermine progress towards its realization<sup>69</sup> as well as an obligation to “refrain from interfering directly or indirectly with the enjoyment” of it.<sup>70</sup>

Another challenge is that the right to health is not universally binding. One hundred fifty-seven countries have ratified the ICESCR.<sup>71</sup> Thus, five countries, including the United States, are not bound to its expression of the right to health.<sup>72</sup> Moreover, the right to health does not enjoy the status of customary international law,<sup>73</sup> which would be binding on the United States in certain contexts despite the absence of a formal recognition of the right.<sup>74</sup> Additionally, unlike the ICCPR, there currently is no formal system in place for adjudicating violations of the ICESCR.<sup>75</sup> Fi-

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(art. 2.1) towards the full realization of article 12. Such steps must be deliberate, concrete and targeted towards the full realization of the right to health.”).

69. *Id.* ¶ 32 (“As with all other rights in the Covenant, there is a strong presumption that retrogressive measures taken in relation to the right to health are not permissible. If any deliberately retrogressive measures are taken, the State party has the burden of proving that they have been introduced after the most careful consideration of all alternatives and that they are duly justified by reference to the totality of the rights provided for in the Covenant in the context of the full use of the State party’s maximum available resources.”).

70. *Id.* ¶ 33.

71. Office of the United Nations High Commission for Human Rights, ICESCR Ratifications and Reservations, <http://www2.ohchr.org/english/bodies/ratification/3.htm> (last visited Feb. 14, 2008).

72. Other abstainers are Belize, Pakistan, Sao Tome and Principe, and South Africa. *Id.* All of these countries, including the United States, have signed the covenant without reservation but have not yet ratified it. *Id.* One, South Africa, has a domestic constitutional right to health. S. AFR. CONST. 1996 art. 27.

73. *Flores v. S. Peru Copper Corp.*, 414 F.3d 233, 254 (2d Cir. 2003) (holding that the right to health is “insufficiently definite to constitute rules of customary international law”).

74. For example, in the Alien Tort Claims Act (“ATCA”), which gives federal district courts original jurisdiction over civil actions by aliens for torts committed “in violation of the law of nations or a treaty of the United States.” 28 U.S.C. § 1350 (2000). In this context, courts “have consistently used the term ‘customary international law’ as a synonym for the term the ‘law of nation.’” *Flores*, 414 F.3d at 237 n.2.

75. Article 16 of the ICESCR requires states parties to submit “reports on the measures which they have adopted and the progress made in achieving the observance of the rights recognized herein,” which includes the right to health, to the Commission on Economic, Social, and Cultural Rights (“CESCR”), the body charged with overseeing the implementation of the ICESCR. This generally takes the form of a written and oral discussion between the CESCR and a state government that concludes with the CESCR adopting “concluding observations in relation to a specific state report.” Allan Rosas & Martin Scheinin, *Implementation Mechanisms and Remedies*, in *ECONOMIC, SOCIAL, AND CULTURAL RIGHTS* 426–427 (Asbjørn Eide, Catarina Krause & Allan Rosas eds., 2d rev. ed. 2001). This system “is more and more resembling a quasi-judicial complaint proce-

nally, many governments are ambivalent or hostile to economic and social rights generally in part because they believe civil and political rights are more basic and urgent and should be prioritized.<sup>76</sup>

The fact that the right to health is a progressive right, lacks binding force, and struggles along with other economic and social rights to be taken seriously leaves individuals hoping to assert it with no venue to challenge general violations. However, as will be argued in Part II of this Note, the access to essential medicines component of the right to health is now ripe for elevation to customary international law. Assigning such status to the access issue is a step towards judicial enforcement.

### *C. The Legal Dilemma: The Conflict between Intellectual Property Rights and Health Rights*

Another issue that complicates the realization of the right to health is that, like all rights, it competes and conflicts with other rights. Often, these other rights are more widely accepted and are supported by a much more robust jurisprudence consisting of generations of statutes, treaties, and case law.<sup>77</sup> It is, in a sense, an uneven fight. Consequently, right to

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dure[.]" but there still is no official complaint procedure. *Id.* at 427. This is in contrast to the ICCPR (the treaty that guarantees civil and political rights, see *supra* note 47), which is authorized to receive, review, and issue opinions on complaints from individuals claiming that a state has violated an ICCPR provision. See STEINER & ALSTON, *supra* note 46, at 738. This individual complaint system was made possible through the enactment of a binding optional protocol to the ICCPR, *id.*, and has enabled the development of international case law and jurisprudence on civil and political rights. See John Quigley, *The International Covenant on Civil and Political Rights and the Supremacy Clause*, 42 DEPAUL L. REV. 1287, 1294 (1993). Efforts to enact a similar system for the ICESCR have been underway since 1990, but no consensus has been reached thus far. Michael J. Dennis & David P. Stewart, *Justiciability of Economic, Social, and Cultural Rights: Should There be an International Complaints Mechanism to Adjudicate the Rights to Food, Water, Housing, and Health?*, 98 AM. J. INT'L L. 462, 463 (2004). "Proponents of a complaints mechanism have long argued that the absence of strong enforcement mechanisms in the ICESCR has marginalized economic, social, and cultural rights and stymied their full realization." *Id.*

76. STEINER & ALSTON, *supra* note 46, at 249–51.

77. Cf. Asbjørn Eide & Allan Rosas, *Economic, Social, and Cultural Rights: A Universal Challenge*, in ECONOMIC, SOCIAL, AND CULTURAL RIGHTS at 4 (describing one theory advanced by many that regards civil and political rights as first generation rights and economic, social, and cultural rights as second generation rights); *id.* at 5 ("It is a well-known fact that economic, social, and cultural rights are surrounded by controversies, both of an ideological and technical nature. To some, they are not true rights at all . . .").

health issues are not prioritized.<sup>78</sup> The right to access to essential medicines, in particular, is in direct competition most significantly with patent rights.

Unlike the right to health, patent rights are longstanding<sup>79</sup> and universally accepted.<sup>80</sup> They are a component of intellectual property rights<sup>81</sup> and give inventors the ability to legally exclude others from profiting from their innovations.<sup>82</sup> The theory of patent rights is based on the premise that inventions are “public goods that are costly to make and that are difficult to control once they are released into the world.”<sup>83</sup> Thus, patent rights provide the economic incentive necessary to spur invention by giving inventors the ability to take legal action against those that attempt to profit from their invention, whether by stealing it, reverse engineering it, or discovering it independently.<sup>84</sup>

Patent protection directly conflicts with access to essential medicine because it prevents the production and sale of generic versions of patented drugs.<sup>85</sup> Generic drugs significantly increase the accessibility of

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78. *Cf. id.* at 3 (In the years since the passage of the ICCPR and the ICESCR, “civil and political rights have attracted much more attention in theory and practice, while economic, social, and cultural rights have often been neglected.”).

79. The history of the patent system can be traced back to the Renaissance. *Id.* at 106. Patent law first started becoming internationalized (such that an inventor with patent rights in one country could assert them in another country) in 1883 with the Paris Convention. *Id.* at 293.

80. For example, patent protection is alluded to in article 27(2) of the UDHR, *supra* note 46. Article 15(1)(c) of the ICESCR, *supra* note 48, states that every person has “the right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.” (Interestingly, this same article guarantees the right of everyone to benefit from scientific advancement.) In 1893, fourteen countries formed the predecessor to the World Intellectual Property Organization (“WIPO”). WIPO, About WIPO, <http://www.wipo.int/treaties/en/general/> (last visited Feb. 14, 2008). In 1974, WIPO became an official part of the United Nations and currently has 184 member countries. *Id.*

81. MERGES ET AL., *supra* note 12.

82. *Id.*

83. *Id.* at 119.

84. *Id.* Other theories justifying patent rights include reward-based theories, natural law theories, personhood theories, and property theories but these other theories play a less significant role in patent law. *Id.* at 119 & n.38.

85. *Cf.* Robert Weissman, *A Long, Strange Trips: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1099 (1996) (“Justified even on its own terms, the patent is not an unmitigated good. . . . It does accomplish its stated goal of placing information regarding the newly invented item in the public domain, but it does so at the expense of conditioning the right to use this information commercially on securing a license from the patent holder. A license can

medicine because they are cheaper than the patented brand name versions. “It is well documented that drug prices drop when countries promote the use of generics, abolish patents, or impose direct price controls.”<sup>86</sup>

At the international level, the production of generic drugs was primarily impeded by TRIPS, an agreement passed in 1994 by the WTO.<sup>87</sup> The agreement “brings together . . . a broad range of intellectual property rights (“IRPs”) previously protected by subject-specific agreements”<sup>88</sup> and is “the first significant multilateral agreement requiring member countries to provide certain minimum levels of protection to owners of intellectual property.”<sup>89</sup> It also contains an enforcement mechanism. A state party alleging violations of the agreement by another state party may have its claim adjudicated by WTO dispute settlement procedures.<sup>90</sup> Member states that fail to comply with the provisions of the agreement may be subject to trade sanctions.<sup>91</sup> Additionally, TRIPS requires member states to maintain both civil and criminal enforcement procedures within their own borders to protect individual rights holders.<sup>92</sup> Currently, 151 countries are members of the WTO and TRIPS.<sup>93</sup>

Part II, section 5 of TRIPS governs patents. It sets the minimum substantive protections that all member governments must provide to eligi-

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usually only be acquired for a fee and, in the case of pharmaceuticals, is often not available for any feasible price.”)

86. Rahul Rajkumar, Note, *The Central American Free Trade Agreement: An End Run Around The Doha Declaration on Trips and Public Health*, 15 ALB. L.J. SCI. & TECH. 433, 438 (2005) (citing Fredrick T. Schut & Peter A.G. Van Bergeijk, *International Price Discrimination: The Pharmaceutical Industry*, 14 WORLD DEV. 1141, 1147 (1986)).

87. *Supra* note 14; *cf.* Doha Public Health Declaration, *supra* note 18, ¶ 3 (WTO declaration issued after trade rules were hindering access to medicines and acknowledging the effect of intellectual property rights on prices).

88. Laurence R. Helfer, *Adjudicating Copyright Claims Under the TRIPS Agreement: The Case for a European Human Rights Analogy*, 39 HARV. INT’L L.J. 357, 358–59 (1998).

89. Bagley, *supra* note 17, 782.

90. TRIPS, *supra* note 14, art. 64.1 (stating that disputes arising under TRIPS shall be settled by the standard WTO dispute settlement procedures established in “articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding . . .”).

91. Bagley, *supra* note 17, 782–83.

92. TRIPS, *supra* note 14, arts. 41–61.

93. WTO, Members and Observers, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) (last visited Feb. 14, 2008). There are also thirty-two observer countries, some of which are currently in accession negotiations and all of which, excluding the Holy See, must begin accession negotiations within five years of becoming an observer. *Id.*

ble innovations and provides criteria that tightly control the circumstances under which derogation of patent rights is permitted.<sup>94</sup> Under article 27, pharmaceutical drugs are generally eligible for patent protection.<sup>95</sup> However, products must be new and innovative in order to receive protection.<sup>96</sup> Article 28 defines the patent holder's rights. These include the right to exclude third parties from making, using, selling, or importing the patented product or process without consent<sup>97</sup> as well as the right to assign, transfer, and license the patent.<sup>98</sup> Under article 33, the patent holder has the right to exercise these rights for a term of twenty years.<sup>99</sup> Article 30 allows the government of a member state to limit a patent holder's right to exclude other generic manufacturers "provided that such exceptions do not unreasonably conflict with the 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."<sup>100</sup>

Under article 27, a member government is permitted to deny a patent to an otherwise eligible invention if preventing the commercialization of the invention "is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment . . . ."<sup>101</sup> This provision is known as the public health exception.<sup>102</sup> Article 31 establishes parameters under which a

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94. Bagley, *supra* note 17, at 785.

95. *Cf.* TRIPS, *supra* note 14, at art. 27.3 (listing the types of products that are ineligible for patent protection under TRIPS as "diagnostic, therapeutic and surgical methods" and "plants and animals other than micro-organisms"). Although article 27 does not explicitly mention pharmaceuticals, that they were intended to receive patent protection is evident from article 70(8). That article is a special provision for countries that did not already provide patent protection for pharmaceuticals that required those countries to begin to do so as they transitioned into TRIPS compliance. *See* Peggy B. Sherman & Ellwood F. Oakley, III, *Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 AM. BUS. L.J. 353, 363 (2004). The inclusion of article 70.8 was "[o]ne of the most significant victories in TRIPS for the pharmaceutical industry." *Id.* at 364.

96. TRIPS, *supra* note 14, at art. 27.1.

97. TRIPS, *supra* note 14, at art. 28.1(a)–(b).

98. *Id.* art. 28.2.

99. *Id.* art. 33 ("The term of protection available shall not end before the expiration of a period of twenty years.").

100. *Id.* art. 30.

101. *Id.* art. 27.2.

102. *See* Weissman, *supra* note 85, at 1099. Some have argued that article 27, which states that therapeutic processes are ineligible for patent protection, is also a public health exception because pharmaceuticals are a therapeutic process for the treatment of illnesses. However, this interpretation is "extreme" and "inconsistent" with article 70.8, which specifically discusses the patentability of pharmaceuticals. Sherman & Oakley,

member government may exercise the public health exception by breaking a pharmaceutical drug patent, also known as compulsory licensing.<sup>103</sup> The decision to break a patent in this manner must be made on a case-by-case basis.<sup>104</sup> Additionally, the patent can only be broken for a limited scope and duration.<sup>105</sup> The majority of the goods produced as a result of the patent break must be used domestically<sup>106</sup> and thus they cannot be exported to another country.<sup>107</sup> The member government must also pay the patent holder remunerations if it breaks the patent.<sup>108</sup>

These mechanisms that allow member governments to loosen patent protection in cases of national emergencies are commonly referred to as “flexibilities.”<sup>109</sup> The flexibilities make TRIPS compatible with an international patent system that adequately balances patent interests with the need for access to essential medicines. The system was able to address the concerns of the pharmaceutical industry<sup>110</sup> while allowing member

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*supra* note 95, at 368. Public health is also mentioned in article 8.1, which states that “[m]embers 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, *supra* note 14, art. 8.1.

103. Compulsory licensing allows a country to give someone other than the patent-holder, such as a manufacturer of generic drugs, the right to manufacture and sell the patented product without the patent-holder’s permission. BEIGBEDER, *supra* note 1, at 65. The article makes specific reference to a “case of a national emergency or other circumstances of extreme urgency,” TRIPS, *supra* note 14, art. 31(b), however, compulsory licensing is also permitted for non-emergency situations such as non-commercial public use, *id.* art. 31(c), or to correct anti-competitive practices, *id.* art. 31(k). Additionally, article 30 of TRIPS “potentially provides for very broad exceptions to the patent requirements of the Agreement . . . [as it] does not limit the purposes for which a country may make exceptions to the Agreement.” Weissman, *supra* note 85, at 1108.

104. TRIPS, *supra* note 14, art. 31(a).

105. *Id.* art. 31(c).

106. *Id.* art. 31(f).

107. *Id.*; *see also* Fact Sheet: TRIPS and Pharmaceutical Patents, *supra* note 19.

108. *Id.* art. 31(h).

109. *See, e.g.*, Sherman & Oakley, *supra* note 95, at 368 (referring to provisions that compose the public health exception as “TRIPS flexibilities”).

110. Indeed, as described in Weissman, *supra* note 85, the American pharmaceutical industry aggressively and successfully sought out deference to its international interests both before and during the TRIPS drafting process. Through intense lobbying and political maneuvering, it was the pharmaceutical industry that prompted the United States to demand that intellectual property be negotiated into the GATT. Once TRIPS negotiations began, the industry “completely seized control of the terms of the debate.” *Id.* at 1085. “Throughout the . . . negotiations, the United States maintained a firm stance; for an agreement to be reached, other countries would have to adjust to its position. That position, essentially calling for the world to adopt U.S.-style patent law, was developed

governments the ability to modify their patent rules where necessary to secure the citizens' right to health.

Unfortunately, these flexibilities proved unsuccessful. Despite the inclusion of a public health exception in TRIPS, patent protection still prevented access to essential medicine. The TRIPS flexibilities were underutilized because they were unclear and developing nations feared retaliation from other countries if they invoked them.<sup>111</sup> For example, when South Africa attempted to invoke the flexibilities for patented AIDS drugs, forty-two pharmaceutical companies filed suit alleging violation of TRIPS and the United States Trade Representative ("USTR")<sup>112</sup> pressured the South African government to maintain normal patent protection.<sup>113</sup>

Another problem with the public health exception was the "Paragraph 6 Problem," a reference to TRIPS article 31(f) (the sixth paragraph of article 31).<sup>114</sup> As discussed above, article 31(f) requires that goods produced pursuant to compulsory licensing<sup>115</sup> be used "predominantly for

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largely by the pharmaceutical industry, according to the industry itself." *Id.* at 1084. For an excellent description of the American pharmaceutical industry's tactics and influence on international patent law, both before and after TRIPS, see *id.* at 1075-93.

111. Bagley, *supra* note 17, at 784-85.

112. The office of the United States Trade Representative is an executive agency responsible for formulating and implementing U.S. trade policy. Its responsibilities include advising the president on international trade policy and the impact of other U.S. government policies on international trade, conducting international trade negotiations, coordinating trade policy with other agencies, and reporting to the president and Congress on the administration of the trade agreements program. See USTR—History of the United States Trade Representative, [http://ustr.gov/Who\\_We\\_Are/History\\_of\\_the\\_United\\_States\\_Trade\\_Representative\\_printer.html](http://ustr.gov/Who_We_Are/History_of_the_United_States_Trade_Representative_printer.html) (last visited Jan. 28, 2008).

113. Bagley, *supra* note 17, at 784-85. The lawsuit was prompted by South Africa's passage of the Zuma Law in December of 1998 in the hopes of driving down drug prices by opening the market to generic imports. The American pharmaceutical industry, which at the time enjoyed a \$2 billion-a-year drug market in South Africa, believed the law would threaten their profits and that other countries would enact similar laws. In addition to the law suit, some companies closed their plants in South Africa, forty-seven members of Congress asked the USTR to take action to oppose the law, and President Clinton met personally with the South African Health Minister, after whom the law was named, to express his administration's opposition to it. The *New York Times* described the dispute as "bitter[] and driven by deep suspicions." Donald G. McNeil, Jr., *South Africa's Bitter Pill for World's Drug Makers*, N.Y. TIMES, Mar. 29, 1998, § 3 at 1. The lawsuit was eventually dropped due largely to intense pressure from humanitarian nongovernmental organizations ("NGOs"). See BEIGBEDER, *supra* note 1, at 59.

114. See Thomas A. Haag, *TRIPS Since Doha: How Far Will the WTO Go Toward Modifying the Terms for Compulsory Licensing?*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 945, 952 (2002).

115. *Supra* note 103.

the domestic market.”<sup>116</sup> The problem with this provision is that many countries able to efficiently to produce generic drugs<sup>117</sup> could not export them to countries that needed cheaper versions but lacked the infrastructure and industry to produce them domestically.<sup>118</sup> “Thus, for a state lacking a drug manufacturing base, the ability to issue a compulsory license [was] largely academic.”<sup>119</sup> Others have argued that the language of TRIPS itself does not impede access as much as the power disparity between developed and developing nations.<sup>120</sup>

## II. LEGAL RESPONSES TO THE CONFLICT OF RIGHTS

### A. The WTO Approach

In 2001, the African members of the WTO asked the WTO council to clarify the TRIPS public health exception and the extent of members’ rights to use it.<sup>121</sup> The WTO agreed,<sup>122</sup> and the clarification was announced in 2001 in the Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”).<sup>123</sup> “The Doha Declaration . . . explicitly addressed some of the most problematic TRIPS provisions from the standpoint of access to essential medicines, and returned a significant measure of freedom to member countries to provide such access to their citizens within the framework of the existing the TRIPS Agreement language.”<sup>124</sup>

The Doha Declaration resulted in several positive steps towards harmonizing intellectual property rights and access to essential medicine. First, it officially “recognized the gravity of the public health problems

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116. TRIPS, *supra* note 14, art. 37(f).

117. These include India—which was the largest supplier of generic anti-AIDS drugs to the world before it ratified TRIPS, requiring it to provide patent protection to pharmaceuticals, Sherman & Oakley, *supra* note 95, at 381–82, 392—and Brazil, *id.* at 388.

118. Haag, *supra* note 114, at 951.

119. *Id.* The practice of importing cheaper generic versions of drugs under patent in one’s own country is known as parallel importing. BEIGBEDER, *supra* note 1, at 65. A detailed explanation of TRIPS, which does not explicitly address parallel importing but has been interpreted to disallow it, can be found in Haag, *supra* note 114.

120. See Dr. Susan K. Sell, *Legal Movements in Trade & Intellectual Property*, 17 EMORY INT’L L. REV. 591, 593 (2003).

121. See Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 IND. INT’L & COMP. L. REV. 613, 623 (2004); Press Release, WTO, Decision Removes Final Patent Obstacle To Cheap Drug Imports (Aug. 30, 2003), *available at* [http://www.wto.org/english/news\\_e/pres03\\_e/pr350\\_e.htm](http://www.wto.org/english/news_e/pres03_e/pr350_e.htm).

122. *Id.*

123. Doha Public Health Declaration, *supra* note 18.

124. Bagley, *supra* note 17, at 785.

. . . resulting from HIV/AIDS” and “the concerns about [intellectual property rights’] effects on prices.”<sup>125</sup> It also stated in unequivocal terms that TRIPS “does not and should not prevent members from taking measures to protect public health”<sup>126</sup> and “reaffirm[ed] the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”<sup>127</sup> The Doha Declaration also clearly established the right of member governments to use compulsory licensing in national emergencies and to determine for themselves what constitutes a national emergency while also recognizing public health issues related to HIV/AIDS as a legitimate national emergency under the agreement.<sup>128</sup>

The Doha Declaration also took concrete steps towards policy change. It instructed the TRIPS council to find an “expeditious solution” to the parallel imports problem faced by developing nations with no capacity to produce their own generic drugs.<sup>129</sup> This was achieved via the 2003 Implementation Decision.<sup>130</sup> That decision created a waiver that explicitly allowed countries to export generic versions of essential medicines to countries that did not have domestic generic manufacturing capabilities and met certain other criteria.<sup>131</sup> In 2005, the general council agreed on

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125. Doha Public Health Declaration, *supra* note 18, ¶¶ 1, 3.

126. *Id.* ¶ 4.

127. *Id.* ¶ 4.

128. *Id.* ¶ 5(b)–(c).

129. *Id.* ¶ 6.

130. WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, 43 I.L.M. 509 (Sept. 1, 2003) [hereinafter 2003 Implementing Decision], available at [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm).

131. *Id.* The waiver includes several safeguards intended to prevent abuse of the system, including a notification provision that requires countries to submit a detailed report of their intention to employ the flexibility, specific eligibility requirements, limits on the quantity of drugs that may be produced that correspond to what is needed, distinctive labeling requirements so that products produced under the system can be easily distinguished, provision requiring countries to set up administrative measures preventing unauthorized use and sale, and the payment of remunerations by either the importing or exporting country to the patent holder. On July 17, 2007, Rwanda became the first country to request generic imports in response to a domestic public health crisis. Press Release, WTO, Patents and Health: WTO Receives First Notification Under “Paragraph 6” System (July 20, 2007), available at [http://www.wto.org/english/news\\_e/news07\\_e/public\\_health\\_july07\\_e.htm](http://www.wto.org/english/news_e/news07_e/public_health_july07_e.htm). On October 4, 2007, Canada notified the WTO that it planned to invoke the compulsory license provisions of the Doha Declaration to provide Rwanda with the needed medicine—260,000 packs of a generic version of TriAvir, a triple combination AIDS therapy drug. Press Release, WTO, Canada is First to Notify Compulsory License to Export Generic Drug (Oct. 4, 2007), available at [http://www.wto.org/english/news\\_e/news07\\_e/trips\\_health\\_notif\\_oct07\\_e.htm](http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm).

an amendment to TRIPS that would permanently incorporate the new exceptions into the agreement.<sup>132</sup>

*B. U.S. Multilateral and Bilateral FTAs*

With these new developments, an explicit acknowledgement by the WTO asserting its commitment to facilitate increased access to medicine and its demonstrated willingness to adjust patent laws in pursuit of this goal, the international intellectual property regime seemed to have struck a proper balance between the interests of patent-holders and the right to health. However, TRIPS and its accompanying instruments do not represent the full body of law on the matter. Currently, the United States is party to seventeen bilateral and regional FTAs.<sup>133</sup> Each of these agree-

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132. WTO, Amendment of the TRIPS Agreement, WT/L/641 (Dec. 6, 2005) [hereinafter TRIPS Amendment], available at [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm). The amendment will become official once two-thirds of the WTO member countries ratify it. WTO, Countries Accepting Amendment of the TRIPS Agreement, [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm) (last visited Feb. 5, 2008). The United States was the first on board, ratifying it on December 18, 2005, just twelve days after the decision was announced. *Id.* As of January 2008, twelve other countries and the European Union have also ratified the amendment. *Id.* The waiver remains in effect for each of the countries that has not ratified the amendment and until they do so. *Id.* The WTO has also demonstrated its commitment to the access to essential medicines concerns in other less monumental but nonetheless important ways. In 2002, the council issued a pair of decisions that extended the patent protection compliance deadline for least developed countries from 2005 to 2016. WTO, Least-Developed Country Members—Obligations Under article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, WT/L/478 (July 8, 2002), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/art70\\_9\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm); WTO, Extension of the Transition Period under article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, IP/C/25 (June 27, 2002), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/art66\\_1\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm). On December 18, 2005, the members reaffirmed the importance and their approval of WTO efforts to clarify the relationship between TRIPS and public health. *See* WTO, Ministerial Declaration of 18 December 2005, ¶ 40, WT/MIN(05)/DEC, available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min05\\_e/final\\_text\\_e.htm#public\\_health](http://www.wto.org/english/thewto_e/minist_e/min05_e/final_text_e.htm#public_health). In 2006, the WTO held workshops in Geneva and Mauritius aimed at training government officials on how to use the TRIPS public health flexibilities. WTO, Workshop Helps Officials Use Health Patent Flexibilities (Nov. 27, 2006), [http://www.wto.org/english/news\\_e/news06\\_e/trips\\_wp\\_27nov06\\_e.htm](http://www.wto.org/english/news_e/news06_e/trips_wp_27nov06_e.htm).

133. The bilateral agreements are the Colombia Trade Promotion Agreement, Peru Trade Promotion Agreement, Australia Free Trade Agreement, Bahrain Free Trade Agreement, Chile Free Trade Agreement, Central American-Dominican Republic Free Trade Agreement, Israel Free Trade Agreement, Jordan Free Trade Agreement, Malaysia Free Trade Agreement, Morocco Free Trade Agreement, Oman Free Trade Agreement, Panama Free Trade Agreement, Republic of Korea Free Trade Agreement, Singapore Free Trade Agreement, South African Customs Union Free Trade Agreement, Thailand

ments contains provisions governing patent protection that far exceed the protections offered by TRIPS.<sup>134</sup> Hence, they are referred to as TRIPS-plus provisions.<sup>135</sup>

The effect of TRIPS-plus provisions in American bilateral and multi-lateral FTAs include “limit[ing] the potential exclusions from patentability, require[ing] the grant of patents for ‘new uses’ of known compounds, requir[ing] the extension of patent terms under certain conditions, prevent[ing] parallel importation, limit[ing] the grounds on which compulsory licenses may be granted, and permit[ing] the prosecution of nonviolation nullification or impairment claims.”<sup>136</sup> U.S. trading partners, in particular least developed nations, routinely agree to such provisions despite their detrimental effects on the accessibility of essential medicines because they hope that acquiescing to U.S. demands on the patent issues will help them gain leverage in other trade areas and that such concessions will help build a friendly relationship with an important world su-

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Free Trade Agreement, and the United Arab Emirates Free Trade Agreement. The regional agreements are the Central American Free Trade Agreement, North American Free Trade Agreement, Asian-Pacific Economic Cooperation, Free Trade Area of the Americas, and Middle East Free Trade Area Initiative. See Office of the U.S. Trade Representative, Trade Agreements, [http://ustr.gov/Trade\\_Agreements/Section\\_Index.html](http://ustr.gov/Trade_Agreements/Section_Index.html) (last visited Feb. 5, 2008).

134. See Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 349–50 (2005) (arguing that the U.S. patent provisions “restrict the use of the flexibilities under the TRIPS agreement”); see also Bagley, *supra* note 17, at 791–93 (“[C]ountries like the United States and member-states of the European Union . . . were independently engaging in negotiations to bind several developing countries to even higher levels of protection of intellectual property rights (IPRs) via bilateral agreements.”).

135. Bagley, *supra* note 17, at 793.

136. Abbott, *supra* note 134, at 350. Some of the specific TRIPS-plus provisions included in U.S. FTAs include restricting compulsory licenses to public manufacturers only, thereby taking this WTO endorsed flexibility away from governments that do not have the capacity to publicly manufacture generics; prohibiting parallel imports, contrary to the 2005 WTO decision to make the waiver permanent; increasing patents terms by requiring an offset for delays that would result from the partner country’s marketing approval process; heightening the penalties for patent violations; prohibiting the partner country from giving marketing approval to a generic drug until after the brand name company’s patent expires, thus delaying delivery of cheaper generics to the market; and requiring partner countries to keep the test data for a patented drug secret for the first five years of the patent term, thus preventing the use of TRIPS flexibilities for the first five years of a patent and further delaying the availability cheap generics to patients. See Human Rights Watch, *The FTAA, Access to HIV/AIDS Treatment*, <http://www.hrw.org/press/2002/10/ftaa1029-bck.htm> (last visited Feb. 6, 2008).

perpower.<sup>137</sup> Thus far, the United States has declined to adjust its patent policy to conform to the international standard.<sup>138</sup>

As a result of this policy, American FTAs upset the balance between the right to health and intellectual property rights struck by the WTO. In turn, essential antiretroviral drug therapies for HIV/AIDS remain prohibitively expensive in many countries and people in need of treatment do not have the access to medicine that the right to health guarantees. One way to regain the balance so that the patent flexibilities devised by the WTO can retain their effectiveness is to force a change in U.S. policy. Until recently, there was no effective legal mechanism for prompting such change. The United States was not bound by the right to health guaranteed by the International Bill of Rights<sup>139</sup> and TRIPS, as initially adopted, establishes only a minimum level of patent protection that parties are free to enhance as long as they did not contravene the thrust of the agreement.<sup>140</sup> However, as Part III argues, the access to essential medicines issue can now be given legal force in ways that were unavailable before.

### III. THE CHANGING LEGAL LANDSCAPE

Widespread international acceptance of access to essential medicines as a priority health issue and the 2005 WTO decision to make the Public Health Waiver permanent by amending TRIPS have two consequences that will require the United States to change its policy on pharmaceutical patents. First, these developments enable the access to essential medicines component of the right to health to acquire international customary law status, thereby giving it binding force. Second, if the TRIPS amendment is ratified, it will potentially make TRIPS-plus provisions illegal and thus subject the United States, as a GATT signatory, to review by the WTO dispute settlement process.

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137. Abbott, *supra* note 134, at 353–54.

138. In response to assertions that its patent policy detrimentally curtails TRIPS flexibilities, the USTR issued side letters asserting that they do not undermine the right of governments to take action for the public health. However, of the various agreements that the USTR has negotiated, the side letters only address three agreements, the Central American Free Trade Agreement, the U.S.-Bahrain Free Trade Agreement, and the U.S.-Morocco Free Trade Agreement. *Id.* at 352. Additionally, “they are drafted in a substantially more restrictive way than the [WTO] texts” and “the USTR has questioned whether the understanding will have legal effect.” *Id.*

139. *See supra* Part I.B

140. *See Bagley, supra* note 17, at 792 (“The TRIPS Agreement specifies minimum levels of protection members must afford to IPRs, but explicitly allows members to implement ‘more extensive protection’ as long as it does not contravene the Agreement.”).

*A. Access to Essential Medicines as a Matter of Customary International Law*

It is long-standing and well-established that the United States is bound by international law.<sup>141</sup> This includes customary international law<sup>142</sup> or “the law of nations.”<sup>143</sup> Customary international law consists of (1) “a general and consistent practice of states” that is (2) “followed by them from a sense of legal obligation” or *opinio juris*.<sup>144</sup> In the context of human rights, the issue of customary international law has been most prominently brought to U.S. courts via claims seeking relief through the Alien Tort Claims Act (“ATCA”).<sup>145</sup> However, case law regarding customary

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141. See, e.g., *Sosa v. Alvarez-Machain*, 542 U.S. 692, 729–30 (2004) (“For two centuries we have affirmed that the domestic law of the United States recognizes the law of nations”); *The Paquete Habana*, 175 U.S. 677, 700 (1900) (“International law is part of our law, and must be ascertained and administered by the courts of justice of appropriate jurisdiction, as often as questions of right depending upon it are duly presented for their determination.”); RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 111(a) (1987) [hereinafter RESTATEMENT OF FOREIGN RELATIONS LAW] (“International law and international agreements of the United States are law of the United States and supreme over the law of the several States.”). International law “consists of rules and principles of general application dealing with the conduct of states and of international organizations and with their relations inter se, as well as with some of their relations with persons, whether natural or juridical.” RESTATEMENT OF FOREIGN RELATIONS LAW, *supra*, § 101. Though international treaties are also a part of U.S. law, the fact that the United States is party to treaty concerning the right to health, namely TRIPS, is insufficient to bind it in this case because under U.S. law, international treaties are non-self-executing and thus do not in themselves impose obligations on the United States until separate legislation is passed. Cf. *Sosa*, 542 U.S. at 735. For a contrary view asserting that customary international law is not binding on the United States, see generally Curtis A. Bradley & Jack L. Goldsmith, *Customary International Law as Federal Common Law: A Critique of the Modern Position*, 110 HARV. L. REV. 815 (1997) (arguing in response to the RESTATEMENT OF FOREIGN RELATIONS LAW that because the decision in *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938), eliminated federal common law, customary international law is not binding).

142. RESTATEMENT OF FOREIGN RELATIONS LAW, *supra* note 141, § 102. International law can also be formed by “(b) international agreement; or (c) by derivation from general principles common to the major legal systems of the world.” *Id.*

143. *Flores v. S. Peru Copper Corp.*, 414 F.3d 233, 377 n.2 (2d Cir. 2003) (“In the context of the ATCA, we have consistently used the term ‘customary international law’ as a synonym for the term the ‘law of nations.’”) (citing *Kadic v. Karadzic*, 70 F.3d 232, 239 (2d Cir. 1995) and *Filartiga v. Pena-Irala*, 630 F.2d 876, 884 (2d Cir. 1980)).

144. RESTATEMENT FOREIGN RELATIONS, *supra* note 141, § 102(2).

145. 28 U.S.C. § 1350 (2000). The ATCA, which was passed in 1789, states in full that “[t]he district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States.” *Id.* The viability of an ATCA claim for a health rights violation is beyond the scope of this Note. However, in order for courts to review the viability of a claim under the ATCA,

international law in general is sparse. The leading case is *Sosa v. Alvarez-Manchain*,<sup>146</sup> an ATCA claim for relief alleging arbitrary detention as a violation of customary norms. In *Sosa*, the Supreme Court affirmed the view that new norms of customary international law are judicially cognizable.<sup>147</sup> While the Court recognized that it had “no congressional mandate to seek out and define new and debatable violations of the law of nations,”<sup>148</sup> it held that “the door [to independent judicial recognition of international norms] is still ajar subject to vigilant doorkeeping, and thus open to a narrow class of international norms today.”<sup>149</sup>

In *Sosa*, the Court held that at least where the ATCA is concerned “any claim based on the present-day law of nations [must] rest on a norm of international character accepted by the civilized world and defined with a specificity comparable to the features of the 18th-century paradigms” that were already established at the time the ATCA was enacted.<sup>150</sup> While the ATCA is not directly implicated here in the essential medicines context, review of that case law is appropriate as it is the only area that has led to any modern analysis of the mechanics of customary international law, especially with regard to the subset of international law, human rights, at issue here. In determining whether a practice or rule constitutes customary international law, courts may look to judgments and opinions of national and international tribunals, scholarly works, and unchallenged “pronouncements of states that undertake to state a rule of international law.”<sup>151</sup> Thus general acceptance and *opinio juris* serve as the touchstones of international customary law while specificity enables such a norm to develop into a private right of action that can be pursued

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they had to discuss the issue of customary international law, as that is one of the statute’s three main elements. Therefore, a discussion of the ATCA cases is particularly relevant to the central thesis of this Note (that access to essential medicines is a binding right established by customary international law). Indeed, they are necessary as the overwhelming bulk of U.S. jurisprudence regarding customary international law was developed by the ATCA cases.

146. 542 U.S. 692 (2004).

147. As pointed out by the *Sosa* Court, this view also bears congressional support. *Id.* at 728. The majority opinion notes that the Torture Victim Protections Act provides a mandate to define new violations of international law related to torture and that “the legislative history includes the remark that [the ATCA] should remain intact to permit suits based on other norms that already exist or may ripen in the future into rules of customary international law though congress as a body has done nothing to promote such suits.” *Id.* (internal quotations and citations omitted).

148. *Id.*

149. *Id.* at 729.

150. *Id.* at 725. The eighteenth century norms identified by the Court were violation of safe conduct, infringement of the rights of ambassadors, and piracy. *Id.* at 724.

151. RESTATEMENT OF FOREIGN RELATIONS LAW, *supra* note 141, § 103(d).

under the ATCA. While the right to health in general is still evolving towards these levels,<sup>152</sup> the access to essential medicines component of that right at least has arrived as a norm of customary international law. However, though access to medicines is quite specific it is unlikely that U.S. courts would recognize it as providing a private right of action justiciable under the ATCA.

### 1. General Acceptance

The first requirement for elevation to customary international law is that the norm be generally accepted and practiced among the states. "Practice . . . includes diplomatic acts and instructions as well as public measures and other governmental acts and official statements of policy, whether they are unilateral or undertaken in cooperation with other states . . . . The practice necessary to create customary law may be of comparatively short duration . . . . A practice can be general even if it is not universally followed . . . ." <sup>153</sup> To establish that prohibition of arbitrary detention was a customary norm, the plaintiff in *Sosa* relied on "a survey of national constitutions, . . . a case from the International Court of Justice, *United States v Iran*, 1980 I. C. J. 3, 42; and some authority drawn from the federal courts."<sup>154</sup> The Court held that these authorities were insufficient to establish a customary norm not because they were inappropriate proof of the standard but rather because the consensus they demonstrated was at too general a level to meet the standard.<sup>155</sup> In reaching this conclusion, the Court emphasized that there may be a norm against prolonged arbitrary detention, but the plaintiff in *Sosa* was only detained for one day.<sup>156</sup> The Court rejected the ICJ case because it was decided on different grounds and did not deal directly with arbitrary detention.<sup>157</sup> Like the norm against arbitrary detention, the right of access to medicine is widely recognized by the international community. However, it does not suffer from the generality that was fatal to the plaintiff's claim in *Sosa*.

First, through General Comment 14, the right of access to medicine has been specifically adopted as a part of the ICESCR, which is binding international law for 157 countries. Since the ICESCR was established, the international community's commitment to honor the right of access to

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152. This is especially true given that the content and definition of the right to health are still being developed and the right still operates as a progressive right, as discussed *supra* Part I.B.

153. RESTATEMENT OF FOREIGN RELATIONS, *supra* note 141, § 102 cmt. b.

154. *Sosa*, 542 U.S. at 737 n.27 (internal citations omitted).

155. *Id.*

156. *Id.* at 738.

157. *Id.* at 737 n.27

essential medicines has been reaffirmed again and again. Major United Nations initiatives have been launched to make access to essential medicines a factual reality.<sup>158</sup> The 193 member countries of the World Health Organization have made essential medicines a policy priority for that organization. The WTO, with its 193 member countries, has taken several active steps in the last decade to ensure a legal regime conducive to realization of the right for all. This has culminated in the unprecedented 2005 decision to amend TRIPS for the first time in the agreement's history. Even though the amendment has not yet been ratified by the two-thirds of member governments necessary to make it an official part of TRIPS, it was approved by the WTO General Council, which is the main decision-making body and has representatives for every member country.<sup>159</sup> Thus, it serves as an official statement of 193 members of the world community that the right of access to essential medicines must be protected. Additionally, more so than other such statements, such as the ICESCR itself, this decision is a powerful statement of state practice because it takes a very specific and concrete position on the issue and was the product of deliberation and negotiation.

In addition to international level commitment, several countries have unilaterally prioritized the issue, both as a matter of law and fact. By the end of 1999, over 100 countries had a national drug policy, which by definition includes access to essential medicine as a core objective.<sup>160</sup> The issue has also been successfully litigated fifty-nine times between 1992 and 2003 in domestic courts.<sup>161</sup> In 2000, President Bill Clinton issued Executive Order 13155, in which he recognized the importance of access to essential medicines as dealt with in TRIPS and affirmed the United States' commitment to enabling increased access in sub-Saharan Africa.<sup>162</sup>

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158. See, e.g., *3 by 5 Report*, *supra* note 6; The United Nations Millennium Development Goals, <http://www.un.org/millenniumgoals/goals.html> (last visited Feb. 24, 2008); The Special Rapporteur's Mission to the WTO, *supra* note 3.

159. WHO, The WTO General Council, [http://www.wto.org/english/thewto\\_e/gcounc\\_e/gcounc\\_e.htm](http://www.wto.org/english/thewto_e/gcounc_e/gcounc_e.htm) (last visited Feb. 14, 2008).

160. WHO, How to Develop and Implement a National Drug Policy (2003), [http://www.who.int/medicines/publications/policyperspectives/PPM\\_No6-6pg-en.pdf](http://www.who.int/medicines/publications/policyperspectives/PPM_No6-6pg-en.pdf) (last visited Feb. 14, 2008).

161. Hans V. Hogerzeil, et. al., *Is Access to Essential Medicines as Part of the Fulfillment of the Right to Health Enforceable through the Courts?*, 368 THE LANCET 305, 305 (2006) (presenting the results of a study that examined domestic litigation of the access to essential medicines component of the right to health).

162. Exec. Order No. 13155, 65 Fed. Reg. 30,521 (May 10, 2000). The Order used muted language, never mentioned the word "patent," and emphasized that access was only one and not the most important issue in the fight against HIV/AIDS but it nonethe-

Second, unlike arbitrary detention in the *Sosa* case, access to essential medicines is a very specific and narrowly defined norm. It is based on the concept of essential medicines as developed by the World Health Organization, which the ICESCR and the WTO have both adopted. Thus it applies to a very specific and finite list of pharmaceuticals. While it encompasses more than drug affordability, cost is a key component among all of the international organizations that address the right to health and access as well as the countries that have domestic policies regarding health.

## 2. *Opinio Juris*

“For a practice of states to become a rule of customary international law it must appear that the states follow the practice from a sense of legal obligation (*opinio juris sive necessitatis*); a practice that is generally followed but which states feel legally free to disregard does not contribute to customary law.” At the same time, departures from the practices do not invalidate it as a customary norm. The *Sosa* Court did not address *opinio juris* and very few lower courts have had occasion to apply it.<sup>163</sup> In *Kane v. Winn*, the Court accepted the existence of international treaties and non-treaty instruments such as the UDHR as evidence of *opinio juris* for a torture claim under the ATCA.<sup>164</sup> The Court reached a similar conclusion in *Lareau v. Manson*, a prisoners’ rights case ultimately decided under domestic law.<sup>165</sup>

Several aspects of the development of the right to access to essential medicines demonstrate that it is followed from a sense of legal obligation. As established above, access to medicine is an essential component

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less recognized the “right” of countries to promote public health and the United States’ commitment to make sure its policies did not interfere with that right. Additionally, the Order was entitled “Access to HIV/AIDS Pharmaceuticals and Medical Technologies.” However, it specifically stated that it did not create any substantive or procedural rights enforceable against the United States as it was “intended only to improve the internal management of the executive branch.” *Id.*

163. The relevant cases include: *Buell v. Mitchell*, 274 F.3d 337 (6th Cir. 2001); *Vietnam Ass’n for Victims of Agent Orange/Dioxin v. Dow Chemical Co.* (In re Agent Orange Prod. Liab. Litig.), 373 F. Supp. 2d 7 (S.D.N.Y. 2005); *Kane v. Winn*, 319 F. Supp. 2d 162 (D. Mass. 2004); *Aldana v. Fresh Del Monte Produce, Inc.*, 305 F. Supp. 2d 1285 (S.D. Fla. 2003) *vacated in part by*, *Aldana v. Del Monte Fresh Produce, N.A., Inc.*, 416 F.3d 1242 (11th Cir. 2005); *Sarei v. Rio Tinto Plc*, 221 F. Supp. 2d 1116 (C.D.Cal. 2002) *rev’d on other grounds by* *Sarei v. Rio Tinto PLC*, 221 F. Supp. 2d 1116, (9th Cir. 2005); *Mehinovic v. Vuckovic*, 198 F. Supp. 2d 1322 (N.D. Ga. 2002); *Lareau v. Manson*, 507 F. Supp. 1177 (D. Conn. 1980).

164. *Kane*, 319 F. Supp. 2d at 197.

165. *Lareau*, 507 F. Supp. at 1193 n.18.

of the right to health. The right to health in turn is a firmly established human right. A human right by definition imposes a legal obligation on states. It is a limit upon state action that stems from the humanity all individuals are born with and thus precedes the existence of the state. As in *Kane* and *Lareau*, the right is expressed in various treaties and in the UDHR, which U.S. courts have acknowledged as legitimate evidence of *opinio juris*. The language of legal obligation is also present in the WTO statements and the Executive Order 13155 concerning access to medicine. Both refer to the “right” of states to promote public health. The WTO documents go even further and refer to the right of nations to promote access to essential medicines. Finally, the most powerful evidence that states are compelled to protect the right of access to essential medicines is the 2005 decision to amend TRIPS.<sup>166</sup> One hundred ninety-three nations agreed that the international trading regime, an aspect of law facially unrelated to health or human rights and a pillar of international relations, needed to be changed in order to eliminate conflicts with the human rights obligations of developing nations to their people.

That the language used by the international community to express the concept is one step removed from the direct assertion that individuals have a legal right of access to essential medicines does not undermine the *opinio juris* claim. The phrase “the right of countries to promote access to essential medicines” would be meaningless if it did not a fortiori mean that the people have a corresponding right of access to essential medicines. It only makes sense if read to mean that the states have a right to fulfill their *duty* to their people. The *opinio juris* aspect of the right of access to essential medicines is also not undermined by the fact that the issue is often discussed in terms of a practical need to respond to the AIDS epidemic. The law does not require that a norm be followed exclusively out of a sense of legal obligation to qualify as a matter of international customary law. For example, the prohibition against torture, which has been accepted as customary norm<sup>167</sup> is similarly followed out of a sense of legal as well as moral obligation.<sup>168</sup>

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166. Practice and *opinio juris* can be proven by the same evidence. *Cf. Kane*, 319 F. Supp. 2d at 197 (holding that the treaties relevant to the case “constitute both state practice and evidence of *opinio juris*”).

167. *Filartiga v. Pena-Irala*, 630 F.2d 876 (2d Cir. 1980).

168. *Cf. Filartiga*, 630 F.2d at 890 (“In the modern age, *humanitarian* and *practical* considerations have combined to lead the nations of the world to recognize that respect for fundamental human rights is in their individual and collective interest. Among the rights universally proclaimed by all nations, as we have noted, is the right to be free of physical torture.”) (emphasis added).

*B. The Impact of the TRIPS Amendment on U.S. TRIPS-Plus Policy*

Prior to the WTO's 2005 decision to amend TRIPS, the flexibilities incorporated in it represented minimum protections for intellectual property rights. Thus, the United States and other countries were free to institute more stringent protection, which by necessary implication would undermine the right of access, without violating the agreement. The amendment, if ratified, has the potential to turn the WTO patent regime on its head with respect to pharmaceuticals. That is, it could be interpreted as a ceiling above which member governments may not increase pharmaceutical patent protection. This in turn could mean that governments that institute patent policies that exceed the TRIPS ceiling, i.e., TRIP-plus policies, could be violating TRIPS and be subject to sanction. Whether this will occur is, of course, contingent on the amendment becoming official and how the amendment will be interpreted.

To become official, the amendment must be ratified by two-thirds of the WTO members.<sup>169</sup> This will likely occur without incident. It was already approved by the WTO council, which consists of representatives from each member country.<sup>170</sup> Additionally, access to essential medicines is not a controversial issue. As discussed above, it already enjoys widespread acceptance. Moreover, given the international shame brought upon pharmaceutical companies that attempted to sue South Africa for invoking TRIPS flexibilities,<sup>171</sup> it is unlikely that any government would take the public relations risk of opposing the amendment. Finally, the country wielding the most power in the debate and the one that would be expected to put up the most opposition given the trade policies it negotiates outside the WTO, the United States, has already ratified the amendment.<sup>172</sup>

Whether the amendment will be interpreted as a prohibition on TRIPS-plus is much less certain. Of course, the fact that the biggest proponent of TRIPS-plus has ratified the treaty cuts against such a reading. Additionally, despite the reports of scholars and NGOs identifying the detrimental effects of TRIPS-plus that are cited throughout this Note, the WTO's latest review of U.S. trade policy barely mentions pharmaceutical patents in its over two hundred pages.<sup>173</sup> The report was issued in 2006, well af-

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169. See WTO, Countries Accepting Amendment of the TRIPS Agreement, [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm) (last visited Feb. 5, 2008).

170. See TRIPS Amendment, *supra* note 132.

171. See *supra* note 113.

172. See *supra* note 132.

173. See WTO, Trade Policy Review—United States, WT/TPR/S/160 (Feb. 15, 2006). The only mention of U.S. versus WTO policy regarding intellectual property protection

ter the adoption of the TRIPS flexibility waiver and the decision to make the waiver permanent via amendment. Thus it appears that the WTO was either unwilling or uninterested in addressing TRIPS-plus so far as multi-lateral and bilateral FTAs were concerned. However, there are factors that suggest this could change once the amendment becomes official.

First, the language of the amendment is much stronger than the original TRIPS-flexibilities. It expressly forbids reservations to the new protocols without the consent of other members.<sup>174</sup> It states unequivocally that the obligations of the patent section of TRIPS that limit parallel imports “shall not apply” to countries that face a health crisis.<sup>175</sup> It also forbids members from challenging a country that invokes a flexibility.<sup>176</sup> Underlying all of these provisions, and expressed in various WTO statements, is the WTO’s express commitment to promoting a world trade regime that is in harmony with the right of access. It can be argued that all of this language taken together means that by pushing for TRIPS-plus, the United States and its trading partners are “violating a commitment [they have] made in the WTO”<sup>177</sup> or that while it may “not involve a violation of obligations under a covered agreement . . . nevertheless . . . benefits are being nullified or impaired.”<sup>178</sup>

Second, the WTO undertook to reevaluate TRIPS flexibilities and ultimately to adopt an amendment to strengthen them in response to a formal request from its least developed member nations.<sup>179</sup> The amendment is designed to eliminate the legal ambiguities resulting from the intersection of intellectual property and the right to health that prompted these nations to seek clarification. Thus, it can be further argued that interpreting the amendment in any manner other than as categorically prohibiting TRIPS-plus defeats its very purpose and its reason for being.

## CONCLUSION

Despite the international prioritization of health issues, adequate access to essential medicines continues to elude millions across the globe. One

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of pharmaceutical patents is a brief, one-sentence note acknowledging that U.S. FTAs “go beyond the commitments of the TRIPS Agreement.” *Id.* at 18.

174. TRIPS Amendment, *supra* note 132.

175. *Id.*

176. *Id.*

177. WTO, Dispute Settlement, [http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_e.htm#intro](http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm#intro) (last visited Feb. 14, 2008).

178. WTO, Understanding on Rules and Procedures Governing the Settlement of Disputes, [http://www.wto.org/english/docs\\_e/legal\\_e/ursum\\_e.htm#Understanding](http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#Understanding) (last visited Feb. 14, 2008).

179. *See supra* note 121.

major obstacle has been international trade and intellectual property laws. While significant strides have been made in harmonizing those regimes with the right of access to essential medicines, U.S. TRIPS-plus policy thwarts progress. Until recently, there were no legal mechanisms to prompt the United States and its trading partners to honor the right. However, the WTO's recent decision to amend TRIPS heralds new possibilities for enforcing countries' legal obligations under the right of access to medicine.

That the right can now properly be considered a norm of international customary law is immensely significant because as such, it is universally binding regardless of a country's formal acceptance of the ICESCR and comparable instruments. Thus, in continuing to push TRIPS-plus trade provisions, the United States is violating the law. While there is no specific manner in which the United States can be sanctioned, it should be enough that by continuing to pursue TRIPS-plus in the face of specific, narrowly defined, and widely accepted international standards, the "[g]overnment itself would become a lawbreaker."<sup>180</sup>

If that is not enough, however, the TRIPS amendment, once ratified, has the potential to force a reversal of TRIPS-plus policy by declaring it a violation of the GATT and by imposing sanctions on countries that pursue policies that undermine TRIPS flexibilities. The United States is powerful and there surely is a general reluctance among the other nations of the world to subject such an indispensable ally to trade sanctions. However, if the WTO is sincere about its commitment to securing the right of access to essential medicines, it will encourage member states to hold the United States accountable and will support them when they do.

*Tina S. Bhatt*\*

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180. *Olmstead v. United States*, 277 U.S. 438, 483 (1928) (Brandeis, J., dissenting).

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