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# Vindicating the Rights of People Living with AIDS Under the Alien Tort Claims Act

By Margaret B. Kwoka\*

## INTRODUCTION

Despite centuries of development of the “rule of law” and courts’ attempts to stand on the shoulders of precedent, legal doctrine does not usually appear to follow a singular, logical, or linear path—in fact it frequently defies common sense entirely.<sup>1</sup> However, the re-employment of common sense in the law is vital in some instances; it does not, for example, make sense that people have a fundamental right to travel between states,<sup>2</sup> but no right of access to life-saving medication which costs less than fifty cents a day.<sup>3</sup> Indeed, life-saving medications are being withheld from millions of people suffering from human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), who will die as a result.<sup>4</sup> Advocates for people living

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\* Equal Justice Works Fellow, Public Citizen Litigation Group. J.D., Northeastern University School of Law 2007; A.B., Brown University 2002. Special thanks to Professor Brook K. Baker, for his invaluable guidance and wealth of knowledge, to say nothing of his dedication to fighting the AIDS injustice, and to Professor Hope Lewis, whose example inspires my interest in international human rights law. I am also deeply indebted to César Cuauhtémoc García Hernández for, among many other things, his unfailing encouragement and tireless comments on earlier drafts. Finally, I dedicate this to my mom, Anita Marie Benvignati.

1. See, e.g., William Burnham, *“Beam Me Up, There’s No Intelligent Life Here”: A Dialogue on the Eleventh Amendment with Lawyers from Mars*, 75 NEB. L. REV. 551 (1996) (humorously addressing the complexity and absurdity of Eleventh Amendment doctrine through an imaginary conversation with Martians); see also OLIVER WENDELL HOLMES, *THE COMMON LAW* 1 (1881) (asserting that law is based on human experience).

2. The right to travel is derived from the privileges and immunities clauses found in Article IV of the U.S. Constitution and the Fourteenth Amendment, and has three separate components including 1) the right of a citizen of one state to enter and leave another state; 2) the right of a citizen of one state to be a welcome visitor in another state; and 3) the right of a citizen of one state to relocate to another state as a resident and be treated as other residents of the new state. *Saenz v. Roe*, 526 U.S. 489, 500 (1999).

3. Importing generic anti-retroviral therapy medicines can cost as little as \$149 per year, per patient. TONY BARNETT & ALAN WHITESIDE, *AIDS IN THE TWENTY-FIRST CENTURY: DISEASE AND GLOBALIZATION* 367 (2d ed. 2006).

4. Though HIV and AIDS are distinct medical afflictions, for the purposes of this Article they are considered as one. Since the early 1980s, when AIDS awareness truly began, over twenty-

with HIV/AIDS (PWAs)<sup>5</sup> are therefore compelled to argue logic into the law.

Of course, some governments—especially those with few funds, many obligations, and large populations of PWAs—cannot afford even the fifty cents a day for each citizen in need.<sup>6</sup> Logic would dictate, and international law espouses, a standard that recognizes the reality of the situation for such governments and demands only their best efforts to provide life-saving medications to their populations.<sup>7</sup> This standard may be somewhat amorphous,<sup>8</sup> but certainly is not unreasonable. Even if countries are falling far short of this best-efforts standard, it seems evident that such a goal is both sensible and necessary.<sup>9</sup> It is on this

five million people have died from the disease. YANN ARTHUS-BERTRAND, *THE NEW EARTH FROM ABOVE: 365 DAYS*, at May 18 (Anthony Roberts trans., 2007). Treatment programs are extremely effective in prolonging the life of people living with AIDS. In Brazil, where universal treatment was implemented in the mid-1990s, statistics show that the median length of survival for patients diagnosed with AIDS in the 1980s was five months, for patients diagnosed in 1995 eighteen months, and for cases diagnosed in 1996 fifty-eight months. ANNE-CHRISTINE D'ADESKY, *MOVING MOUNTAINS, THE RACE TO TREAT GLOBAL AIDS* 36 (2004). The program was characterized by “quickly restored health and a return to productivity” in the Brazilian population. *Id.*; see STEPHANIE NOLEN, *28 STORIES OF AIDS IN AFRICA* 14 (2007) (“I have seen people at the edge of death get suddenly, gloriously well again, just like they do at home.”).

5. Throughout this Article, the term PWA will be used to describe the class of individuals who could bring a lawsuit under the theory of this Article. This group would include those individuals who have been unable to access medicines in countries affected by the drug companies' lawsuits discussed in this Article. Lack of access constitutes their cognizable injury. It could also include families of individuals who have died from AIDS. For simplicity, PWA will encompass all of these potential plaintiffs.

6. The reasons for developing countries' inability to afford basic necessities for their citizens—even though such necessities are not only humanitarian but also necessary to maintain a sufficiently healthy workforce to sustain the economy—are complex. Throughout the 1990s, when the AIDS pandemic became an urgent agenda item, one factor weighing heavily on developing countries and strapping them further for cash was the percentage of developing countries' foreign exchange earned from exports spent repaying international debt acquired through foreign aid. For instance, in 1990, many developing countries spent between one-quarter and one-third of their entire foreign exchange earnings servicing their debt burden. JAMES M. CYPHER & JAMES L. DIETZ, *THE PROCESS OF ECONOMIC DEVELOPMENT* 483 (2d ed. 2004). By 1999, economic crises in Latin America raised that percentage to 75% in the case of Argentina and a horrifying 110.9% in the case of Brazil. *Id.*; see also D'ADESKY, *supra* note 4, at 292 (arguing that debt relief could have a “major impact” on governments' ability to pay for increased treatment efforts).

7. See *infra* Part III.A (exploring the rights to health and life as defined by international law).

8. See *infra* Part IV.A (discussing courts' reluctance to enforce rights that are not specific and definite, and PWA plaintiffs' potential cure for such a problem).

9. UNAIDS, a joint United Nations program formed in response to HIV/AIDS sponsored by numerous other United Nations agencies and based in Geneva, Switzerland, has commented on the necessity of such a goal. See About UNAIDS, <http://www.unaids.org/en/AboutUNAIDS/default.asp> (last visited Aug. 10, 2008).

The commitment to universal access is not a target itself. Instead, it emphasizes the need for far greater urgency, equity, affordability, and sustainability in national

premise that the citizens of a country arguably have a right to their governments' best efforts, if not a right to any singular or specific action.

Even though many governments have made substantial efforts to provide access to these medications,<sup>10</sup> they are a long way from universal access to medicines; these efforts simply represent governments *trying* to meet the needs of their people, a standard which guarantees nothing tangible for PWAs. A government in this position is likely one of the 153 parties to the Agreement on Trade-Related Aspects to Intellectual Property Rights (TRIPS), the leading international intellectual property agreement.<sup>11</sup> A TRIPS member country is left with two basic choices. It could simply buy medicines from the patent-holding U.S.-based corporations, which sell them at between two-and-a-half<sup>12</sup> and 100<sup>13</sup> times the price of a generic. Alternatively, the government could pursue one of a few options available under TRIPS for accessing lower-cost medications. The latter is a particularly likely course of action for a government with few resources, which is a common situation in countries with large populations of PWAs.<sup>14</sup> The

responses to AIDS. . . . Governments therefore made a commitment to rapidly set national targets that reflect the urgent need to scale up toward the goal of universal access by 2010.

The Secretary-General, *Declaration of Commitment on HIV/AIDS and Political Declaration on HIV/AIDS: Focus on Progress over the Past 12 Months*, ¶ 2, U.N. DOC A/61/816 (Mar. 20, 2007) [hereinafter *Declaration of Commitment 2007 Progress Report*]; see *infra* Part I (providing background on the extent of the AIDS pandemic and the necessity of treatment).

10. See *infra* Part II.A, B (exploring examples of countries' attempts to provide low-cost medications).

11. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 14(1)-(3), Legal Instruments—Results of the Uruguay Round, 1869 U.N.T.S. 299, 301 (1994) [hereinafter TRIPS]. All WTO member countries are de facto parties to the TRIPS Agreement. Understanding the WTO: The Agreements, Intellectual Property: protection and enforcement, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm) (last visited Aug. 10, 2008). Currently, there are 153 member countries. Understanding the WTO: The Organization, 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 Jan. 28, 2009).

12. Colleen V. Chien, *HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?*, 2 PLOS ONE e278 (2007), <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1805689>. The differential prices of second line therapies are much higher than first line therapies, in part as a result of stronger patent protections. *Id.*

13. Treatment for one patient at U.S. prices costs \$15,000. Rick Hink, *AIDSTRIPS: Intellectual Property and AIDS Medication in South Africa*, <http://www.american.edu/ted/aidstrips.htm> (last visited Aug. 10, 2008).

14. The bulk of people living with HIV and AIDS are in poor countries. For instance, "Sub-Saharan Africa remains the region most heavily affected by HIV, accounting for 67% of all people living with HIV and 75% of AIDS deaths in 2007." UNAIDS, 2008 REPORT ON THE GLOBAL AIDS EPIDEMIC 32 (2008), available at <http://www.unaids.org/en/KnowledgeCentre/>

two options most often employed under TRIPS are (1) issuing what are known as “compulsory licenses” and (2) engaging in “parallel importation.”<sup>15</sup> The details of compulsory licensing and parallel importation are in some ways less important than the fact that these mechanisms are recognized as lawful options under TRIPS.<sup>16</sup> Governments attempting to meet the needs of their populations would be well-advised to use either of these methods.<sup>17</sup>

In theory, this situation, where international law both espouses a standard of best efforts and provides mechanisms with which governments can make such efforts, represents a move toward increased access to medicines. Although a country may have a staggering number of people with an illness otherwise equated to a death sentence,<sup>18</sup> the government’s legal obligation to try to help its population by providing life-saving medications allows it to exercise its lawful rights under international intellectual property rules to access those medications at a low cost. However, this model fails to account for pharmaceutical companies’ repeated and systematic reactions, which include lawsuits. Pharmaceutical companies have made the tactical decision to sue governments exercising their rights under TRIPS, despite the well-settled interpretations of TRIPS under which governments may take precisely those actions.<sup>19</sup> These governments, already strapped for cash, must defend their well-intentioned efforts to save lives by spending precious money addressing legal claims drafted by well-funded, industry-hired lawyers.<sup>20</sup>

Understandably, this conduct has been widely condemned on moral grounds.<sup>21</sup> Furthermore, the bare assertion that everyone, including

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HIVData/GlobalReport/2008/2008\_Global\_report.asp.

15. See *infra* Part II.A (discussing these mechanisms in detail).

16. See generally BROOK K. BAKER, DFID HEALTH SYSTEMS RESOURCE CENTRE, PROCESSES AND ISSUES FOR IMPROVING ACCESS TO MEDICINES: WILLINGNESS AND ABILITY TO UTILISE TRIPS FLEXIBILITIES IN NON-PRODUCING COUNTRIES (2004), available at <http://www.dfid.gov.uk/pubs/files/dfidbrookbakertrips.pdf> (discussing various ways in which countries currently not producing medicines can exercise TRIPS flexibilities to meet pharmaceutical needs).

17. *Id.*

18. The United States Bureau of the Census projects that, for instance, in Botswana, the life expectancy in 2010 without AIDS would be 74.4 years, and the life expectancy with AIDS would be 26.7. BARNETT & WHITESIDE, *supra* note 3, at 299.

19. See *infra* Part II.B (discussing examples of such lawsuits).

20. See Mark Heywood, *People Come Before Profit; The Drug Companies' Litigation Against South Africa Is Immoral*, THE GUARDIAN (Mar. 5, 2001), available at <http://www.guardian.co.uk/world/2001/mar/05/aids.comment> (estimating that the lawsuits are costing millions of pounds).

21. For instance, when thirty-nine pharmaceutical companies sued the South African

these companies, has the right to have their disputes adjudicated in court is simply insufficient justification. Indeed, people in many instances do not have a right to sue. For example, plaintiffs in the United States cannot bring frivolous lawsuits,<sup>22</sup> they cannot sue without standing,<sup>23</sup> they cannot sue if they are in the wrong jurisdiction,<sup>24</sup> they cannot sue if the harm suffered is not recognized by the court,<sup>25</sup> they cannot sue if the people they want to sue have immunity,<sup>26</sup> and they cannot sue if the government has not created the right by statute or common law.<sup>27</sup>

This Article proposes merely one more prohibition on suing: no one—individuals or corporations—should be able to sue if the mere act of the lawsuit would result in a human rights violation. More specifically, this Article argues that companies can and should be liable when their costly and meritless lawsuits prevent a government from meeting the needs of its citizens, thereby violating those citizens' human rights. In that vein, this Article explores one method of using existing law—the Alien Tort Claims Act<sup>28</sup> (ATCA)—to render pharmaceutical companies' lawsuits actionable conduct for which they can be held accountable. It may be one method of vindicating the rights

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government for passing its 1997 amendments to the Medicines Act, which permitted the governments to exercise lawful options to reduce the price of AIDS medicines, the European Union, the World Health Organization, the National AIDS Council in France, and 250,000 signers of a Doctors Without Borders petition publicly supported the South African government. Rachel L. Swarns, *Companies Begin Talks with South Africa on Drug Suit*, N.Y. TIMES, Apr. 18, 2001, at A3.

22. See FED. R. CIV. P. 11 (allowing sanctions against a lawyer who files a lawsuit for an improper purpose, which is frivolous, or whose allegations or denials lack evidentiary support).

23. See *Allen v. Wright*, 468 U.S. 737 (1984) (denying parents of black schoolchildren the right to sue the IRS for granting tax-exempt status to private schools that discriminate on the basis of race in violation of the law).

24. See *Asahi Metal Indus. Co., Ltd. v. Super. Ct. of Cal.*, 480 U.S. 102 (1987) (dismissing a suit for lack of personal jurisdiction over the defendant, a company whose parts were incorporated into products sold in the state in which the suit was brought).

25. See *Sullivan v. Boston Gas Co.*, 605 N.E.2d 805 (Mass. 1993) (holding that emotional injury alone is not sufficient to sustain a tort action, it must be accompanied by physical injury resulting from the emotional distress).

26. For instance, absolute immunity is afforded to judges, legislators, and prosecutors when they are acting in their job function. *Bogan v. Scott-Harris*, 523 U.S. 44 (1998) (legislative immunity); *Burns v. Reed*, 500 U.S. 478 (1991) (prosecutorial immunity); *Forrester v. White*, 484 U.S. 219 (1988) (judicial immunity). All other government officials are afforded qualified immunity when a constitutional right is not clearly established such that a reasonable official would not know he was violating someone's rights. *Saucier v. Katz*, 533 U.S. 194 (2001).

27. See FED. R. CIV. P. 12(b)(6) (allowing a court to dismiss a claim for failure to state a claim upon which relief can be granted).

28. The Alien Tort Claims Act is also known as the Alien Tort Statute (ATS). 28 U.S.C. § 1350 (2006); see *Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co.*, 517 F.3d 104, 113 n.2 (2d Cir. 2008).

of people dying en masse from a disease that modern medicine has the full ability to treat.

Part I provides background, including information about the AIDS pandemic<sup>29</sup> and its relationship to the pharmaceutical companies. Part II examines instances, particularly one in South Africa, where pharmaceutical companies have sued to stop the governments' lawful conduct under TRIPS, and the outcomes of those cases. Part III discusses the ATCA and how a PWA, unable to obtain medications in one of the countries subject to a pharmaceutical company lawsuit, might make out a claim under the ATCA.

### I. AIDS LITIGATION BACKGROUND

It is no secret that the world is in the midst of a crisis of horrifying proportions.<sup>30</sup> Globally, thirty-nine million people are living with HIV or AIDS.<sup>31</sup> Of these, almost twenty-five million are living in sub-Saharan Africa.<sup>32</sup> In 2006 alone, over four million people were newly infected, and almost three million died from the disease.<sup>33</sup> Although treatment has increased tenfold in the last three years, even the most optimistic estimates show that only twenty-three percent of the more than four million people in Sub-Saharan Africa whose lives could be saved by Highly Active Antiretroviral Therapy (ARV) are receiving it.<sup>34</sup> Moreover, deaths are increasing annually, a phenomenon that is "largely the result of an increase in the number of people with advanced HIV infection and in urgent need of treatment, whose numbers are rising faster than the scale-up of antiretroviral therapy."<sup>35</sup> This failure

29. The word pandemic is used to describe the spread of a disease "throughout an entire country, continent, or the whole world." WEBSTER'S ENCYCLOPEDIA UNABRIDGED DICTIONARY OF THE ENGLISH LANGUAGE 1042 (1996). In contrast, an epidemic is "affecting at the same time a large number of persons in a locality, and spreading from person to person." *Id.* at 479.

30. For instance, every five years, ten countries in Sub-Saharan Africa lose ten percent of their active adult population to HIV/AIDS. ARTHUS-BERTRAND, *supra* note 4, at May 18. Recently, the U.N. wasted no words in addressing the scale of the crisis: "[We n]ote with alarm that we are facing an unprecedented human catastrophe." Political Declaration on HIV/AIDS, G.A. Res. 60/262, ¶ 2, U.N. Doc. A/RES/60/262 (June 15, 2006).

31. UNAIDS, 2006 AIDS EPIDEMIC UPDATE 1 (2006) [hereinafter 2006 AIDS EPIDEMIC UPDATE], available at [http://data.unaids.org/pub/EpiReport/2006/2006\\_EpiUpdate\\_en.pdf](http://data.unaids.org/pub/EpiReport/2006/2006_EpiUpdate_en.pdf).

32. *Id.* at 10.

33. *Id.* at 1.

34. *Id.*; see LAWRENCE O. GOSTIN, THE AIDS PANDEMIC: COMPLACENCY, INJUSTICE, AND UNFULFILLED EXPECTATIONS 304 (2004) (estimating that ninety-five percent of people needing treatment are not receiving it).

35. *Declaration of Commitment 2007 Progress Report*, *supra* note 9, at 2.

to adequately scale up treatment is in a context where, for instance, one in five adults in Zimbabwe is living with HIV.<sup>36</sup>

Historically, international consensus on how to address the AIDS crisis in developing countries has focused heavily on prevention.<sup>37</sup> Indeed, hailed as a “major milestone” in the global response to AIDS, the “Declaration of Commitment on HIV/AIDS” issued in 2001 by the United Nations (UN) states that “[p]revention must be the mainstay of our response.”<sup>38</sup> Despite the prevalent view that “a choice between prevention and treatment [was] unavoidable for poor countries” because of insufficient resources,<sup>39</sup> AIDS activists have raised awareness about the dreadful consequences of such an approach for the vast number of people already living with HIV/AIDS, as well as their families, communities, and economies.<sup>40</sup>

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36. 2006 AIDS EPIDEMIC UPDATE, *supra* note 31, at 11.

37. See, e.g., *Prevention ‘Focus of HIV Fight.’* BBC NEWS, Dec. 1, 2005, available at <http://news.bbc.co.uk/1/hi/health/4484662.stm> (reporting that the EU ministers “backed efforts to give people around the world better access to condoms and effective information on how to reduce their risk of infection,” and that the UK pledged support for research on vaccines and microbicides).

38. Declaration of Commitment on HIV/AIDS, G.A. Res. S-26/2 ¶ 17, U.N. Doc. A/RES/47/1 (Aug. 2, 2001).

39. ALEXANDER IRWIN, JOYCE MILLEN & DOROTHY FALLOWS, GLOBAL AIDS: MYTHS AND FACTS; TOOLS FOR FIGHTING THE AIDS PANDEMIC 60 (2003). Not only do prevention-only advocates stress the cost of providing universal access to treatment, they also cite the difficulties of delivering medications appropriately in areas with little health care infrastructure, which, they claim, results in an inability to ensure proper adherence to a complex drug regime. *Id.* at 73. These seemingly neutral logistical arguments can reveal their true xenophobic and racist origins, with comments like those of one high-ranking U.S. official that Africans “have a different concept of time” and therefore couldn’t adhere to a treatment plan, or the implication that some people are simply “too poor to treat” by dubbing treatment to not be “cost-effective” in poor countries. *Id.* at xix–xx. See NOLEN, *supra* note 4, at 102–103 (quoting then head of the United States Agency for International Development (USAID) as saying, in 2001, that people in Africa “do not know what watches and clocks are . . . they use the sun.”). This notion even made its way into the popular television series, *The West Wing*, in an episode portraying negotiations between drug companies and a fictional African leader, where one character explained that the problem with providing free universal treatment was that Africans cannot tell time in order to follow a complex treatment plan. *THE WEST WING, IN THIS WHITE HOUSE* (Warner Brothers Entertainment 2004). Moreover, such characterizations have been disproven. From the poorest parts of Haiti to remote villages in Uganda, community-based AIDS treatment programs have demonstrated compelling results. See IRWIN, MILLEN & FALLOWS, *supra* at 83–86 (describing a commitment-based AIDS treatment program in Haiti); Paul J. Weidle et. al., *Adherence to Antiretroviral Therapy in a Home-Based AIDS Care Programme in Rural Uganda*, 388 *THE LANCET* 1587 (2006); see also NOLEN, *supra* note 4, at 103 (explaining how Doctors Without Borders programs in African countries had adherence rates as high or even higher than those in North America).

40. IRWIN, MILLEN & FALLOWS, *supra* note 39, at 63 (“Many of these infected people will die of AIDS in the midst of their most productive years of work and parenting, generating enormous losses not only for individuals and families, but for society as a whole.”); see also NOLEN, *supra* note 4, at 68 (“In Zambia today, basic demographics are horribly skewed. One in three children



As a result, among international organizations concerned with the AIDS pandemic, treatment is gaining global attention. In June 2006, the UN declared that the international community had a goal of “universal access” to treatment by 2010.<sup>41</sup> It has reaffirmed its commitment to that goal in subsequent statements.<sup>42</sup> UNAIDS<sup>43</sup> issued its first comprehensive progress report on this goal in April 2007.<sup>44</sup> Although this report indicated a significant increase in treatment rates in sub-Saharan Africa, those rates fell far short of universal access to medication, at best indicating that a quarter of the population in need of treatment was receiving it.<sup>45</sup> The President’s Emergency Plan For AIDS Relief (PEPFAR) also began to take treatment goals seriously and to provide some funds for treatment programs in fifteen “focus” countries.<sup>46</sup> Likewise, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), founded in 2002,<sup>47</sup> aimed to fund treatment for

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is an orphan. One in five people has HIV/AIDS. In a country of eleven million, at least 600,000 people have already died, almost all of them young adults.”). Some have labeled this two-tiered system, wherein people living with HIV/AIDS in developed countries have access to effective treatment, and those in poor countries are denied such access and thus left to die, to be a form of “global medical apartheid.” NOLEN, *supra* note 4, at 61. The ethical implications of such a situation are beyond the scope of this Article, but remain central to its motivation.

41. Political Declaration on HIV/AIDS, *supra* note 30, ¶ 20. The Declaration states:

[W]e commit ourselves to pursuing all necessary efforts to scale up nationally driven, sustainable and comprehensive responses to achieve broad multisectoral coverage for prevention, treatment, care and support, with full and active participation of people living with HIV, vulnerable groups, most affected communities, civil society and the private sector, towards the goal of universal access to comprehensive prevention programmes, treatment, care and support by 2010.

*Id.*

42. Specifically, the U.N. issued a progress report on the goals outlined in the Declaration of Commitment in 2007, and further called for the organization of a comprehensive review of progress achieved to be undertaken in 2008. See *Declaration of Commitment 2007 Progress Report*, *supra* note 9; G.A. Res. 62/178, U.N. Doc. A/RES/62/178 (Jan. 25, 2008).

43. See *supra* note 9 and accompanying text (describing UNAIDS).

44. UNAIDS, WORLD HEALTH ORGANIZATION, UNICEF, TOWARDS UNIVERSAL ACCESS: SCALING UP PRIORITY HIV/AIDS INTERVENTIONS IN THE HEALTH SECTOR (2007), available at [http://www.who.int/hiv/mediacentre/universal\\_access\\_progress\\_report\\_en.pdf](http://www.who.int/hiv/mediacentre/universal_access_progress_report_en.pdf).

45. In three years, this report claims, the rate of treatment among those people living with AIDS for whom treatment was necessary rose from approximately two percent to twenty-eight percent. *Id.* at 5.

46. About PEPFAR, <http://www.pepfar.gov/about/> (last visited Nov. 21, 2008). PEPFAR was announced in President George W. Bush’s 2003 State of the Union address, where he pledged \$15 billion over five years. On May 27, 2003, President Bush gave authorization for PEPFAR. On July 30, 2008, President Bush signed into law H.R. 5501, the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, which answered his call to extend the PEPFAR program for five additional years. *Id.*

47. The Global Fund is a partnership organization created by international organizations, UN agencies, and national governments. It operates as a channel for funding and does not administer

1.8 million people over five years.<sup>48</sup> All of these organizations that provide medicines, however, are limited by the market prices of the drugs that they purchase.<sup>49</sup>

The differential in prices between patented medications and generics is considerable and can mean the difference between access to treatment and a lack of or much more limited access.<sup>50</sup> In fact, the 2006 UNAIDS report itself indicates that the price of medicines had dropped substantially and “contributed significantly to the wider availability of treatment.”<sup>51</sup> Paul Farmer, a leading expert on the treatment of disease in resource-poor countries, is notorious for providing aggressive treatment for a variety of diseases with great success to some of the poorest communities in Haiti.<sup>52</sup> As early as 1998, he provided free

its own projects. The Global Fund, How the Fund Works, <http://www.theglobalfund.org/en/about/how/> (last visited Aug. 10, 2008); The Global Fund, The Road to the Fund, <http://www.theglobalfund.org/en/about/road/> (last visited Aug. 10, 2008).

48. The Global Fund, Fighting AIDS, <http://www.theglobalfund.org/en/hivaids/> (last visited Jan. 9, 2009).

49. For instance, PEPFAR requires that medicines purchased by the program’s money be approved by the United States Food and Drug Administration; currently seventy-three percent of the medicines it purchases are sourced from name-brand innovator companies for frequently double, or even triple the price. PEPFAR, Critical Intervention in the Focus Countries: Treatment, <http://www.pepfar.gov/pepfar/press/81208.htm> (last visited Jan. 9, 2009).

50. For instance, in 2002, when no generic alternatives were available in Thailand, the cost of the standard triple therapy HIV/AIDS treatment regimen was \$924, and only 3,000 people were able to access treatment. After it implemented a program to acquire generic medications, at the cost of one-eighteenth the price of the name-brand drugs, over 85,000 people were receiving treatment by 2006. Medics sans Frontieres, MSF Welcomes Move to Overcome Patent on AIDS Drug in Thailand, [http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=37D61AAB-5056-AA77-6CC24F9946C41565&method=full\\_html](http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=37D61AAB-5056-AA77-6CC24F9946C41565&method=full_html) (last visited Aug. 10, 2008). Moreover, the common refrain that patent-protection is necessary to promote innovation and compensate pharmaceutical companies for their research and development outlays has been severely undermined. Notably, advertising, marketing and administrative expenditures vastly exceed research and development costs, sometimes by a factor of three. IRWIN, MILLEN, & FALLOWS, *supra* note 39, at 118. One study showed that U.S. pharmaceutical companies use only 1.3 cents of every dollar of revenue for the development of new drugs. Donald W. Light & Joel Lexchin, *Foreign Free Riders and the High Price of US Medicines*, 331 BRITISH MED. J. 958, 959 (2005). Moreover, public funds, administered through the National Institutes of Health, aid in the development of some of the drugs that generate the largest profits, including many AIDS medications. IRWIN, MILLEN, & FALLOWS, *supra* note 39, at 118. Finally, even if unaffordable prices for life-saving medicines were necessary to compensate for research and development, this would merely indicate that the funding mechanism for research and development needed to be rethought wholesale; indeed, this is the case regardless.

51. TOWARDS UNIVERSAL ACCESS, *supra* note 44, at 6. The report indicates that the price of first-line ARVs decreased between thirty-seven percent and fifty-three percent in low- and middle-income countries between 2003 and 2006. *Id.* The report also notes, however, that second-line ARVs, for which no generic alternatives are widely available, remain “unaffordably high.” *Id.*

52. See generally TRACY KIDDER, MOUNTAINS BEYOND MOUNTAINS: THE QUESTION OF DR.

ARV therapy for patients in advanced stages of AIDS.<sup>53</sup> However, Farmer has frequently encountered the bitter reality that in order to fully treat his patients he has to pay market prices for the necessary drugs, no matter how expensive.<sup>54</sup> Although Farmer tried buying medicines in countries whose markets provided the lowest prices, patented drugs were often simply out of reach.<sup>55</sup> Farmer's U.S.-based non-governmental organization, Partners in Health, eventually turned some of its attention away from direct patient services, focusing instead on political solutions to the high cost of necessary medications. Despite making some headway, it was clear at each step that the pharmaceutical companies presented a unified front against any reduction in prices.<sup>56</sup>

Although access to AIDS medication has not been the subject of extensive litigation controversy thus far, litigation in the United States surrounding the topic of HIV and AIDS is not new. In fact, AIDS-related litigation represents the largest number of cases attributable to a single disease in American history.<sup>57</sup> Courts have addressed claims concerning AIDS education, blood supply, public health surveillance, state regulation of public places such as bathhouses and bookstores, tort

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PAUL FARMER, A MAN WHO WOULD CURE THE WORLD (2003). Kidder chronicles the path of Paul Farmer from modest upbringings to service in Haiti at various clinics while a medical student, to his creation of Zanmi Lasante, a full-service no-cost clinic in the rural region of Cange, Haiti, where he single-handedly changed the lives of entire communities of desperately poor Haitians through comprehensive health care. *See id.*

53. IRWIN, MILLEN, & FALLOWS, *supra* note 39, at 83. Farmer has dubbed his philosophy to "prioritize patients' urgent need for lifesaving treatment over deliberations about the appropriateness of introducing 'first world' therapies in a 'third world' setting" as the "preferential option for the poor," a concept rooted in Latin American liberation theology. *Id.* at xxi, 83-84.

54. KIDDER, *supra* note 52, at 175-76. Although Farmer also treats people living with HIV and AIDS, Kidder focuses on Farmer's programs to treat multi-drug resistant tuberculosis, which requires an expensive regimen of second-line medications still strictly held under patent. *Id.* Farmer's experience trying to obtain medications at any practicable cost is instructive as to the necessity of affordable solutions for treatment of a wide range of diseases in the developing world. *See id.*

55. *Id.* at 170, 175 (explaining how Partners in Health went from saving substantial money for a crisis to becoming completely bankrupt after funding just a small pilot program to treat drug-resistant tuberculosis in Peru).

56. According to a Partners in Health worker, at an international meeting called to explore price reductions of essential medicines for people in developing countries, drug companies argued that prices ought to remain high because there was a very small potential paying demand for the drugs. *Id.* at 170-71. Furthermore, the WHO backed out of the meeting entirely, despite its initial promise of support. *Id.* at 170. In addition to the drug companies' resistance to lower prices, the public health experts seemed to believe that treatment was simply "too expensive" for certain diseases, without considering the possibility of lowering the primary cost—the patented drugs themselves. *Id.* at 166. This fact prompted Kidder to observe that "[expensive] treatment was cost-effective in a place like New York, but not in a place like Peru." *Id.* at 166.

57. GOSTIN, *supra* note 34, at 27-28.

litigation for false diagnoses and fear of exposure, administration of justice discrimination, and family law.<sup>58</sup>

First Amendment and Equal Protection doctrines have been particularly crucial in gaining rights both for PWAs and AIDS activists.<sup>59</sup> Courts have held that the First Amendment protects the right to distribute various prevention messages.<sup>60</sup> Furthermore, the Supreme Court has extended protection against discrimination to classes of people living with infectious diseases.<sup>61</sup> The Americans with Disabilities Act deems discrimination in places of public accommodation against people living with HIV or AIDS to be unlawful<sup>62</sup> and health care providers are prohibited from discriminating against people living with HIV or AIDS.<sup>63</sup> A definable collection of rights has therefore emerged.<sup>64</sup>

With a history of litigation over the rights of PWAs in U.S. courts and the emerging consensus on the need for treatment in light of the magnitude of the international crisis, the stage is set for PWA plaintiffs to assert the right of access to treatment. Specifically, PWAs abroad can use the courts to stop the pharmaceutical company lawsuits which hinder governments' attempts to provide them with treatment.

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58. *Id.* at 28–29.

59. *See* U.S. CONST. amend. I (Free Speech Clause); U.S. CONST. amend. XIV (Equal Protection Clause).

60. *Gay Lesbian Bisexual Alliance v. Pryor*, 110 F.3d 1543 (11th Cir. 1997) (concerning prevention messages distributed on a college campus); *AIDS Action Comm. v. Mass. Bay Transit Auth.*, 42 F.3d 1 (1st Cir. 1994) (concerning prevention messages on public transit); *see* GOSTIN, *supra* note 34, at 30.

61. *Sch. Bd. of Nassau County v. Arline*, 480 U.S. 273 (1987) (classifying a person with tuberculosis as protected from discrimination and entitled to reasonable accommodation).

62. GOSTIN, *supra* note 34, at 50 (noting that cases have been brought against hotels, securities brokerage firms, public transportation authorities, athletic facilities, day care providers, prisons, and public services). Although insurers are also subject to the ADA, they are still permitted to conduct the ordinary “underwriting” or risk assessment process, which may nonetheless end up denying coverage to people living with HIV. *Id.* at 52.

63. *Id.* at 51. *But see* 8 U.S.C. § 1182(a)(1) (2006) (excluding applicants for admission to the United States on the basis of their HIV status because equal protection does not apply in the immigration context).

64. It is important to note that in American jurisprudence, frequently the rights of PWAs are adverse to arguable interests in public health, such as mandatory testing, screening, or treatment and disclosure of HIV status. *See* GOSTIN, *supra* note 34, at 65. However, because the rights of PWAs are not in tension with any public health goal in the case of access to treatment, this conflict is outside the scope of this Article.

## II. PHARMACEUTICAL COMPANIES' STRATEGY: LAWSUITS AS RETALIATION

The international intellectual property regime, favorable as it is to drug companies generally, does provide explicit and important flexibility for developing countries with health crises. However, recent history suggests that pharmaceutical companies will challenge even completely legitimate actions by countries whose governments seek to reduce the price of medicines or increase access to generics.

### *A. International Intellectual Property Regime: Options for Developing Countries?*

In 1994, the member states of the World Trade Organization<sup>65</sup> (WTO) signed the TRIPS agreement into law.<sup>66</sup> TRIPS was designed to be a comprehensive international instrument concerning intellectual property; it addresses copyright, trademarks, patents, trade secrets, test data, and other industry-related topics.<sup>67</sup> TRIPS also created an enforcement mechanism, providing for dispute resolution through the WTO.<sup>68</sup>

The protections for patent holders under TRIPS are very strong. TRIPS grants patent holders exclusive rights to produce and price their products under a provision stating that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”<sup>69</sup> This standard therefore

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65. The WTO, with 153 member countries, was established in 1995 and is located in Geneva, Switzerland; it administers international trade agreements and handles trade disputes between nations. World Trade Organization, What Is the WTO?, [http://www.wto.org/english/thewto\\_e/whatis\\_e/whatis\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm) (last visited Aug. 10, 2008).

66. TRIPS, *supra* note 11. The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization. *Id.*

67. World Trade Organization, Overview: The TRIPS Agreement, [http://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm) (last visited Aug. 10, 2008). Prior to TRIPS, other conventions, namely the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works, governed the international intellectual property landscape. *Id.* TRIPS incorporated by reference most of the standards in those existing agreements, but also strengthened some existing intellectual property protections and added new ones in areas where there had been none. *Id.*

68. *Id.* The inclusion of a dispute mechanism within TRIPS itself necessarily implies that TRIPS was meant to be enforced in that venue, not by means of lawsuits in national legal systems of individual countries. The fact that pharmaceutical companies would choose the latter option, discussed *infra* Part II.B, may belie the companies' fear—or even certainty—that the WTO would, if given the opportunity, find the countries exercising TRIPS options to be acting within the law.

69. TRIPS, *supra* note 11, at art. 27 ¶ 1.

mandates that each member country grant patents of both “products,” giving the patent holders of medicines exclusive rights over the composition of the drug itself regardless of how it is produced, and of “processes,” giving the patent holder of medicines exclusive rights over the scientific method of producing the drug.<sup>70</sup> Moreover, TRIPS does not permit countries to adopt national laws exempting certain classes of products from patent protection, such as medicines.<sup>71</sup> Although frequently characterized as “minimum” patent-protection standards,<sup>72</sup> these provisions significantly change many countries’ historical practices of refusing patent grants to medicines entirely, or granting patents for processes rather than end-product drugs, thus allowing for reverse engineering of medicines.<sup>73</sup> Moreover, these “minimum” protections explicitly provide a floor but no ceiling as to the amount of protection that a pharmaceutical company in the U.S. may receive through bilateral or multilateral treaties; indeed, agreements heightening the protections beyond the already high TRIPS standards are so common that they are collectively referred to as “TRIPS-plus” agreements.<sup>74</sup>

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70. Overview: the TRIPS Agreement, *supra* note 67.

71. Brook K. Baker, *Producing HIV/AIDS Medicines for Export/Import Under TRIPS, Articles 31(F), (K), and 30*, at 3 (Trans Atlantic Consumer Dialogue Briefing Paper, Nov. 6, 2001).

72. See Overview: the TRIPS Agreement, *supra* note 67 (stating that “the Agreement sets out the minimum standards of protection to be provided by each Member”).

73. Indeed, approximately fifty countries did not patent pharmaceutical products prior to TRIPS. Baker, *supra* note 71, at 2. For instance, India and Brazil previously did not classify medicines as a patentable product at all, preferring to grant “process” patents. *Id.* at 3. However, TRIPS did exempt pre-ratification products; thus, those medicines or products discovered before 1995 were subject to the country’s pre-1995 rules. *Id.* As a result, India and Brazil can and have continued to manufacture reverse-engineered pre-1995 medicines in accordance with TRIPS. *Id.*

74. The TRIPS agreement explicitly provides that more “extensive” protections can be negotiated bilaterally or multilaterally. See TRIPS, *supra* note 11, at 321. For an updated list of TRIPS-plus agreements, most initiated by the United States or the European Union, see Genetic Res. Action Int’l [GRAIN], “TRIPS-plus” Through the Back Door (update 2008), available at <http://www.grain.org/rights/tripsplus.cfm?id=68>. TRIPS-plus agreements have heightened standards as to specific countries on a variety of issues, including parallel importation and compulsory licenses, discussed *infra* pp. 115–20. See World Bank Group, *Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements*, TRADE NOTE 20, Feb. 7, 2005, at 5–6. Moreover, some TRIPS-plus agreements have heightened the protection for test data on drugs’ safety and efficacy, which, under TRIPS, is protected only from “unfair commercial use” rather than providing for complete data exclusivity. *Id.* at 2. Unilateral action can, on occasion, benefit developing countries, such as instances where the United States and others have unilaterally declared that they will not enforce certain TRIPS provisions when breached to address particular public health crises. Margo A. Bagley, *Legal Movements in Intellectual Property: TRIPS, Unilateral Action, Bilateral Agreements, and HIV/AIDS*, 17 EMORY INT’L L. REV. 781, 787 (2003). The true benefit of that kind of action is questionable, however, where there is no guarantee that such an enforcement moratorium will continue or be

The strong protections for U.S. corporate interests found in TRIPS come as no surprise.<sup>75</sup> One analysis asserts that:

[D]eveloping countries signed TRIPS because of a failure of democratic processes, both nationally and internationally, that enabled a small group of men within the U.S. to capture the U.S. trade-agenda-setting process and then, in partnership with European and Japanese multinationals, draft intellectual property principles that became the blueprint for TRIPS.<sup>76</sup>

Adopting the position that trade should be linked to intellectual property even prior to TRIPS, the U.S. first harnessed an old program designed to give greater access to U.S. markets for developing countries' basic agricultural exports—the General System of Preferences (GSP)—and infused it with a system of rewards and punishments based on those countries' compliance with U.S.-style intellectual property laws.<sup>77</sup> Under the refashioned GSP, the U.S. Trade Representative (USTR) was given the power to initiate a “section 301” action against a country, at the request of an “interested party,” to determine if the country lacked “adequate and effective” protection for U.S. intellectual property.<sup>78</sup> If the USTR determined that the country

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honored, and where such moratoriums are not negotiated in a recognized international forum. Moreover, seemingly unrelated trade provisions can affect access to medicines; for instance, heightening intellectual property regimes as to other products, such as engineered plants (which affect food prices), can hinder a country's ability to provide medicines as a result of increased cost of other necessities. See generally *id.*

75. See GOSTIN, *supra* note 34, at 305 (“The international trade system is specifically designed to safeguard the proprietary interests of corporations.”); Baker, *supra* note 71, at 3 (noting that the pharmaceutical industry “played a lead role in the negotiation of TRIPS, not only by convincing trade representatives to champion its interests, but by direct lobbying during the negotiation.”); Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 28 (2002) (“The implementation of TRIPS is expected to have a further upward effect on drugs prices, while increased R&D investment, despite higher levels of intellectual property protection, is not expected.”). The pharmaceutical industry was particularly involved. For instance, Pfizer was “instrumental” in developing the idea that intellectual property rules should be linked to the international trade regime. The Corner House, *Who Owns the Knowledge Economy? Political Organising Behind TRIPS* 8 (2004), available at <http://www.thecornerhouse.org.uk/pdf/briefing/32trips.pdf>.

76. The Corner House, *supra* note 75, at 2. Getting the U.S. government on board in the first place was a triumph of corporate ingenuity. First, corporations had to convince the political leaders that intellectual property and the lack of systematic protections internationally was hindering the U.S. economy as a whole, and that other countries were widely transgressing the rights of U.S. patent-holders. *Id.* at 10–11. The U.S. governments' wholesale purchase of this party line was a necessary precursor to the international campaign in which it engaged. *Id.*

77. *Id.* at 11–12. GSP originated in 1976. *Id.* at 12. The refashioning of GSP occurred when the program was due to end as a result of the 1984 Trade and Tariff Act. *Id.* at 13. At that time, some countries protested that a program originally designed to provide assistance to less developed countries had been perverted into a method of control. *Id.*

78. 19 U.S.C. § 2412 (2004). This provision is an amendment to Section 182 of the Trade Act of 1974 by the Omnibus Trade and Competitiveness Act of 1988, codified at 19 U.S.C. The

lacked adequate and effective protections, the country was placed on a trade “watch list” and faced possible trade sanctions.<sup>79</sup> The goal of the section 301 system was to bilaterally negotiate tougher intellectual property protections across the planet.<sup>80</sup> These bilateral agreements then weakened developing countries’ incentives to fight TRIPS during negotiations because the countries had already given up so much through bilateral agreements.<sup>81</sup>

Despite the industry-influenced patent standards embodied in TRIPS, there are still very important flexibilities within the document. The two most important flexibilities written into TRIPS itself are known as parallel importation and compulsory licensing.<sup>82</sup> Parallel importation—sometimes referred to as parallel trade—arises when pharmaceutical companies sell the same brand-name drug at differing prices in different countries.<sup>83</sup> Purportedly, these different prices arise because of varying economic, social, or legal landscapes in different markets.<sup>84</sup> A purchaser in a country where the drug’s prices are high will acquire pharmaceuticals from dealers in the countries with lower prices, thereby reducing the end cost in the high-priced country.<sup>85</sup>

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Corner House, *supra* note 75, at 13 & n.62.

79. The Corner House, *supra* note 75, at 13. Notably, there was considerable support for the notion that Section 301 was itself illegal under the General Agreement on Tariffs and Trade (GATT), the precursor to the WTO. *Id.* at 16; see The WTO, [http://www.wto.org/english/thewto\\_e/thewto\\_e.htm](http://www.wto.org/english/thewto_e/thewto_e.htm) (last visited Aug. 10, 2008).

80. The Corner House, *supra* note 75, at 15. This strategy worked, as countries attempted to “appease” the USTR so as not to create a true dispute. *Id.*

81. *Id.* at 16. For example, the U.S. used section 301 against Brazil for failing to enact patent protections for medicines, and Brazil eventually was forced to cave to U.S. pressure so as not to lose access to U.S. markets, trade with which constituted 25% of the country’s total trade. *Id.* After Brazil enacted new patent laws, the U.S. concluded that Brazil would not block the effort to multilateral patent standards because it would have nothing left to lose. *Id.* Indeed, this broke up the unified resistance of several South American countries to patents on medicines. *Id.*

82. There is also a general statement providing that countries may be exempted from TRIPS obligations, but this provision does not grant specific rights, and therefore is less useful to countries trying to provide AIDS medications at low cost to their citizens. See TRIPS, *supra* note 11, at 332. The text of this provision reads: “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” *Id.*

83. Julia A. Moore, *Parallel Trade, Unparallel Laws: An Examination of the Pharmaceutical Parallel Trade Laws of the United States, the European Union and the World Trade Organization*, 6 RICH. J. GLOBAL L. & BUS. 77, 80 (2006).

84. See *id.* In reality, the pharmaceutical companies charge “whatever a local market will bear.” BAKER, *supra* note 16, § 3.2, at 22.

85. Moore, *supra* note 83, at 80. This is, essentially, “comparison-shopping on an international scale.” BAKER, *supra* note 16, § 3.2, at 21.



Parallel importation is permissible when a country has adopted, through national legislation, a “rule of exhaustion” of intellectual property rights. A rule of exhaustion dictates that after the first sale of a product into a market, the patent-holder’s rights have been “exhausted,” and the holder has no further ability to prevent, control, or profit from future sales or trading.<sup>86</sup> TRIPS declines to regulate parallel importation in its provisions because the exclusive rights granted to the patent holder for “making, using, offering for sale, selling, or importing” a patented product are always “subject to the provisions of Article 6.”<sup>87</sup> Article 6 declares TRIPS’ neutrality towards the issue of exhaustion by stating that “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”<sup>88</sup> The issue of exhaustion, therefore, was left to member states to determine under national law, which then dictates whether a country can engage in parallel importation.<sup>89</sup>

Pharmaceutical companies are deeply opposed to parallel importation because price discrimination on a global scale is a highly profitable marketing strategy.<sup>90</sup> There may be a legitimate concern that enforcing

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86. Jeffery Atik & Hans Henrik Lidgard, *Embracing Price Discrimination: TRIPS and the Suppression of Parallel Trade in Pharmaceuticals*, 27 U. PA. J. INT’L ECON. L. 1043, 1046 (2006). The majority of developing countries without the ability to produce AIDS medications on their own have not adopted a rule of exhaustion. BAKER, *supra* note 16, § 3.2, at 22. However, some have. For instance, Kenya has a very strong rule of exhaustion, which includes generic drugs that are produced pursuant to compulsory licenses. *Id.* This approach may or may not fit within the permissible exhaustion rule under TRIPS, but certainly could be valid if the TRIPS provision were read broadly. *Id.*

87. TRIPS, *supra* note 11, at 331, 332 & n.6.

88. *Id.* at 323; Atik & Lidgard, *supra* note 86, at 1046. At least one commentator suggests that the 2005 Amendments to TRIPS, codifying the Doha Declaration, alter TRIPS’ neutrality on parallel importation, favoring a prohibition of the practice. See Atik & Lidgard, *supra* note 86, at 1076. This is not the position of the World Health Organization, which asserts that Doha did not alter the neutrality of TRIPS toward exhaustion. See World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/W/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration]. In any event, the potential test cases, particularly the events that occurred in South Africa, discussed below, all occurred before the Doha Declaration and are thus not affected by any changes that Doha made. Indeed, Doha is widely viewed as simply reaffirming and strengthening the already announced flexibilities in TRIPS. See Hoen, *supra* note 75, at 28 (stating that the Doha Declaration “gave primacy to public health over private intellectual property, and clarified WTO Members’ rights to use TRIPS safeguards.”).

89. See TRIPS, *supra* note 11, at 323. The rule of exhaustion is dispositive of a country’s ability to engage in parallel importation of name-brand medications sold by the patent-holder or a licensee. BAKER, *supra* note 16, § 3.2, at 22. However, it is unclear whether such rule would permit parallel importation of medications produced under compulsory licenses, as those licenses may be a non-permissive use of the patent. *Id.*; see Moore, *supra* note 83 and accompanying text (for a brief discussion of parallel importation).

90. BAKER, *supra* note 16, § 3.2, at 22. Pharmaceutical companies also claim that parallel importation, amid other “anti-patent” behavior, causes reduced profits, falling stock values, and

price discrimination is necessary to enable companies to market drugs to developing countries at reduced cost without risk that those drugs will be re-imported into developed countries.<sup>91</sup> However, that risk, if actualized, would suggest a need for a ban on parallel importation into developed countries only, not impoverished nations.<sup>92</sup> Furthermore, parallel importation can greatly benefit developing countries by assuring the quality of a product through access to name-brand drugs.<sup>93</sup> In any case, the policy interests and resulting debate on the merits of parallel importation do not change the fact that TRIPS has unambiguously left the question of exhaustion up to each member country to decide as a matter of national law.

Unlike parallel importation, which is a strategy for lowering the cost of brand-name medication, compulsory licensing is a method of obtaining generic drugs at low cost by nationally authorizing production and sale of a generic version of an otherwise-patented medication.<sup>94</sup> Compulsory licensing is permitted by TRIPS, which provides that a member may, through national law, allow others to use the subject matter of a patent without the patent-holder's authorization in limited circumstances and subject to a number of conditions.<sup>95</sup>

Compulsory licenses can be issued for any reason, provided that the government first attempts to negotiate a permissive license from the patent holder.<sup>96</sup> Even the negotiation requirement is waived, however,

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less available money for research and development. *See* Moore, *supra* note 83, at 81. Moreover, Moore asserts that parallel importation is not dictated by the rule of exhaustion, because exhaustion was only ever meant to apply within a certain market, *i.e.*, domestically, and that international exhaustion reaches beyond the rationale of the rule. *Id.* This position fails to recognize that only a small amount of drug company revenues are spent on research and development, that drug companies, left unchecked, do not price medicines humanely, and that a public health crisis is an acceptable reason to utilize exemptions from a harsh intellectual property regime. *See supra* note 47 and accompanying text; *see also* Hoen, *supra* note 75, at 29 (stating that Médecins sans Frontières (MSF) asserts that increased patent protections leads to higher drug prices, which leaves drugs out of reach for people in poor countries).

91. Atik & Lidgard, *supra* note 86, at 1058.

92. BAKER, *supra* note 16, § 3.2, at 23. The European Union has adopted a rule such as this, which allows for price discrimination and parallel importation, but not re-importation of medicines back into EU countries. *Id.*

93. *Id.* § 3.2, at 23, chart 8.

94. *See id.* § 3.3, at 24.

95. TRIPS, *supra* note 11, at 333. The provision states in pertinent part: "Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected. . . ." *Id.*

96. *Id.* at 333. The provision states:

[S]uch use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable

when a country faces a national emergency, or if the country is only issuing a license for governmental non-commercial use, also known as a government use order.<sup>97</sup> As Jeffery Atik and Hans Henrik Lidgard argued, “[t]here can be little doubt that least-developed and developing countries most affected by epidemic diseases are in an emergency situation under TRIPS Article 31 and that they are fully entitled to use the system of compulsory licensing.”<sup>98</sup> A country issuing a compulsory license must also provide for compensation of the patent-holder based on the economic value of the license.<sup>99</sup> Moreover, TRIPS permits compulsory licenses without many of the otherwise applicable restrictions in the event that the patent holder has acted anti-competitively, although such provision has not played a major role in increasing access to AIDS medications to date.<sup>100</sup>

It is important to note that although these flexibilities were built into TRIPS from the outset, they are seldom used. Part of the reason for the lack of compulsory licensing is that most developing countries in need of pharmaceuticals do not have the technology or industrial infrastructure necessary to produce medicines under compulsory licenses.<sup>101</sup> Moreover, countries were hesitant to use compulsory licenses and parallel importation for fear that they would suffer retaliation from the international community, as eventually occurred in a variety of ways.<sup>102</sup>

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period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

*Id.*

97. *Id.*; BAKER, *supra* note 16, § 3.3, at 24.

98. Atik & Lidgard, *supra* note 86, at 1050.

99. TRIPS, *supra* note 11, at 333.

100. *Id.* at 334 (“Members are not obliged to apply the conditions set forth [previously] where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.”).

101. Atik & Lidgard, *supra* note 86, at 1050–51. As of 2004, only Mozambique, Zimbabwe and Malaysia have issued compulsory licenses or government use orders. BAKER, *supra* note 16, § 3.3, at 26, chart 9.

102. Moore, *supra* note 83, at 105 (“Although the TRIPS Agreement contained provisions allowing countries to override patent rights in some situations, to allow compulsory licensing of patents, and to adopt necessary measures to protect public health, the provisions were ambiguous and countries were hesitant to employ them for fear of trade reprisals.”). See *infra* Part II.B (discussing various instances of retaliation).

As a result of the scarce use of these TRIPS flexibilities,<sup>103</sup> in 2001 the WTO reexamined TRIPS and issued what is known as the “Doha Declaration,” a statement focused on public health crises in the developing world and access to medicines.<sup>104</sup> In particular, Paragraph Six of the Doha Declaration recognizes the need for increased flexibility for countries with insufficient or no manufacturing capabilities in pharmaceuticals.<sup>105</sup> This was a problem particularly because TRIPS itself limits the use of compulsory licenses to production “predominantly” to supply the domestic market.<sup>106</sup> However, the Doha Declaration and a subsequent amendment to TRIPS created an exception to this limitation, allowing for export of products produced under compulsory licenses beyond fifty percent of production in limited circumstances.<sup>107</sup> This provision has been implemented in a 2003 WTO decision granting such a waiver with respect to the exportation of medications produced under compulsory licenses to countries without production capacity when the importing country has demonstrated need.<sup>108</sup> The decision was later codified in a 2005 amendment to the TRIPS Agreement.<sup>109</sup>

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103. Atik & Lidgard, *supra* note 86, at 1051.

104. Doha Declaration, *supra* note 88.

105. This section reads:

We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

Doha Declaration, *supra* note 88, ¶ 6.

106. TRIPS, *supra* note 11, at 333.

107. BAKER, *supra* note 16, § 3.5 at 30. Other exceptions to the predominately-for-domestic-use requirement exist as well, such as in the case of anti-competitive behavior on the part of the patent holder. TRIPS, *supra* note 11, at 334. Others possibly exist under the Article 30 provision allowing limited exceptions to patents where the exception does not unreasonably interfere with the rights of the patent holders. BAKER, *supra* note 16, §§ 3.3, 3.4; *see supra* note 82 and accompanying text.

108. General Council Decision, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 2, WT/L/540 (Aug. 30, 2003) (“The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below . . . .”). The Chairman of the General Council issued a statement accompanying this decision which can provide some clarification to the Paragraph 6 Decision, but has uncertain legal effect. *See* Press Release, Carlos Pérez del Castillo, General Council, World Trade Organization, General Council’s Statement (Aug. 30, 2003), available at [http://www.wto.org/English/news\\_e/news03\\_e/trips\\_stat\\_28aug03\\_e.htm](http://www.wto.org/English/news_e/news03_e/trips_stat_28aug03_e.htm).; BAKER, *supra* note 16, § 2, at 11.

109. Amendment of the TRIPS Agreement, Dec. 6, 2005, WT/L/641, 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).

Finally, TRIPS also offers developing countries further flexibility through transition periods which allow countries more time to comply, and by not applying TRIPS retroactively, thereby exempting some older drugs from TRIPS requirements.<sup>110</sup> Taken together, TRIPS itself, the Doha Declaration, and the Paragraph Six implementation constitute the major legal framework governing access to medicines in the global market.<sup>111</sup>

*B. The Public Verdict Is In: Drug Company Lawsuits Are Unconscionable*

1. Pharmaceutical Manufacturers Association v. South Africa<sup>112</sup>

South Africa has one of the most progressive constitutions in history,<sup>113</sup> guaranteeing the right to health care, including reproductive care, and stating that the government must “take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights.”<sup>114</sup> Soon after the South African Constitution was ratified, the legislature amended the 1965 Medicines and Related Substances Control Act (Medicines Act) to be consistent with the rights enumerated in the constitution.<sup>115</sup>

The Medicines Act tried to fulfill the progressive health care guarantees of the South African Constitution by exercising the limited flexibility permitted under the international trade regime.<sup>116</sup> For

110. BAKER, *supra* note 16, § 2, at 12, chart 2.

111. *Id.* § 2, at 11.

112. Pharm. Mfrs. Ass’n of S. Afr. v. The Republic of S. Afr., 1998 High Court of South Africa, Case No. 4138/98 (S. Afr.).

113. Jennifer Joni, *Access to Treatment for HIV/AIDS: A Human Rights Issue in the Developing World*, 17 CONN. J. INT’L L. 273, 274 (2002). “Progressive” in this context is characterized by heightened protections for socio-economic rights, or, in the international human rights context, what are labeled economic, social, and cultural rights. *See id.*; *see also* International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3, entered into force January 3, 1976 [hereinafter ICESCR].

114. S. AFR. CONST. 1996 § 27, available at <http://www.info.gov.za/documents/constitution/index.htm>.

115. Medicines and Related Substances Control Amendment Act, No. 90 (1997), available at <http://www.info.gov.za/documents/acts/1997.htm> [hereinafter Medicines Act]; Joni, *supra* note 113, at 276.

116. South Africa’s courts have determined that there are, in fact, positive duties owed by the government that arise from its constitution, including the duty of the government to provide health care services and to take all reasonable steps to meet that obligation in spite of resource constraints. Joni, *supra* note 113, at 275–76. This positive right concept is in contrast to most other constitutional provisions which guarantee only negative rights, including the vast majority of those in the U.S. Constitution (e.g., the right to be free from unreasonable searches and seizures, protected by the Fourth Amendment, or the right not to have one’s speech proscribed by

instance, section 22(f) provided for the automatic substitution of generic medicines by pharmacists when brand-name prescriptions were filled.<sup>117</sup> Additionally, section 22(g) regulates the pricing mechanism for medicines and establishes a pricing committee.<sup>118</sup> And, most notably, the amendments included the addition of section 15(c), addressing “[m]easures to ensure supply of more affordable medicines.”<sup>119</sup> This section provided for lawful parallel importation in circumstances “to protect the health of the public,” by allowing the Minister to determine that the patent-holder’s rights had been exhausted when the product entered the original market.<sup>120</sup>

The response to the Medicines Act—both from the U.S. government and from the pharmaceutical industry—was immediate and hostile.<sup>121</sup> The Clinton Administration repeatedly expressed its displeasure with the effects of the Medicines Act on patent-holders’ intellectual property rights.<sup>122</sup> Vice President Albert Gore, Jr., sent a letter to Deputy President of South Africa Thabo Mbeki expressing concerns about the parallel importation provisions.<sup>123</sup> Soon thereafter, the USTR, spurred by a complaint from the Pharmaceutical Researchers and Manufacturers of America (PhRMA), a lobbying group that promotes the interests of pharmaceutical companies, publicly threatened South Africa with trade

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the government, protected by the First Amendment). See U.S. CONST. amend. I, IV.

117. Medicines Act, *supra* note 115, § 22(f).

118. *Id.* § 22(g).

119. *Id.* § 15(c).

120. *Id.* This Section provides:

The minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may—  
(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent; (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported; (c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

*Id.*

121. See generally James Love, Consumer Project on Technology, *Appendix B: Timeline of Disputes over Compulsory Licensing and Parallel Importation in South Africa* (Aug. 5, 1999), <http://www.cptech.org/ip/health/sa/sa-timeline.txt> [hereinafter *Timeline*].

122. *Id.*

123. *Id.*

sanctions under section 301 of the Patent Act.<sup>124</sup> South Africa was, in fact, later placed on the U.S. government's 301 "watch list" after tremendous political and corporate pressure.<sup>125</sup> However, public shaming by AIDS activists—criticizing Gore's position in particular and U.S. trade policy in general—prevented South Africa from actually incurring trade sanctions as a result of the Medicines Act.<sup>126</sup> Eventually the U.S. government retreated slightly from its initial ultra-aggressive approach.<sup>127</sup>

Nonetheless, in 1998, thirty-nine multinational drug companies brought suit against South Africa to challenge the law.<sup>128</sup> The lawsuit alleged a host of constitutional claims in an effort to invalidate the Act, ranging from a violation of drug companies' property rights, to a discrimination claim, to the violation of pharmacists' right to practice their profession.<sup>129</sup> However, the pharmaceutical companies also argued that the Medicines Act violated the TRIPS agreement.<sup>130</sup> In particular, section 15(c), the companies contended, allowed for parallel

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124. *Id.* (PhRMA stated that "[t]his issue is a centerpiece of our annual 'Special 301' review of countries' intellectual property practices. Our concerns about the Medicines Act were the central focus of a bilateral IPR teleconference we conducted March 11. We will raise the issue again during the President's visit to South Africa. USTR and other agencies with both trade and health policy responsibilities will continue to press the South African Government in all possible fora as long as possible.").

125. *Id.*

126. *Id.*

127. Debora Halbert, *Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs*, 1 SEATTLE J. SOC. JUST. 257, 274 (2002). One particular public awareness campaign was known as "zapping," and was characterized by surprise protest actions. Mark Milano, *Persona Perspective: Zapping For Drugs*, ACRIA UPDATE, Fall 2006, at 12. These actions particularly targeted Vice President Gore for his role in pressuring South Africa to repeal the relevant portions of the Medicines Act, and included actions at Gore's own announcement of his presidential candidacy and several subsequent events in the days that followed. *Id.*

128. Pharm. Mfrs. Ass'n of S. Afr. v. The Republic of S. Afr., 1998 High Court of South Africa, Case No. 4138/98 (S. Afr.); see Swarns, *supra* note 21; Consumer Project on Technology, *Pharmaceutical Company Lawsuit Against the Government of South Africa*, <http://www.cptech.org/ip/health/sa/pharmasuit.html> (last visited Feb. 26, 2009).

129. Joni, *supra* note 113, at 276. The variety of claims made by the pharmaceutical companies that the provisions violated South Africa's own Constitution were themselves an attempt "to use the constitution to annex additional powers and safe-guards for intellectual property that are not part of TRIPS; to fill in some of the ambiguities in TRIPS, particularly its vagueness around 'parallel importation'; and to warn other developing countries off a similar path." Mark Heywood, *Debunking 'Conglomo-talk': A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation* 6 (Center for Applied Legal Studies, Dec. 3, 2001), available at [www.tac.org.za/Documents/MedicineActCourtCase/Debunking\\_Conglomo.rtf](http://www.tac.org.za/Documents/MedicineActCourtCase/Debunking_Conglomo.rtf). These other claims also, therefore, can be safely categorized as mere retaliation and nuisance law suits.

130. Swarns, *supra* note 21.

importation in conflict with TRIPS;<sup>131</sup> this, in spite of the clear consensus that parallel importation was legal under TRIPS.<sup>132</sup> In fact, in 1998 the Supreme Court of the United States upheld the lawfulness of a parallel importation provision under the U.S. Copyright Act, ignoring plaintiffs' pleas to look to policy concerns surrounding the adoption of an international rule of exhaustion factoring against parallel importation, as exhibited in various bilateral agreements.<sup>133</sup>

Despite the clarity of the TRIPS provisions and the United States' decision not to impose trade sanctions, the companies pursued the lawsuit vigorously in 2001, insisting that the law would "destroy patent protections."<sup>134</sup> The drug companies "march[ed] to the beat of a steady chant—that patent protection for drugs is essential for innovation."<sup>135</sup> However, it is clear that pharmaceutical companies waged this suit to keep the prices of, and therefore profits from, medications very high.<sup>136</sup> During the suit, Treatment Action Campaign, an organization in South Africa dedicated to achieving universal access to treatment, was permitted to file an amicus curiae brief which addressed the scope and impact of the pandemic as well as the legal basis for upholding the Medicines Act.<sup>137</sup> Six weeks later, the pharmaceutical companies dropped the lawsuit.<sup>138</sup>

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131. Joni, *supra* note 113, at 276.

132. See Swarns, *supra* note 21 ("Legal experts say the key components of the law do not threaten patent protections spelled out in World Trade Organization agreements.")

133. Quality King Distrib., Inc. v. L'anza Research Int'l, Inc., 523 U.S. 135, 153 (1998).

134. Henri E. Cauvin, *Access to AIDS Drugs at Issue in South African Trial This Week*, N.Y. TIMES, Mar. 5, 2001, at A7.

135. Andrew Pollack, *Defensive Drug Industry: Fueling Clash Over Patents*, N.Y. TIMES, Apr. 20, 2001, at A6.

136. GOSTIN, *supra* note 34, at 305.

137. Brief for Treatment Action Campaign as Amicus Curiae Supporting Respondent, Pharm. Mfrs. Ass'n of S. Afr. v. The Republic of S. Afr., No. 4183/98 (Feb. 16, 2001), available at <http://www.tac.org.za/Documents/MedicineActCourtCase/MedicineActCourtCase.htm>.

Treatment Action Campaign (TAC) was founded in 1998 specifically to target pharmaceutical companies on access to medicines issues. NOLEN, *supra* note 4, at 171. Zachie Achmat, one co-founder, publicly declared that he would not take ARVs until treatment was available to all South Africans through the public health system. *Id.* TAC also waged successful suits on other access issues, including a case in the highest court, which decided that the government was constitutionally required to provide drugs to prevent mother to child transmission of HIV during birth. *Id.* at 177. Interestingly, TAC originally found itself at odds with Nelson Mandela, who in fact did very little about HIV during his tenure as president, but who later became an ardent advocate of treatment, and in fact went public with the news that his own son died of AIDS. *Id.* at 173, 313, 315–16.

138. Rachel L. Swarns, *Drug Makers Drop South Africa Suit Over AIDS Medicine*, N.Y. TIMES, Apr. 20, 2001, at A1.



Under a “barrage of public pressure,”<sup>139</sup> the companies admitted that the Medicines Act was lawful and could be enforced as written, and agreed to pay legal fees to the government of South Africa for the defense against the suit.<sup>140</sup> The chief executive officer of GlaxoSmithKlein admitted that the public pressure impacted their decision: “We’re a very major corporation. We’re not insensitive to public opinion. That is a factor in our decision-making.”<sup>141</sup>

Despite this apparent concession by the pharmaceutical companies, it is important to note that during the period of time between the filing of the lawsuit and the companies’ decision to drop the case, implementation of the Medicines Act was put on hold.<sup>142</sup> As a result, “measure[s] which would have drastically brought down the price of many medicines (as well as their profitability) were delayed, saving the pharmaceutical companies many millions of dollars and delaying the advent of affordable health care in South Africa.”<sup>143</sup> Thus, it is questionable how complete a victory any country defending against such a suit may have, even if legal victory is eventually achieved.

An industry analyst, commenting on the lasting deterrent effect of the suit, stated that “[t]his has been a public relations disaster for the companies. . . . The probability of any drug company suing a developing country on a life-saving medication is now extremely low based on what they learned in South Africa.”<sup>144</sup> That prediction turned out to be overly optimistic. Drug companies have been equally aggressive in other situations, perhaps because of the strategy’s latent benefits to the companies.

## 2. Other Possible Test Cases

The suit in South Africa is a prime example of a lawsuit aimed at preventing a government from exercising its lawful right—indeed, obligation—to provide life-saving medications to its people. However, there are other instances where conduct by pharmaceutical companies might give rise to liability for the death or injury of PWAs unable to

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139. Press Release, Oxfam, Medecins Sans Frontiers & Treatment Action Campaign, Drug Companies in South Africa Capitulate Under a Barrage of Public Pressure (April 19, 2001), available at <http://www.doctorswithoutborders.org/press/2001/04-19-2001.htm>.

140. Swarns, *supra* note 138, at A1.

141. *Id.*

142. Heywood, *supra* note 129, at 6.

143. *Id.* at 7.

144. Swarns, *supra* note 138, at A1 (quoting Hermant K. Shah, an industry analyst, discussing the fact that drug companies will be unlikely to engage in similar lawsuits given their past experiences in South Africa).

access medications. Sadly, these instances show that the deterrent effect of the negative publicity surrounding the South Africa suit was minimal and short-lived, at best.

Finding itself in a public health crisis very similar to that in South Africa, Thailand issued compulsory licenses for the production and importation of a generic form of Kaletra, a second-line AIDS medication patented by Abbott Laboratories.<sup>145</sup> The initiative was part of Thailand's campaign to provide universal access to treatment for its citizens.<sup>146</sup> Although the compulsory license was for government use only and therefore did not require prior negotiations for a permissive license, the Thai government had made substantial efforts to obtain such a license.<sup>147</sup> Moreover, issuance of the compulsory license would allow the Thai government to save an additional 8,000 lives.<sup>148</sup>

Abbott Laboratories, however, publicly stated that the Thai government was ignoring patent protections, and, as a result refused to register new drugs in Thailand and withdrew pending applications for drug registration there, effectively cutting off the Thai market from access to new Abbott-patented drugs.<sup>149</sup> Although Abbott's action was

145. Oxfam America, *Abbott Pharmaceuticals in Thailand: Fact Sheet* (Apr. 13, 2007), [http://www.oxfamamerica.org/whatwedo/campaigns/access\\_to\\_medicines/news\\_publications/Abbott%20in%20Thailand](http://www.oxfamamerica.org/whatwedo/campaigns/access_to_medicines/news_publications/Abbott%20in%20Thailand) (last visited Nov. 22, 2008) (discussing how pharmaceutical companies are on the offensive against developing countries who seek to use compulsory licenses in order to get access to generic drugs at lower prices). Second-line therapies are necessary for about twenty percent of patients after they have been on first-line ARV therapies for five years. See MSF Press Release, *MSF Denounces Abbott's Move to Withhold Medicines from People in Thailand* (Mar. 15, 2007), [http://www.msf.org/msfinternational/invoke.cfm?component=pressrelease&objectid=55646135-15C5-F00A-25D3DAC13D288586&method=full\\_html](http://www.msf.org/msfinternational/invoke.cfm?component=pressrelease&objectid=55646135-15C5-F00A-25D3DAC13D288586&method=full_html) (stating that an MSF study in South Africa found that twenty percent of patients needed to switch to second-line therapies after using first-line therapies for five years). As patents have expired on first-line therapies and prices of those medications have diminished enormously, the prices of second line therapies have become the major battle ground for AIDS activists trying to secure access to cheaper medications. *Id.*

146. See MSF Press Release, *supra* note 145.

147. Brook K. Baker, *Standing Up To Abbott's Decision to Withhold Registration and Marketing of Life-Saving Medicines—A New Variant of Pharmaceutical Apartheid*, *INTELL. PROP. DISP. IN MED.*, Mar. 13, 2007, <http://www.cptech.org/blogs/ipdisputesinmedicine/2007/03/standing-up-to-abbotts-decision-to.html> (discussing Abbott Laboratories' critical response to the Thai government issuing a compulsory license on its second-line medication).

148. See Oxfam America, *supra* note 145. At the time of the dispute, Abbott was providing Kaletra at \$2,200 per year per patient, although it has now reduced that cost to \$1,440 per year. *Id.* See also Celia Dugger, *Clinton Foundation Announces a Bargain on Generic AIDS Drugs*, *N.Y. TIMES*, May 9, 2007, at A9 (stating that Abbott has dropped its price of Kaletra to \$1,000). The Clinton Foundation announced an even lower price for a generic version of the drug, produced by Indian manufacturers. *Id.*

149. Bruce Japsen, *Abbott, Activists Tangle: Drug Giant's Chief Defends Response to Thailand Patent Break*, *CHI. TRIB.*, Apr. 28, 2007, at C1; Baker, *supra* note 147. At the time, the medicines that were withdrawn from the registration process in Thailand included a new heat-

not as clearly defined as filing a lawsuit, and thus is outside the technical scope of this Article, potential liability based on retaliation against the Thai government for its choice to exercise its rights under TRIPS could be explored.

There are also two examples of lawsuits by pharmaceutical companies against governments exercising their rights under TRIPS in instances involving medications other than those for the treatment of AIDS. Pfizer sued the Philippine government after it used parallel importation to import tiny quantities of a patented drug for the purpose of registering it in preparation for its marketing once the patent had expired.<sup>150</sup> The early registration of the generic was TRIPS-compliant under what is known as the “Bolar provision.”<sup>151</sup> Pfizer undertook this lawsuit even though the imported generic was not profited from, marketed, or sold.<sup>152</sup> The case was settled without a conclusive statement on whether or not the Philippine government had violated Pfizer’s patent.<sup>153</sup>

The most recent example of a pharmaceutical company’s retaliation against a government exercising TRIPS flexibility is Novartis’s lawsuit

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stable form of Kaletra, which was desperately needed in Thailand because of the lack of common availability of refrigeration. Oxfam America, *supra* note 145. There were six other medications that were also withdrawn, including medications to treat pain, high blood pressure, kidney disease, blood clots, and antibiotics. *Id.*

150. Tove Iren S. Gerhardsen, *Pfizer Fights IP Flexibilities in The Philippines*, INTELL. PROP. MONTHLY REP. (Apr. 30, 2006), available at <http://www.ip-watch.org/weblog/index.php?p=285>.

151. *Id.*; see also WTO Fact Sheet: TRIPS and Pharmaceutical Patents, Obligations and Exceptions, [http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm#art30](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#art30) (last visited Aug. 10, 2008) (stating that Article 30 has been interpreted to provide a research exception and “Bolar” provision, which permits the use of a patented drug to obtain marketing approval for generics to be produced and registered upon the expiration of the patent period). The Philippines had amended its intellectual property laws in 2007 to include TRIPS flexibilities, specifically to address access to affordable medicines. See An Act Providing for Cheaper Medicines and for Other Purposes, H.R. 6035, 13th Cong. (2007) (Phil.), available at <http://www.cptech.org/ip/health/c/phil/philippines-bill-hb6035.pdf>; see also An Act to Make the Laws of Patents, Tradenames, and Trademarks More Responsive to the Health Care Needs of the Filipino People by Clarifying Non-Patentable Inventions, Allowing the Importation and Early Development of Patented Medicines, and Modifying Government Use Provisions for Drugs or Medicines, to Lower Prices and Increase Access to and Supply of Quality Drugs or Medicines, Amending for this Purpose Certain Provisions of Republic Act No. 8293 Otherwise Known as the Intellectual Property Code of the Philippines, S. 2263, 13th Cong. (2006) (Phil.), available at <http://www.cptech.org/ip/health/c/phil/philippines-bill-sn2263.doc>.

152. Gerhardsen, *supra* note 150 (stating that the Philippine International Trading Corporation informed Pfizer it would not market the generic drug until Pfizer’s patent expired).

153. Consumer Project on Technology, CPTech Analysis of the Settlement Order Republic of the Philippines, Civil Case No. 06-172 (Aug. 31, 2006), <http://www.cptech.org/ip/health/c/phil/Settlement.pdf> (discussing how the settlement order was not a fair compromise between Pfizer and the Philippine International Trading Corporation).

against the government of India.<sup>154</sup> To comply with TRIPS requirements, India amended its Patent Act in 2005 to start granting patents for pharmaceutical products.<sup>155</sup> This legislation, however, defined “patentability” narrowly, to prevent products from being patented unless they were truly innovative (rather than slight modifications on existing medications), which is consistent with the baseline requirement of TRIPS.<sup>156</sup> Despite this lawful requirement, Novartis sued the Indian government over its decision not to grant a patent to a modified version of its leukemia medication, Gleevec, alleging both that the denial of the patent violated TRIPS, and also that the provisions of the Patent Act were unconstitutionally vague.<sup>157</sup> According to the activist organization Health GAP, “[t]he implications of the case are much broader than one drug . . . [because g]eneric Indian antiretrovirals are used for about half of all HIV treatment in poor countries.”<sup>158</sup> Furthermore, the effects of such lawsuits are indisputable: drug prices will increase and people in these countries will go without medications.<sup>159</sup> Fortunately, the trial court in India concluded that it had no jurisdiction to decide whether the patent provision complied with WTO rules contained in TRIPS, and that the provision did not violate the Indian Constitution.<sup>160</sup> Novartis indicated that it was unlikely to appeal the decision.<sup>161</sup>

Nevertheless, even losses are victories for the drug companies. While none of these suits has yet been successful, very few countries have exercised their rights to issue compulsory licenses despite the clear legal basis to do so under TRIPS.<sup>162</sup> Intimidation, frivolous lawsuits, and false accusations by pharmaceutical companies are clearly an

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154. See generally Media Advisory, Novartis' India Patent Lawsuit Threatens Access to Lifesaving Medicines, HEALTH GAP (Jan. 29, 2007), <http://www.healthgap.org/camp/novartis/novartis.html> [hereinafter HEALTH GAP].

155. *Id.*

156. *Id.*

157. *Id.*; see Amelia Gentleman, *Setback for Novartis in India Over Drug Patent*, N.Y. TIMES, Aug. 7, 2007, at C1 (discussing how the court ruling in favor of the India government will help more patients by allowing Indian companies to continue manufacturing generic drugs).

158. HEALTH GAP, *supra* note 154. Although the drug at issue in this case is a leukemia drug, the challenge to India's denial of a patent for this drug would have invalidated a central component of India's Patent Act, namely that patents may not be issued for a merely “incremental innovation.” See Gentleman, *supra* note 157. As Doctors Without Borders explained, invalidating this provision could result in a “shutdown of the pharmacy for the developing world.” *Id.*

159. HEALTH GAP, *supra* note 154.

160. Gentleman, *supra* note 157.

161. *Id.*

162. Atik & Lidgard, *supra* note 86, at 1044.

effective strategy to prevent governments from realizing their goals of universal access to AIDS medication.

### III. THE ATCA: DRUG COMPANIES ON THE DEFENSIVE

The ATCA was originally enacted as part of the Judiciary Act of 1789, but lay almost entirely dormant until the recent past.<sup>163</sup> Not only does it not have any formal legislative history whatsoever,<sup>164</sup> the ATCA was not developed through judicial interpretation until the 1980s.<sup>165</sup> In the past quarter century, however, the ATCA has been rediscovered as a vehicle for the private vindication of human rights violations.<sup>166</sup> Reinvigoration of the ATCA in this way is particularly remarkable because no other country has a comparable statute.<sup>167</sup> Although first used in suits against state actors, the ATCA has now provided a vehicle

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163. Lucien J. Dhooze, *Lohengrin Revealed: The Implications of Sosa v. Alvarez-Machain for Human Rights Litigation Pursuant to the Alien Tort Claims Act*, 28 LOY. L.A. INT'L & COMP. L. REV. 393, 394 (2006); see also Thomas H. Lee, *The Safe-Conduct Theory of the Alien Tort Statute*, 106 COLUM. L. REV. 830, 840 (2006) (asserting that the statute was "reborn" in 1980 with *Filártiga v. Pena-Irala*, 630 F.2d 876, 880–84 (2d Cir. 1980)).

164. Dhooze, *supra* note 163, at 398. The lack of legislative history has led to wide-ranging theories as to the intent behind its passage, ranging from advancing national security and foreign policy interests to the need for a federal forum to adjudicate claims asserted by foreigners, to the desire to have a uniform federal interpretation of international law. *Id.* Courts' speculation on the original purpose of the ATCA remains a frustration today as they are called on ever more frequently to interpret its application. *Id.* at 397–98.

165. Although the first judicial reference to the ATCA was made in 1795 with respect to a dispute over the ownership of slaves on a seized ship, the next reference was over 100 years later. Dhooze, *supra* note 163, at 400. In a 1908 case, the Supreme Court made a passing reference to the Act and lower courts twice suggested its possible application in cases dating back to 1961 and 1975. *Id.* The 1975 reference, made by the Ninth Circuit, was the first inkling of ATCA's potential future use for human rights purposes against governments and private actors alike. See *Nguyen Da Yen v. Kissinger*, 528 F.2d 1194, 1201 n.13 (9th Cir. 1975) (asserting the context of liability for the illegal removal of children from Vietnam by U.S. agencies in conjunction with private adoption companies, both of which the court suggested might be subject to suit under the jurisdiction of the ATCA). In none of these 20th Century cases until *Filártiga*, however, was the ATCA squarely relied upon or used as the jurisdictional basis for a suit. Dhooze, *supra* note 163, at 400–01.

166. Lee, *supra* note 163, at 832–33.

167. SARAH JOSEPH, CORPORATIONS AND TRANSNATIONAL HUMAN RIGHTS LITIGATION 21 (2004) (explaining that most transnational human rights cases against corporations have been brought under the ATCA in the United States); see also Beth Stephens, *Translating Filártiga: A Comparative and International Law Analysis of Domestic Remedies for International Human Rights Violations*, 27 YALE J. INT'L L. 1, 3 (2002) ("Civil human rights litigation generally continues to be viewed as a peculiarly U.S. phenomenon."). Stephens asserts that the lack of ATCA-type claims in other countries is due to the differing procedural practices of foreign legal systems, but that the central goals of these suits are addressed through other forms of domestic remedies. *Id.* at 5. She frames the *Filártiga* goals as broadly providing avenues to justice for victims of human rights violations and narrowly holding perpetrators accountable wherever they are found. *Id.* at 4.

for suits against a host of transnational corporations, including Unocal, Shell, Rio Tinto, Freeport McMoran, Exxon-Mobil, Pfizer, and Coca-Cola.<sup>168</sup>

In a scant sentence, the ATCA provides that “[t]he district court shall have original jurisdiction of any civil action by an alien for tort only, committed in violation of the law of nations or a treaty of the United States.”<sup>169</sup> From the language of the ATCA, there are three required elements: (1) the plaintiff is an alien; (2) the plaintiff’s claim is based in tort; and (3) the alleged tort is a violation of a treaty of the United States or the law of nations.<sup>170</sup> It is the third element that provides a significant hurdle to PWAs alleging human rights violations by pharmaceutical companies, not only in defining what constitutes the “law of nations”, but also in some cases, the necessity of proving state action or complicity thereto.

### A. *The Law of Nations*

In *Filártiga v. Pena-Irala*, the 1980 landmark decision that revived the ATCA,<sup>171</sup> the Second Circuit first squarely addressed the meaning of the “law of nations,” a definition that still carries weight despite further evolution of ATCA law since that time.<sup>172</sup> In that case, Mr. Filártiga was a political dissident living in the U.S. He sued an individual who allegedly tortured his son in retribution for Mr.

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168. JOSEPH, *supra* note 167, at 22.

169. 28 U.S.C. § 1350 (2000).

170. Luis Enrique Cuervo, *The Alien Tort Statute, Corporate Accountability, and the New Lex Petrolea*, 19 TUL. ENVTL. L.J. 151, 164 (2006).

171. Tarek F. Maassarani, *Four Counts of Corporate Complicity: Alternative Forms of Accomplice Liability Under the Alien Tort Claims Act*, 38 N.Y.U. J. INT’L L. & POL. 39, 42 (2006) (asserting that *Filártiga* paved the way for contemporary human rights litigation by establishing that courts must interpret international law as it evolved and exists among the nations of the world today).

172. *Filártiga v. Pena-Irala*, 630 F.2d 876, 880–84 (2d Cir. 1980). Joseph notes, however, that some courts, rather than follow *Filártiga*, required that a breach of the “law of nations” be “definable, obligatory, and universally condemned.” JOSEPH, *supra* note 167, at 23 (quoting *Forti v. Suarez-Mason*, 672 F. Supp. 1531, 1539–40 (N.D. Cal. 1987), *superseded by statute*, Torture Victim Protection Act of 1991, Pub. L. No. 102-256, 106 Stat. 73, *as recognized in* *Papa v. U.S.*, 281 F.3d 1004 (9th Cir. 2002)). However, Joseph argues that this alternate standard is not derived from international law at all, but rather was created by U.S. jurisprudence as an attempt to “translate the test for identifying customary international law.” JOSEPH, *supra* note 167, at 24. Indeed, she posits that the universality requirement is actually in conflict with the standards of customary international law, which allow “persistent objectors” to an international standard not to, by means of their non-consent, be bound by it. *Id.* Customary international law, therefore, recognizes an inherently non-universal standard. *See id.* However, Joseph asserts that most courts interpreted the universality requirement in the spirit of the customary international law standard, requiring only that plaintiffs show a general recognition among states, rather than unanimity. *Id.*

Filártiga's political activities and beliefs.<sup>173</sup> Although he had commenced a criminal action in Paraguay, the political machinery there repressed the action.<sup>174</sup> Upon learning that the defendant was living in the U.S., Mr. Filártiga filed suit in federal court under the ATCA.<sup>175</sup> In applying the "law of nations" prong of the ATCA, the court sought to define customary international law and looked to the United Nations Charter to determine that the way a government treats its own citizens "is a matter of international concern."<sup>176</sup> It found that customary international law was "evidenced and defined" in the Universal Declaration of Human Rights,<sup>177</sup> the Declaration on the Protection of All Persons from Being Subjected to Torture and Other Cruel, Inhumane or Degrading Treatment or Punishment,<sup>178</sup> and modern international legal standards.<sup>179</sup>

The ATCA issue addressed in *Filártiga*—the meaning of the "law of nations"—has now been the subject of much controversy, as plaintiffs have alleged a wide range of harms to personal welfare.<sup>180</sup> Twenty-four years later, in *Sosa v. Alvarez-Machain*, the Supreme Court of the United States issued its sole decision addressing the meaning of the "law of nations" under the ATCA.<sup>181</sup> In *Sosa*, the Court considered the claims of a Mexican national, Humberto Alvarez-Machain. Alvarez-Machain alleged that the U.S. Drug Enforcement Agency conspired to hire Mexican operatives to capture and transport him to the United States for the purpose of his arrest and detention, in violation of clear international law against arbitrary arrest and detention.<sup>182</sup> Although

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173. *Filártiga*, 630 F.2d at 878. Mr. Filártiga was joined by his daughter as a co-plaintiff. *Id.* His daughter allegedly was confronted by the defendant with the tortured body of her brother as a threat against any further political dissidence. *Id.*

174. *Id.* at 878.

175. *Id.* at 879. The Filártigas had applied for political asylum; the defendant overstayed a visitor's visa and was subject to deportation, which was stayed briefly as a result of this suit, but which was eventually realized. *Id.* at 879–80.

176. *Id.* at 881. The United Nations Charter is a treaty of the United States. U.N. Charter art. 55–56, available at <http://www.un.org/aboutun/charter/>.

177. *Filártiga*, 630 F.2d at 882; see Universal Declaration of Human Rights, G.A. Res. 217 A (III), at 71, U.N. Doc. A/810 at 71 (Dec. 10, 1948) [hereinafter UDHR].

178. *Filártiga*, 630 F.2d at 882–83; see Declaration on the Protection of All Persons from being Subjected to Torture and Other Cruel, Inhumane or Degrading Treatment or Punishment, G.A. Res. 3452, at 91, 30 U.N. GAOR Supp. No. 34, U.N. Doc. A/1034 (Dec. 9, 1975) [hereinafter Torture Convention].

179. *Filártiga*, 630 F.2d at 883.

180. See Dhooge, *supra* note 163, at 401–02 (asserting that personal welfare human right claims have been advanced in several cases).

181. See *Sosa v. Alvarez-Machain*, 542 U.S. 692 (2004).

182. *Id.* at 698. The apparent reason for the capture of Alvarez-Machain in this fashion was the inability of the U.S. and Mexico to successfully negotiate getting him into the United States.

Alvarez-Machain brought claims against a host of defendants, his claim against Sosa, one of the Mexican nationals who kidnapped Alvarez-Machain, was entirely based on the ATCA.<sup>183</sup>

In addressing the ATCA claim, the Court determined that the statute was meant to “enable[] federal courts to hear claims in a very limited category defined by the law of nations and recognized at common law.”<sup>184</sup> After an extensive examination of the history of the statute, the absence of legislative history behind this portion of the Judiciary Act prompted the Court to declare that “it is fair to say that a consensus understanding of what Congress intended has proven elusive.”<sup>185</sup> Based on the limited interpretive aides available, the Court concluded that “courts should require any claim based on the present-day law of nations to 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 we have recognized.”<sup>186</sup>

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*Id.* The U.S. had a warrant for Alvarez-Machain’s arrest, based on his alleged involvement in the capture, torture, and murder of a DEA operative in Mexico. *Id.* at 697–98.

183. *Id.* at 698. Alvarez-Machain had also contested the legitimacy of his indictment, but failed in having his case dismissed. *Id.* After trial, his motion for a judgment of acquittal was allowed at the close of the government’s case. *Id.*

184. *Id.* at 712. This statement was meant to answer a longstanding dispute. Prior to *Sosa*, there was a vigorous debate over whether the ATCA provided jurisdiction and international law supplied independent causes of action, or whether the cause of action existed within the ATCA itself, thus transforming it into more than merely jurisdictional in nature. See Beth Stephens, *Sosa v. Alvarez-Machain: “The Door is Still Ajar” for Human Rights Litigation in U.S. Courts*, 70 BROOK. L. REV. 533, 542 (2004). Some jurists and commentators went so far as to argue that the ATCA actually encompassed no existing causes of action, and that in order for it to take effect, further congressional action would be needed. See *id.* at 541 & n.41. Indeed, Sosa argued the latter point, urging the court to find that “ATS was stillborn because there could be no claim for relief without a further statute expressly authorizing adoption of causes of action.” *Sosa*, 542 U.S. at 714. Rather than adopting such a position, the Court held that torts in violation of the laws of nations as causes of action that fell within the common law at the time the statute was enacted were meant to be actionable under the statute. *Id.* It can therefore be said that, although the ATCA does not create independent rights of action not otherwise available, it does provide jurisdiction over rights of action already available under customary international law, because such law has been incorporated into federal common law. See Stephens, *supra*, at 546. Justice Scalia’s dissent, joined by Justices Rehnquist and Thomas, faulted the majority for allowing claims under federal common law in light of the holding in *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938), that there is no general federal common law. See *Sosa*, 542 U.S. at 741, 744 (Scalia, J., dissenting).

185. *Sosa*, 542 U.S. at 718–19.

186. *Id.* at 725. Stephens notes that this approach “mirrors” the standards that had been employed by lower courts and that *Sosa* in fact cites lower court cases with approval, recognizing that its decision is in harmony with many prior decisions, particularly *Filártiga*. Stephens, *supra* note 184, at 551 n.89. Indeed, post-*Sosa* cases continue to positively cite *Filártiga* and other decisions that interpreted the law of nations clause of the ATCA prior to any Supreme Court ruling on point. See, e.g., *Vietnam Ass’n for Victims of Agent Orange v. Dow Chem. Co.*, 517 F.3d 104, 116 (2d Cir. 2008), *aff’g* 373 F. Supp. 2d 7 (E.D.N.Y. 2005) (citing *Filártiga* and



This is, therefore, the tough standard—encompassing requirements both for wide international acceptance and well-defined specificity—that PWA plaintiffs must meet to claim a violation of their rights under the ATCA.<sup>187</sup> Nonetheless, one commentator suggests that “the decision is a clear victory for those human rights advocates who view the statute as a means to hold the most egregious perpetrators accountable for the most egregious violations of international law.”<sup>188</sup> This is especially true because the Court articulated a standard for determining which torts the ATCA remedies that is not limited to those torts that would have been recognized at the time the ATCA was passed.<sup>189</sup>

Despite the fact that the Court in *Sosa* left open the possibility of successful suits under the “law of nations” clause of the ATCA, the Court rejected Alvarez-Machain’s particular claim because a ban on “arbitrary detention” that lasted only one day was “so broad [it could not have] the status of a binding customary norm today.”<sup>190</sup> Although this narrow holding does not bear directly on the question of whether

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Flores v. S. Peru, Copper Corp., 414 F.3d 233 (2d Cir. 2003) for the purpose of articulating the sources of customary international law).

187. See *De Los Santos Mora v. New York*, 524 F.3d 183, 208 (2d Cir. 2008) (“To provide a cause of action under the ATS, a customary international law tort must meet a ‘high bar’ for recognizing new causes of action: it must be both specific and well-accepted.” (citing *Sosa v. Alvarez-Machain*, 542 U.S. 692, 725 (2004))); see also Stephens, *supra* note 184, at 551 & n.89 (“The Court presented this standard—definite content and widespread acceptance—as a stringent test intended to prevent litigation of claims for lesser, more parochial, or idiosyncratic prohibitions,” and noting that this approach “mirrors that applied by most of the lower courts considering ATS claims before *Sosa*.”). This standard was set to be a very difficult one to meet for a variety of reasons explained by the Court. See *Sosa*, 542 U.S. at 725. The Court urged “judicial caution” as a result of the shift in attitudes about the common law (being man-created rather than naturally occurring), the limited nature of federal common law as reflected by the watershed *Erie* decision, and the preference for legislatively created private rights of action rather than implied rights of action. *Id.* at 725–27. Moreover, the Court expressed concerns over the implications for foreign relations and the lack of clarity over the courts’ role in such cases. *Id.* at 727–28.

188. Stephens, *supra* note 184, at 535. In one post-*Sosa* decision, the Sixth Circuit proclaimed that ATCA “holds great potential to bring justice to certain serious violations of human, civil, and environmental rights in a federal forum.” *Tavaras v. Taveraz*, 477 F.3d 767, 771 (6th Cir. 2007). Indeed, some plaintiffs’ claims have already survived the *Sosa* standards. See, e.g., *Mohammed v. Mohammed Vital Bin Tarraf*, 114 F. App’x 417, 419 (2d Cir. 2004).

189. Stephens, *supra* note 184, at 550. In fact, the Court noted that at the time, only three causes of action would have been generally recognized under the law of nations, those being piracy, offenses against ambassadors, and violations of safe conducts. *Sosa*, 542 U.S. at 723–24.

190. *Sosa*, 542 U.S. at 736. The Court later clarified that the tort that Alvarez-Machain suffered did not rise to the level of specificity, i.e. was not sufficiently well-defined, to constitute a violation of customary international law. *Id.* at 738. In part, the Court was persuaded that so many claims would fall into the category of “arbitrary” arrest and detention as Alvarez-Machain defined it (which required only that it be in violation of the law of the jurisdiction in which the arrest and detention occurred) that “the implications would be breathtaking.” *Id.* at 736.

PWA plaintiffs could make out a cause of action under the ATCA, the sources of law the Court credited are instructive to future plaintiffs. First, the Court rejected the notion that the Universal Declaration of Human Rights (UDHR)<sup>191</sup> was persuasive authority, because although it provided “moral authority,” it is not a binding international agreement and therefore does not impose legal obligations.<sup>192</sup> More surprisingly, the Court also rejected the authority of the International Covenant on Civil and Political Rights<sup>193</sup> even though it is a treaty with many signatories, including the United States, and is thus binding international law. The Court reasoned that the United States signed it with the “express understanding that it was not self-executing and therefore did not itself create obligations enforceable in federal courts.”<sup>194</sup>

However, the Court did positively reference the Restatement (Third) of Foreign Relations Law of the United States (hereinafter “Restatement”),<sup>195</sup> which declares that a state policy of “prolonged” arbitrary detention is a violation of customary international law.<sup>196</sup> In part because Alvarez-Machain’s claim was not of a “state policy” or “prolonged” detention, the Court found that there was no alleged

191. UDHR, *supra* note 177. The UDHR, adopted in 1948, was the first attempt to codify a set of human rights guarantees. *See id.*; *see also* JEANNE M. WOODS & HOPE LEWIS, HUMAN RIGHTS AND THE GLOBAL MARKETPLACE: ECONOMIC, SOCIAL AND CULTURAL DIMENSIONS 179 (2005). Although it was “not intended to have the legally binding effect of a multi-lateral treaty,” at least some of its provisions have been incorporated, in practice, into customary international law. WOODS & LEWIS, *supra*, at 179. The UDHR is also the first of three U.N. documents which, collectively, are known as the “International Bill of Rights.” *Id.*

192. *See Sosa*, 542 U.S. at 734.

193. International Covenant on Civil and Political Rights, G.A. Res. 2200A (XXI), ¶ 21, U.N. GAOR Supp. No. 16, U.N. Doc. A/6316 (Mar. 23, 1976), available at [http://www.unhchr.ch/html/menu3/b/a\\_ccpr.htm](http://www.unhchr.ch/html/menu3/b/a_ccpr.htm) [hereinafter ICCPR]. Article 9 of the ICCPR, to which Alvarez-Machain pointed in support of his claim, declares that “no one shall be subjected to arbitrary arrest or detention,” and provides further elaboration of what that right should entail. *Id.* at art. 9. There are 152 states-parties to the ICCPR. *See* U.N. Office of the High Commissioner for Human Rights, Status of Ratifications, <http://www.unhchr.ch/pdf/report.pdf> (last visited Nov. 23, 2008).

194. *Sosa v. Alvarez-Machain*, 542 U.S. 692, 735 (2004). The United States officially declared, upon becoming a party to the ICCPR, that the ICCPR was not “self-executing” and that the “Covenant shall be implemented by the Federal Government to the extent that it exercises legislative and judicial jurisdiction over the matters covered therein.” U.N. Office of the High Commissioner for Human Rights, Declarations and Reservations to the ICCPR, [http://www.unhchr.ch/html/menu3/b/treaty5\\_asp.htm](http://www.unhchr.ch/html/menu3/b/treaty5_asp.htm) (last visited Nov. 23, 2008).

195. RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES (1986); *see Sosa*, 542 U.S. at 737 (“Alvarez’s failure to marshal support for his proposed rule is underscored by the Restatement . . .”).

196. RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 702 (1986); *Sosa*, 542 U.S. at 737.

violation of a customary international law.<sup>197</sup> According to the Court: “[i]t is enough to hold that a single illegal detention of less than a day, followed by the transfer of custody to lawful authorities and a prompt arraignment, violates no norm of customary international law so well defined as to support the creation of a federal remedy.”<sup>198</sup>

Based on the *Sosa* Court’s middle ground approach to the ATCA, PWA plaintiffs could allege a violation of a variety of different recognized human rights.<sup>199</sup> The most plausible claims are violations of the rights to health and life found in numerous statements of international law.<sup>200</sup> Admittedly, “[c]onsiderable disagreement exists as to whether ‘health’ is an identifiable, operational, and enforceable right, or whether it is merely aspirational and rhetorical.”<sup>201</sup> Indeed, lower courts’ interpretations of the ATCA are consistent with the view that the right to “health” or “life” does not meet the “specificity” requirement of the ATCA.<sup>202</sup> For instance, in one case, plaintiffs bringing an ATCA claim asserted *inter alia* that the corporate defendant had violated their rights to life and health by constructing an extremely dangerous and environmentally damaging mine with the assistance of the national government.<sup>203</sup> The district court held that the rights to health and life

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197. *Sosa*, 542 U.S. at 737.

198. *Id.* at 738.

199. Depending on the circumstances of the PWA plaintiffs in a given case, violations of the rights of women or children may occur, or violations of the prohibitions on torture or genocide may occur. In the generalized circumstances discussed in this Article, concerning drug-company lawsuits such as the one in South Africa, these rights are much harder to implicate. One remaining possibility, however, lies in the right to be free from discrimination on the basis of race or national origin, which is protected in many international documents, most specifically articulated under the Convention on the Elimination of All Forms of Racial Discrimination. *See* International Convention on the Elimination of All Forms of Racial Discrimination, G.A. Res. 2106 (XX), at 45, U.N. Doc. A/6014 (Jan. 4, 1969) [hereinafter ICERD]. Although this Article will not address in detail a potential claim based upon racial discrimination, it certainly could be argued that the factual basis for a racial discrimination claim in the context of pharmaceutical access for PWAs in Africa exists. Moreover, pervasive or systematic racial discrimination can arguably form the basis for an ATCA claim. *See* RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 702(f) (1986); *Khulumani v. Barclay Nat’l Bank Ltd.*, 504 F.3d 254, 260–61 (2d Cir. 2007), *aff’d*, 128 S. Ct. 2424 (2008) (reversing the dismissal of an ATCA claim that arose out of South Africa’s apartheid system, which alleged, *inter alia*, violations of the right to be free from racial discrimination); *see also* *Sarei v. Rio Tinto, PLC*, 487 F.3d 1193, 1209 (9th Cir. 2007) (“Acts of racial discrimination are violations of jus cogens norms.”), *reh’g granted en banc*, 499 F.3d 923 (9th Cir. 2007).

200. *See* Dhooge, *supra* note 163, at 432, 435 (discussing the various instruments that recognize the rights to health and life).

201. GOSTIN, *supra* note 34, at 82.

202. *See* JOSEPH, *supra* note 167, at 27 (explaining that U.S. courts have found that the rights to life and health do not activate the ATCA because they are not breaches of the law of nations).

203. *Sarei v. Rio Tinto PLC*, 221 F. Supp. 2d 1116, 1127 (C.D. Cal. 2002) (*Rio Tinto I*), *rev’d in part on other grounds*, 456 F.3d 1069, 1077 (9th Cir. 2006) (*Rio Tinto II*) (noting that neither

in this context were not specifically defined as required for an ATCA claim.<sup>204</sup> Similarly, the Second Circuit, considering the claims of the residents of a Peruvian town where the defendant's mining endeavors claimed many lives, concluded that the rights to health and life were "insufficiently definite to constitute rules of customary international law," and declared that the rights were "vague and amorphous."<sup>205</sup> Finally, one court, nudging the door open slightly for such claims, declared that these rights were "not yet definite enough,"<sup>206</sup> presumably allowing other plaintiffs the opportunity to allege facts that shape the standards into better-defined human rights.

In spite of courts' past unwillingness to allow ATCA claims to proceed based on allegations that plaintiffs' rights to life and health have been violated, PWA plaintiffs in the circumstances discussed here are in a unique position to cure the specificity problem. They would not, for instance, be able to overcome the hurdle if they simply alleged that a government failed to make sufficient efforts to provide medicines; "sufficient" is certainly in the eye of the beholder.<sup>207</sup> The problem of specificity arises where it is unclear what a government's "best efforts" would be. However, if the government already took actions to ensure access to medications, it necessarily demonstrated that those actions were possible. In this way, although failure to make any specific effort may not be actionable under the ATCA,<sup>208</sup> affirmative steps taken by pharmaceutical companies to impede or negate governments' efforts to

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party appealed this holding), *withdrawn and superseded on reh'g in part*, *Sarei v. Rio Tinto, PLC*, 487 F.3d 1193 (9th Cir. 2007) (Rio Tinto III), *reh'g en banc granted*, 499 F.3d 923 (9th Cir. 2007), *reh'g en banc*, 550 F.3d 822 (9th Cir. 2008).

204. *Rio Tinto I*, 221 F. Supp. 2d at 1158 ("[T]he court cannot conclude that the rights are sufficiently 'specific' that their alleged violation states a claim under the ATCA.")

205. *Flores v. S. Peru Copper Corp.*, 414 F.3d 233, 254 (2d Cir. 2003). In support of this notion, the court cites, among others, the UDHR, which states that "[e]veryone has a right to a standard of living adequate for the health and well-being of himself and his family," and the International Covenant on Economic, Social and Cultural Rights, which "recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." *Id.*; see UDHR, *supra* note 177, at 71; see also International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), at art. 12, U.N. GAOR, Supp. No. 16, U.N. Doc A/6316 (Jan 3, 1976) [hereinafter ICESCR]. Cf. *Kiobel v. Royal Dutch Petroleum Co.*, 456 F. Supp. 2d 457, 467 (S.D.N.Y. 2006) (dismissing a claimed violation of the right to life).

206. *Bowoto v. Chevron Corp.*, 557 F. Supp. 2d 1080, 1095 (N.D. Cal. 2008).

207. See generally U.N. Comm. on Econ., Soc. & Cultural Rights [CESCR], Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights, General Comment No. 14, ¶ 9 (2000), available at [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En).

208. See, e.g., *Rio Tinto I*, 221 F. Supp. 2d at 1157 (finding that the right to health is not sufficiently specific and definable).

meet their obligations that were *already made and therefore readily definable*, violates a highly specific right.

For instance, a claim arising in the context of the pharmaceutical companies' lawsuit against the South African government, which passed a law specifically to lower the cost of life-saving medications, presents a type of cure to the specificity problem. Each of the instruments defining the right to health generally, and the right to AIDS medication specifically, define the right as the right to have the government make continual efforts to progressively realize those goals.<sup>209</sup> Therefore, PWA plaintiffs in South Africa may allege that the government's amendment to the Medicines Act to allow parallel importation establishes that parallel importation is an effort that is possible, and the pharmaceutical companies' retaliation against that effort, which effectively impeded its implementation, violated their rights to the government's "best" efforts.

Thus, PWA plaintiffs should be able to cure the problem—specificity—that has plagued other plaintiffs alleging violations of the ATCA based on internationally-recognized rights to health and life. Notably, courts have only dismissed such claims based on the failure of those rights to be specific and definite, not on the basis of non-agreement among the international community.<sup>210</sup> Indeed, PWA plaintiffs can demonstrate the well-accepted nature of these rights, in addition to specificity, to state a cognizable claim.<sup>211</sup>

In light of *Sosa*, the Restatement is a persuasive place to start an analysis of whether a claim implicates a right that is sufficiently well-accepted as to constitute a part of customary international law.<sup>212</sup> Section 702 of the Restatement, entitled "Customary International Law of Human Rights," asserts that a state violates international law if,

[A]s a matter of state policy, it practices, encourages, or condones (a) genocide, (b) slavery or slave trade, (c) the murder or causing the disappearance of individuals, (d) torture or other cruel, inhuman, or degrading treatment or punishment, (e) prolonged arbitrary detention, (f) systematic racial discrimination, or (g) a consistent pattern of gross violations of internationally recognized human rights.<sup>213</sup>

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209. See, e.g., ICESCR, *supra* note 205.

210. See *infra*.

211. See *supra* text accompanying notes 181–85 and note 184.

212. JOSEPH, *supra* note 167, at 25–26 ("One of the most authoritative (and perhaps more conservative) lists of customary human rights for the purposes of findings in U.S. Courts is in the Restatement (Third) of the Foreign Relations Law of the United States § 702.")

213. RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 702 (1986)

The most promising avenue for PWAs under the Restatement is section 702(g), where violations of otherwise unspecified rights, when occurring *en masse*, are said to constitute violations of customary international law.<sup>214</sup> The comment to section 702(g) explains that a violation is “gross” when it “is particularly shocking because of the importance of the right or the gravity of the violation.”<sup>215</sup> Although the right to health or life is not specifically mentioned in this comment, the UDHR and the International Covenant on Civil and Political Rights (ICCPR) are both affirmed as bases for finding aggregate violations of rights protected by customary international law under section 702(g).<sup>216</sup>

The right to life appears prominently in the UDHR, the very first international instrument defining human rights, adopted in 1948.<sup>217</sup> Article Three of the UDHR states that “[e]veryone has the right to life, liberty and the security of person.”<sup>218</sup> Article Twenty-Five, while not specifically enumerating health as a right in and of itself, does state that everyone “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>219</sup> Similarly, the ICCPR declares that “[e]very human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.”<sup>220</sup>

The right to health does not appear in the ICCPR, but does appear prominently in the International Covenant on Economic, Social and Cultural Rights (ICESCR), which states that the “States parties to the present Covenant recognize the right of everyone to the enjoyment of

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214. *Id.* § 702(g); see JOSEPH, *supra* note 167, at 25–26 (“Consistent patterns of gross violations of internationally recognised rights is an avenue for holding perpetrators of multiple or at least mass abuses liable even when the individual abuses fall short of customary human rights violations.”).

215. RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 702, cmt. (m) (1986). The severity of the AIDS pandemic and the nature of the crisis, discussed *supra*, Part II, go to the heart of this comment.

216. See *id.* Specifically mentioned rights under this section include: “systematic harassment; invasions of the privacy of the home; arbitrary arrest and detention (even if not prolonged); denial of fair trial in criminal cases; grossly disproportionate punishment; denial of freedom to leave a country; denial of the right to return to one’s country; mass uprooting of a country’s population; denial of freedom of conscience and religion; denial of personality before the law; denial of basic privacy such as the right to marry and raise a family; and invidious racial or religious discrimination.” *Id.*

217. UDHR, *supra* note 177, art. 3.

218. *Id.*

219. *Id.* at art. 25.

220. ICCPR, *supra* note 193, art. 6.

the highest attainable standard of physical and mental health.”<sup>221</sup> The provision continues to state that governments shall take steps “to achieve the full realization of this right” including “the prevention, treatment and control of epidemic, endemic, occupational and other disease.”<sup>222</sup> Overall, the right to life is enumerated in ten different international legal instruments, while the right to health appears in eight.<sup>223</sup>

In 2000, the U.N. Committee on Economic, Social and Cultural Rights (CESCR) issued a comment to the ICESCR addressing the meaning of the right to the “highest attainable standard” of health.<sup>224</sup> The CESCR notes that the right to health has been recognized by several other prominent international human rights instruments, including the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Elimination of All Forms of Discrimination Against Women, the Convention on the Rights of the Child, and numerous regional instruments.<sup>225</sup> Furthermore, the comment to the ICESCR recognizes that the right to the highest attainable standard of health necessarily takes into account a state’s available resources.<sup>226</sup> The obligations of a state, however, include providing facilities, goods, and services depending necessarily on the state’s developmental level, but including essential drugs.<sup>227</sup>

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221. ICESCR, *supra* note 205, art. 12. The United States is not a party to the ICESCR.

222. *Id.*

223. Dhooge, *supra* note 163, at 432, 435.

224. U.N. Econ. & Soc. Council [ECOSOC], Gen. Comment 14, *The Right to the Highest Attainable Standard of Health*, U.N. Doc. E/C. 12/2000/4 (Nov. 8, 2000) [hereinafter Comment 14]. The ECOSOC is a body of independent experts that monitors the implementation of the ICESCR by receiving reports from States parties, holds working groups, and publishes interpretations of the provisions of the Covenant. U.N. Committee on Economic, Social, and Cultural Rights [CESCR], <http://www.ohchr.org/english/bodies/cescr/index.htm> (last visited April 29, 2007).

225. Comment 14, *supra* note 224, ¶ 2; *see also* ICERD, *supra* note 199; Convention on the Elimination of all Forms of Discrimination against Women, Dec. 18, 1979, 1249 U.N.T.S. 513; Convention on the Rights of the Child, Nov. 20, 1989, 1577 U.N.T.S. 3.

226. Comment 14, *supra* note 224, ¶ 9 (“The notion of ‘the highest attainable standard of health’ in article 12.1 takes into account both the individual’s biological and socio-economic preconditions and a State’s available resources. There are a number of aspects which cannot be addressed solely within the relationship between States and individuals; in particular, good health cannot be ensured by a State, nor can States provide protection against every possible cause of human ill health. Thus, genetic factors, individual susceptibility to ill health and the adoption of unhealthy or risky lifestyles may play an important role with respect to an individual’s health. Consequently, the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health.”).

227. *Id.* ¶ 12(a) (“*Availability*. Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party.

Furthermore, the “progressive realization of the right to health over a period of time . . . 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,” which ensures the “right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>228</sup> Similarly, the Covenant presumptively bans “retrogression” in relation to the right to health.<sup>229</sup>

International authority has also spoken specifically on obligations relating to the AIDS pandemic. As far back as 1978, the United Nations recognized the need for international action regarding HIV/AIDS.<sup>230</sup> In 2002, the United Nations Office of the High Commissioner for Human Rights and UNAIDS jointly issued HIV/AIDS and Human Rights International Guidelines.<sup>231</sup> These guidelines clarify that states should “enact legislation to provide for . . . safe and effective medication at an affordable price.”<sup>232</sup> The premise of these guidelines was that “access to HIV/AIDS-related treatment is fundamental to realizing the right to health.”<sup>233</sup> Thus, through these international statements, PWA plaintiffs can argue that they have a right, protected by customary international law, to their government’s best efforts to provide life-saving AIDS medication.

PWA plaintiffs can therefore demonstrate both the well-accepted and specific nature of the rights to health and life. In this way, a company should be liable under the ATCA when it engages in conduct which it knows or should know will disrupt a government’s legitimate efforts to protect citizens’ rights and to fulfill its obligations under international law.

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The precise nature of the facilities, goods and services will vary depending on numerous factors, including the State party’s developmental level. They will include, however, the underlying determinants of health, such as safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical and professional personnel receiving domestically competitive salaries, and essential drugs, as defined by the WHO Action Programme on Essential Drugs.”).

228. *Id.* ¶ 31; see ICESCR, *supra* note 205, at art. 12.

229. Comment 14, *supra* note 224, ¶ 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.”).

230. GOSTIN, *supra* note 34, at 78.

231. HIV/AIDS and Human Rights International Guidelines, U.N. Doc. UNAIDS/02.49E (Aug. 2002), available at <http://www.ohchr.org/english/about/publications/docs/g6.pdf>.

232. *Id.* at Guideline 6.

233. *Id.* at Guideline 11.



### B. State Action

Customary international law typically governs only the conduct of governments, not private actors.<sup>234</sup> However, some norms do apply equally to private citizens and corporations,<sup>235</sup> and it is unclear under what secondary liability theories state action must be demonstrated.<sup>236</sup> The state action issue presents a second challenge to PWA plaintiffs.<sup>237</sup> In order to state a claim under the ATCA, they will need to show that a pharmaceutical company either violated one of the norms that does not require state action, that the company is liable under a secondary liability theory, or that the company itself constitutes a state actor in the circumstances of the case.

The first possible avenue for any plaintiff alleging a violation of ATCA is to assert that the defendant has violated one of the small group of customary international laws which apply equally to private citizens and to state actors.<sup>238</sup> This principle, as applied to the ATCA, was first announced by the Second Circuit in *Kadic v. Karadzic*. In that case, victims of atrocities committed by Bosnian-Serb military forces during the Bosnian civil war sued the leader of the self-proclaimed Bosnian-Serb republic, not internationally recognized, located within Bosnia-Herzegovina.<sup>239</sup> In *Kadic*, the Second Circuit concluded that “certain forms of conduct violate the law of nations whether undertaken by those acting under the auspices of a state or only as private individuals.”<sup>240</sup> In so deciding, the court looked to section 404 of the Restatement, addressing Universal Jurisdiction to Define and Punish Certain Offenses, which proclaims that

[a] state has jurisdiction to define and prescribe punishment for certain offenses recognized by the community of nations as of universal concern, such as piracy, slave trade, attacks on or hijacking of aircraft,

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234. JOSEPH, *supra* note 167, at 48. See generally Laura A. Dickinson, *Public Law Values in a Privatized World*, 31 YALE J. INT'L L. 383 (2006).

235. See *Kadic v. Karadzic*, 70 F.3d 232, 236–37 (2d Cir. 1995).

236. See *Bowoto v. Chevron Corp.*, No. C99-02506, 2006 U.S. Dist. LEXIS 63209, at \*36 & n.14. (N.D. Cal. Aug. 21, 2006).

237. See, e.g., *Carmichael v. United Techs. Corp.*, 835 F.2d 109, 114 (5th Cir. 1988) (dismissing a suit brought against a corporation for torture committed abroad because of lack of jurisdiction under ATCA where there was no evidence that the corporation “conspire[d] in, or aid[ed] and abet[ted], official acts of torture”).

238. This is a subset of the totality of *jus cogens* norms, which describes international norms that a state itself cannot reject. See BLACK'S LAW DICTIONARY 876 (8th ed. 1999) (defining *jus cogens* as “[a] mandatory or peremptory norm of general international law accepted and recognized by the international community as a norm from which no derogation is permitted. A peremptory norm can be modified only by a later norm that has the same character.”).

239. *Kadic*, 70 F.3d at 236–37.

240. *Id.* at 239.

genocide, war crimes, and perhaps certain acts of terrorism, even where [no other basis of jurisdiction] is present.<sup>241</sup>

The court concluded that the ATCA supported liability for private actors who commit offenses of “universal concern.”<sup>242</sup>

Due to the very limited number of offenses of “universal concern,” listed in the Restatement, it would be difficult for PWA plaintiffs alleging a violation of the rights to health and life to assert that those rights fell within this list, or analogized to a right contained therein. As this Article limited its discussion to potential claims of violations of the rights to health and life, the “universal concern” doctrine under the ATCA would likely be of little help.<sup>243</sup> Moreover, even though the norms of universal concern are not strictly limited by the Restatement, courts look to the definitions of the rights at issue as enumerated in international instruments to see if state action is required when broadening the basis for such violations.<sup>244</sup> The rights to life and health are defined as the rights to the governments’ best efforts, discussed above.<sup>245</sup> Because the definitions of the rights themselves encompass state action, it is unconvincing to argue under current ATCA jurisprudence that these rights should be added to the list of norms of universal concern.

However, the second possible avenue—claims against corporations under a secondary liability doctrine—has great potential. In 1997, for the first time, a district court in California held that a corporation could be held liable for human rights abuses committed abroad under the ATCA using a secondary liability theory, namely aiding and abetting.<sup>246</sup>

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241. *Id.* at 240 n.4; RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 404 (1986)

242. *Kadic*, 70 F.3d at 240.

243. If, however, PWA plaintiffs could garner facts sufficient to support a claim of genocide (certainly possible given the magnitude of fatalities at issue), the “universal concern” theory of liability for private actors would be eminently applicable. *See supra* note 199 and accompanying text. It is important to note that because the facts are such that the pharmaceutical companies are not directly withholding medicines or directly violating PWAs rights to health and life, even if a violation of “universal concern” is alleged, a secondary theory of liability would still need to be viable. Thus, the PWAs would still need to demonstrate that by filing the lawsuit, the pharmaceutical companies were aiding and abetting the state’s violation of its own citizen’s human rights. The details of this theory of liability are discussed *infra*.

244. *See generally Kadic*, 70 F.3d at 241–44 (discussing all of the various international instruments defining genocide, war crimes, torture, and summary execution when determining if each norm required state action or applied generally to all actors).

245. *See supra* Part III.A.

246. Maassarani, *supra* note 171, at 40; *see also* *Doe v. Unocal Corp.*, 963 F. Supp. 880 (C.D. Cal. 1997) (Unocal I), *aff’d*, 395 F.3d 932 (9th Cir. 2002) (Unocal II), *reh’g en banc ordered*, 395 F.3d 978 (9th Cir. 2003). The case settled before the rehearing en banc on the merits. Consequently, the 2002 three-judge panel decision by the Ninth Circuit still stands.

In that case, *Doe v. Unocal*, farmers in Burma brought a class action suit against a California-based oil company alleging forced relocation, forced labor, seized property, torture, rape, assault, and murder of residents in a region where the company had built an oil pipeline.<sup>247</sup> The plaintiffs alleged that the defendant corporation had used the controlling military power in the region to force the relocation of whole villages to further the pipeline project.<sup>248</sup>

In affirming the district court's decision, the Ninth Circuit, relying on *Kadic*, allowed claims of violations of norms of universal concern<sup>249</sup> to go forward on the theory that Unocal could be held liable for aiding and abetting the Burmese military's imposition of forced labor on the plaintiffs.<sup>250</sup> Although *Unocal* applied aiding and abetting liability only to violations of norms of universal concern,<sup>251</sup> some subsequent decisions have applied aiding and abetting liability to corporate or private actors even where state action would otherwise be required. In *Aldana v. Fresh Del Monte Produce*, a post-*Sosa* case, the Eleventh Circuit declared that a claim alleging torture under the ATCA "reaches conspiracies and accomplice liability."<sup>252</sup> Moreover, the *Aldana* court allowed claims to move forward against private security forces for their participation in torture under a secondary liability theory, so long as the government's role itself constituted state action.<sup>253</sup>

Similarly, in *Mujica v. Occidental Petroleum*, a district court in California considered claims of torture and extrajudicial killing by the Columbian military both for the benefit and with the help of the defendant corporation.<sup>254</sup> Although the ATCA was not squarely at issue in that case, the court analogized to it, noting that the ATCA would permit aiding and abetting liability for a corporation in this circumstance.<sup>255</sup> Because torture is a violation of the law of nations

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247. *Unocal I*, 963 F. Supp. at 883.

248. *Id.*

249. The court also reasoned, based on *Kadic*, that "even crimes like rape, torture, and summary execution, which by themselves require state action for ATCA liability to attach, do not require state action when committed in furtherance of other crimes like slave trading, genocide or war crimes, which by themselves do not require state action for ATCA liability to attach." *Unocal II*, 395 F.3d at 946.

250. *Id.* at 947.

251. *Id.* (finding that "Unocal may be liable under the ATCA for aiding and abetting the Myanmar Military in subjecting Plaintiffs to forced labor," which they analogized to slavery, and thus did not require a showing of state action).

252. *Aldana v. Fresh Del Monte Produce, N.A., Inc.*, 416 F.3d 1242, 1248 (11th Cir. 2005) (quoting *Cabello v. Fernandez-Larios*, 402 F.3d 1148, 1157 (11th Cir. 2005)).

253. *Id.* at 1249-50.

254. *Mujica v. Occidental Petroleum Corp.*, 381 F. Supp. 2d 1164, 1168-69 (C.D. Cal. 2005).

255. *Id.* at 1173 n.6.

only when committed by the state,<sup>256</sup> both decisions support the conclusion that corporations can be held liable for aiding and abetting the state's violations of customary international law that is not of "universal concern."

This conclusion is not without disagreement.<sup>257</sup> In one case, a district court objected that "[corporate d]efendants could not be held liable for directly committing the [non-universal concern] offenses; it therefore makes little sense to find them liable for lesser [aiding and abetting] conduct."<sup>258</sup> Nonetheless, PWA plaintiffs can argue that the *Aldana* court correctly determined that aiding and abetting liability can attach to private parties even where state action is required, so long as the private parties are aiding and abetting a state actor's commission of the violation.

In order for PWA plaintiffs to successfully make that argument, they therefore need to show that the actions of the pharmaceutical companies aided or abetted that violation under a standard similar to that enumerated in *Unocal*. In that case, the Ninth Circuit held that the corporate defendant could be held liable under the ATCA if it engaged in "knowing practical assistance or encouragement that has a substantial effect on the perpetration of the crime."<sup>259</sup> This standard is particularly noteworthy, insofar as it does not include a requirement that the corporation harbor the specific intention that the violation occur; rather, it only requires that the corporation knew or should reasonably have known that its conduct would lead to a violation of the law of nations.<sup>260</sup>

Although in *Unocal* the right that was violated was a negative right—that is, the right to be free from forced labor—and the right at issue in

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256. *Doe v. Unocal Corp.*, 395 F.3d 932, 954 (9th Cir. 2002) (*Unocal II*) ("[W]e adopted the Second Circuit's conclusion that 'acts of rape, torture, and summary execution,' like most crimes, 'are proscribed by international law only when committed by state officials or under color of law.'" (quoting *Kadic v. Karadzic*, 70 F.3d 232, 243–44 (2d Cir. 1995)).

257. It is possible to reconcile these decisions if one reads *Aldana*'s holding to require such an amount of "aiding and abetting" that private actions themselves can be considered under "color of law" as a result of those actions being taken together with the actions of state actors. See *Chavez v. Carranza*, 413 F. Supp. 2d 891, 899 (W.D. Tenn. 2005). However, *Aldana* does not explicitly so state, and other courts have noted the tension that *Aldana*'s holding has with the state action doctrine. See *Bowoto v. Chevron Corp.*, No. C99-02506, 2006 U.S. Dist. LEXIS 63209, at \*36 n.14 (N.D. Cal. Aug. 21, 2006).

258. *Bowoto*, 2006 U.S. Dist. LEXIS 63209, at \*33.

259. *Unocal II*, 395 F.3d at 947. The court also stated that it was "leaving the question whether such liability should also be imposed for moral support which has the required substantial effect for another day," although it noted in a footnote that there "may be no difference between encouragement and moral support." *Id.* at 951 & n.28.

260. *Id.* at 950, 953.

this case is a positive right—the right to have one’s government make best efforts to provide for the preservation of one’s health and life—the Ninth Circuit standard does not facially preclude liability. Just as Unocal allegedly took positive steps to *help* the Burmese government commit violations of the rights of Burmese citizens,<sup>261</sup> PWA plaintiffs can allege that the thirty-nine pharmaceutical companies who filed a lawsuit took positive steps to *prevent* the South African government from ensuring the South Africans’ human rights were fulfilled.<sup>262</sup> Indeed, how else could a company aid and abet the violation of a positive right, except to interfere with the government’s attempts to meet their obligations? Moreover, the pharmaceutical companies’ motivations for these actions are irrelevant, so long as they knew or should have known that the violation would occur.<sup>263</sup> An aiding and abetting theory of liability is likely the most potent way of holding pharmaceutical companies liable for PWAs deaths and health declines in these circumstances.<sup>264</sup>

Finally, if a court rejected an aiding and abetting theory for a non-state actor in circumstances where no norm of universal concern was implicated, PWA plaintiffs could take the third approach to satisfying the state action requirement: they could argue that the pharmaceutical companies are themselves acting under “color of law.”<sup>265</sup> State action under the ATCA is typically determined under the same analysis as claims brought under 42 U.S.C. § 1983.<sup>266</sup> Under section 1983, state

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261. *Id.* at 947.

262. *See supra* Part II.

263. *See Unocal II*, 395 F.3d at 947.

264. Finally, it is worth mentioning that, theoretically, there are other possible avenues of secondary liability for private actors. The Ninth Circuit in *Unocal II* acknowledged that other theories for corporate liability—including joint venture, agency, negligence, and recklessness—may be appropriate under ATCA. *Unocal II*, 395 F.3d at 947 n.20. Furthermore, in finding the defendant liable, the court specifically looked to international war crimes tribunals and other sources of international law to ascertain the relevant liability theories. *Id.* at 949. As the court explained, “[W]hat is a crime in one jurisdiction is often a tort in another jurisdiction, and this distinction is therefore of little help in ascertaining the standards of international human rights law.” *Id.* at 948. Tarek Maassarani further suggests that *Unocal* set the stage for possibly even more effective theories, including joint criminal enterprise, conspiracy, instigation, and procurement. *See generally* Maassarani, *supra* note 171.

265. *See, e.g.*, *Sarei v. Rio Tinto PLC*, 221 F. Supp. 2d 1116, 1154 (C.D. Cal. 2002) (Rio Tinto I) (finding the Rio Tinto mining company to have acted under “color of law” because of its various connections to the government of Papua New Guinea), *rev’d in part on other grounds*, 456 F.3d 1069, 1077 (9th Cir. 2006) (Rio Tinto II), *withdrawn and superseded on reh’g in part*, *Sarei v. Rio Tinto, PLC*, 487 F.3d 1193 (9th Cir. 2007) (Rio Tinto III), *reh’g en banc granted*, 499 F.3d 923 (9th Cir. 2007), *reh’g en banc*, 550 F.3d 822 (9th Cir. 2008).

266. *See Wiwa v. Royal Dutch Petroleum Co.*, No. 96 CIV. 8386, 2002 WL 319887, at \*13 (S.D.N.Y. 2002) (“To determine whether a private actor acts under color of law in the context of a claim under ATCA . . . the Court must look to the standards developed under 42 U.S.C. §

action (i.e. acting under “color of law”) can attach even when the action is taken by private parties in various circumstances. For instance, private parties can act under color of law if there is judicial enforcement of unlawful behavior.<sup>267</sup> Moreover, private parties’ actions may be taken “under color of law” where the private party is acting in a capacity that renders him indistinguishable from a state.<sup>268</sup> State regulation of the private party or tangential involvement will typically be insufficient.<sup>269</sup>

One ATCA scholar has argued that “a State’s failure to adequately control a corporation [could] amount[] to ‘state action’ in international law for the purposes of activating ATCA,” which, she notes, “would significantly lessen the burden in establishing the state action element of the ATCA test in any case where a [corporation] has itself perpetrated a breach of the law of nations.”<sup>270</sup> Indeed, this view has support in a recent Ninth Circuit decision, which allowed claims of racial discrimination to go forward against Rio Tinto, a mining company, even

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1983.”) (citing *Kadic v. Karadzic*, 70 F.3d 232, 242 (2d Cir. 1995)). Cf. *Doe v. Unocal Corp.*, 963 F. Supp. 880, 891 (C.D. Cal. 1997) (“[W]here there is a substantial degree of cooperative action between the state and private actors in effecting the deprivation of rights, state action is present.”). In its entirety, 42 U.S.C. § 1983 reads:

Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress, except that in any action brought against a judicial officer for an act or omission taken in such officer’s judicial capacity, injunctive relief shall not be granted unless a declaratory decree was violated or declaratory relief was unavailable. For the purposes of this section, any Act of Congress applicable exclusively to the District of Columbia shall be considered to be a statute of the District of Columbia.

42 U.S.C. § 1983 (2006).

267. *Shelley v. Kraemer*, 334 U.S. 1, 20 (1948) (holding that judicial enforcement of restrictive covenants on housing based on race renders private discrimination state action).

268. *Smith v. Allwright*, 321 U.S. 649, 663 (1944) (finding that the primary election of the Democratic party, though run by private actors, nonetheless constituted state action).

269. See *Moose Lodge No. 107 v. Irvis*, 407 U.S. 163, 175–76 (1972) (holding that regulation of the lodge’s liquor license did not render the lodge’s discrimination state action). Joseph analyzes the possible avenues for determining state action in accordance with § 1983 as including “public function, state compulsion, nexus, joint action, and proximate cause.” JOSEPH, *supra* note 167, at 33. Of these, “proximate cause” is the label Joseph uses to describe the type of liability that attaches when a corporation exercises “control over a State’s perpetration of the abuse.” *Id.* at 34. This is the category in which Joseph places cases such as *Doe v. Unocal*, where corporations fund (and indeed contract for) government functions. *Id.*

270. JOSEPH, *supra* note 167, at 39. Joseph notes that to her knowledge “such an argument has never been raised in an ATCA case.” *Id.* Moreover, she asserts that it is “uncertain the extent to which a duty [to control corporations within one’s territory] exists within customary international law.” *Id.*

though racial discrimination claims require state action.<sup>271</sup> There, the court affirmed a district court decision that Rio Tinto acted under “color of law” when the company, allegedly motivated by racial discrimination, destroyed the environment, sacred sites, and local culture.<sup>272</sup> The district court concluded that “[p]laintiffs assert, in essence, that [the government] made its governmental power of eminent domain available to Rio Tinto so that it could build the mine, and that, because of its profit participation in the mine, [the government] took no steps to control or minimize the negative impact of Rio Tinto’s mining operations.”<sup>273</sup> Thus, the court concluded, plaintiffs had sufficiently pled facts supporting a finding that Rio Tinto was acting under color of law.<sup>274</sup>

PWA plaintiffs could argue that the pharmaceutical companies were acting under color of law because the pharmaceutical companies, in essence, hijacked the judicial process, a state action, thus violating the plaintiffs’ rights. In this way, the lawsuit would constitute the pharmaceutical companies’ method of utilizing the power of the South African government to illegally keep prices and profits high at the cost of the health and lives of South African PWAs, and in violation of the rights of South Africans to have their government make all efforts to meet the needs of people living with HIV/AIDS. Moreover, the failure of the judiciary to immediately dismiss such an action so as to allow the timely implementation of the Medicines Act represents a failure to take steps to control the corporation within its boundaries. This theory may provide a sufficient basis, comparable to the theory in *Sarei v. Rio Tinto PLC*, to demonstrate that the pharmaceutical companies’ lawsuits, in conjunction with the actions taken by the judiciary to allow the suits to continue, constitute the necessary state action for ATCA purposes.

Whether by demonstrating that pharmaceutical companies were aiding and abetting the state’s violations of its people’s customary international law rights to life and health, or by demonstrating that the pharmaceutical companies sufficiently used the power of the government’s judiciary to themselves be acting under color of law, the

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271. *Sarei v. Rio Tinto PLC*, 456 F.3d 1069, 1074 (9th Cir. 2006) (Rio Tinto II), *withdrawn and superseded on reh’g in part*, *Sarei v. Rio Tinto, PLC*, 487 F.3d 1193 (9th Cir. 2007) (Rio Tinto III), *reh’g en banc granted*, 499 F.3d 923 (9th Cir. 2007), *reh’g en banc*, 550 F.3d 822 (9th Cir. 2008).

272. *Sarei v. Rio Tinto PLC*, 221 F. Supp. 2d 1116, 1151 (C.D. Cal. 2002) (Rio Tinto I), *rev’d in part on other grounds*, *Rio Tinto II*, 456 F.3d at 1077.

273. *Rio Tinto I*, 221 F. Supp. 2d at 1154.

274. *Id.* at 1155.

ATCA doctrine is sufficiently undeveloped and full of potential as to accommodate the claims of PWA plaintiffs.

#### IV. CONCLUSION

In the face of a catastrophic pandemic disproportionately affecting people of color in developing countries and continually depriving people of their health, their lives, and the health and lives of their children and families, haste is needed to take action.<sup>275</sup> Despite the fact that treatment exists for HIV/AIDS, the vast majority of people in need of such treatment do not receive it.<sup>276</sup> Meanwhile, the pharmaceutical companies that manufacture these drugs are engaged in a multifaceted campaign to keep the prices of this treatment out of the reach of most people who need it, while limiting the ability of governments to provide these medications to their populations.<sup>277</sup> Where the international community has recognized that governments have an obligation to make their best effort to meet the needs of people living with HIV/AIDS, including providing affordable medications, and where governments are making those best efforts, lawsuits designed to impede this lawful progress should be actionable conduct under the ATCA.<sup>278</sup>

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275. See generally *supra* Part I.

276. See generally *supra* Part I.

277. See generally *supra* Part II.B.

278. See generally *supra* Part III.



