

2003

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## Recommended Citation

James T. Gathii, *The Structural Power of Strong Pharmaceutical Patent Protection in U.S. Foreign Policy*, 7 J. Gender Race & Just. 267 (2003).

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# The Structural Power of Strong Pharmaceutical Patent Protection in U.S. Foreign Policy

*James Thuo Gathii\**

*While the Chief Justice's dissent says there are 'weapons [such as cartels or boycotts] in the arsenals of foreign nations' sufficient to enable them to counter anticompetitive conduct . . . such . . . political remed[ies are] hardly available to a foreign nation faced with the monopolistic control of the supply of medicines needed for the health and safety of its people.<sup>1</sup>*

## I. INTRODUCTION

There are two distinct, albeit mutually reinforcing, stances within U.S. foreign policy on HIV/AIDS. The first of these stances favors strong international pharmaceutical patent protection, unencumbered by any restrictions, as the best alternative to ensuring availability of drugs to *treat* those infected with HIV/AIDS.<sup>2</sup> Unlike the first stance that is

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\* Assistant Professor, Albany Law School. This paper was originally presented at the University of Iowa College of Law, for *The Journal of Gender, Race and Justice's* 7th Annual symposium titled: "American Presence Abroad: U.S. Foreign Policy and Its Implications for Gender, Race and Justice," October 25th and 26th, 2002. I would like to thank my wife Muthoni and our sons Gathii and Mwangi for their unwavering love and support. I would also like to thank Robert Emery, Mary Wood and Linda Murray for their help. To Oko Akwei and Kohei Higo, thanks for your excellent research assistance and to the editors of this journal for all their marvelous help. I dedicate this article to Agnes Njoki Kirera.

1. *Pfizer Inc. v India*, 434 U.S. 308, 318 (1978) (Stewart, J.). In this case, the governments of India, Iran and the Philippines, among others, sought damages against Pfizer for engaging in price fixing, market division and fraud against the U.S. Patent Office with respect to a broad range of antibiotics. *Id.* at 310. The Court had to decide whether it could treat a sovereign nation the same way it did citizens under the Sherman Act. *Id.* at 312. The Court decided in the affirmative with Chief Justice Burger, Powell and Rehnquist dissenting. *Id.* at 308-31. Justice Stewart's epigram at the beginning of the article is a response to the following assertion by Chief Justice Burger on behalf of the dissenters:

[I]t takes little imagination to realize the dramatic and very real differences in terms of coercive economic power and political interests which distinguish our own States from foreign sovereigns. The international price fixing, boycotts, and other current anticompetitive practices undertaken by some Middle Eastern nations are illustrative of the weapons in the arsenals of foreign nations which no domestic State could ever employ. Nor do our domestic States, in any meaningful sense, have the conflicting economic interests or antagonistic ideologies which characterize and enliven the relations among nations . . . .

*Id.* at 327-28 (Berger, C.J., dissenting).

2. A patent right is the right of a person, who has made a patentable invention or discovery,

uncompromising in supporting patent protection, the second position is steeped in humanitarian gestures, such as extending U.S. assistance particularly in efforts to *prevent* the spread of HIV/AIDS outside the United States. Strong patent protection is, however, the primary U.S. foreign policy position on how best to facilitate access to essential medicines under patents held by U.S. and western pharmaceutical corporations. In that sense, provisions of humanitarian assistance ought to be understood as the policy prescription most compatible with the non-negotiability of strong pharmaceutical patent protection.

My basic thesis in this paper is that the humanitarianism underlying U.S. assistance, particularly in preventing the spread of the HIV/AIDS pandemic around the world, plays a significant role in simultaneously disguising and legitimating the uncompromising support of the United States government for strong international pharmaceutical patent protection. Indeed, by loudly proclaiming its generosity, the United States manages to disguise the fact that its commitment to a strong regime of pharmaceutical patent protection has a lot to do with limiting access to antiretroviral drugs to large numbers of those infected with HIV/AIDS outside the United States.

In addition to distancing the relationship between strong pharmaceutical patent protection and access to essential drugs by highlighting the more appealing image of the United States as a major benefactor of the global campaign against HIV/AIDS, U.S. foreign policy on HIV/AIDS has turned to poverty in sub-Saharan Africa as a major explanatory factor to account for the extremely low level of access to antiretroviral drugs on patents to treat the disease. Increasing U.S. financial support to combat the spread of the pandemic, while simultaneously harping on the argument that Africans are too poor to afford antiretroviral drugs, plays particularly well to ward off criticism regarding the apparent harshness of U.S. support for strong patent protection.

Seen in this context, I argue that U.S. policy is moving in the direction of de-linking or discrediting any association between strong patent protection and access to antiretroviral drugs for HIV/AIDS infected populations outside the United States. Placing a high premium on humanitarianism as the primary policy response to the pandemic in turn contributes to the invisibility of the link between strong patent protection and access to essential drugs. It is, therefore, my argument that while the humanitarianism that typifies U.S. foreign policy on HIV/AIDS and other life threatening diseases is important, U.S. support for a strong patent regime imposes huge barriers of access to patented antiretrovirals. Specifically, the strong protection of patents in the WTO's Trade Related Aspects of International Property Rights Agreement,<sup>3</sup> (TRIPS or the treaty hereinafter),

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to exclude others from making, using or selling the patented invention for a limited period of time. See O-Baily Brown, *Compulsory Licensing: Why It's Proposed, Why Dangerous*, 195 J. of Com. & Com. 33 (1943). Strong patent protection means a conception of the patent system which confers an "unconditional right of exclusion," on the patentee. *Id.*

3. Agreement on Trade-Related Intellectual Property Rights, Apr. 15, 1994, 31 MARRAKESH

stands in the way of enabling the treaty to be construed to permit governments to override it with a view to providing antiretrovirals drugs to thousands of Africans infected with HIV/AIDS.<sup>4</sup>

To the extent that patents are therefore a barrier to access antiretrovirals, the TRIPS Agreement is no more than a form of structural power.<sup>5</sup> The United States, together with its coalition of western intellectual property exporting countries, exercises structural power because they prevailed in defining patent protection in the treaty in such a manner as to make antiretrovirals unaffordable and inaccessible to those that need them most.<sup>6</sup> The countries most afflicted by the HIV/AIDS pandemic do not have the wherewithal to undertake the research and development necessary to produce or even manufacture these much-needed drugs. In addition, these countries do not stand in the same position as the United States to be able to shape the international patent protection in a manner that enables them to facilitate affordable access to drugs produced elsewhere.<sup>7</sup> In particular, by defining patents exclusively in terms of the rights of patent holders while simultaneously limiting the obligations patent holders may have to consumers of patented products, as is the case in the U.S. domestic market, the TRIPS Agreement acts as a significant barrier limiting access to essential medicines under patent for countries that do not have the wherewithal to set the international intellectual property agenda like the United States.

Thus, by silencing alternative conceptions of intellectual property rights that balance the rights of patent holders with the obligations patent holders may have to consumers of patented products, which would work better to facilitate access to essential medicines, the law and foreign policy of strong patent protection reflects the relative ability of the United States to impose its will on less powerful countries. This often imperceptible asymmetrical exercise of power through law and policy inscribes outcomes of life and death for millions infected with HIV/AIDS outside the United States.<sup>8</sup> In my

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AGREEMENT ESTABLISHING THE WORLD TRADE ORGANIZATION, ANNEX 1C, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement], available at [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm0\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm).

4. See *infra* Parts III.C.4., III.D.

5. Susan Strange defines structural power as having to do with the ability to set “the rules of the game.” See Conversation With Susan Strange, available at <http://www.geocities.com/jtrevino41/STRANGE.DOC> (last visited June 4, 2003). Note, she gives the following example of the exercise of structural power: “An individual like the Pope has structural power because he manages the Catholic Church, and the Catholic Church, for example, prevents some Catholics from contraception or abortion in their range of options; so he is exercising structural power.” *Id.*

6. Susan Strange argues that it is “only by looking at the structural power exercised—often unconsciously—over other states, markets, private individuals, and firms by the agencies of the United States can the extent of the asymmetries of state power be appreciated.” Susan Strange, *The Defective State*, 124 *Daedulus* 55, 64 (1995).

7. In 1998, 35% of the close to \$300 billion pharmaceutical industry in the world was controlled by the top 10 pharmaceutical companies. U.N. DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 67 (1999).

8. Joseph Nye argues that this type of “soft power,” which involves making other states want to get what another state wants can be referred to as co-optive power behavior or indirect power.

view, to sooth these outcomes, U.S. foreign policy has sought to downplay its crass commitment to strong patent protection while overplaying its magnanimity in providing humanitarian assistance particularly for efforts to prevent the spread of the HIV/AIDS crisis. In short, the discourse of charity and humanitarianism accompanying the uncompromising support of patents at any cost simply disguises the U.S.'s priorities in ensuring its multinational pharmaceutical companies acquire markets for their drugs without any threat to their profitability even in the face of heart-wrenching human need.

This paper also critically examines the efficacy of the claim that poverty is by far the most critical barrier to affordable antiretrovirals. While it is undoubtedly true that poverty is an integral barrier to affordable antiretrovirals, it is not an insuperable barrier. For example, as demonstrated in Part III, over the last five years or so, prices of antiretrovirals in sub-Saharan Africa have fallen by large margins, making them affordable to an increasing number of people. This also means that the funds devoted by donors and governments for treatment can benefit ever-increasing numbers of indigent HIV/AIDS patients. Besides, pricing of antiretrovirals particularly in East Africa is demonstrated to be governed less by the laws of the market than the laws of the jungle.<sup>9</sup> This further undermines the argument that poverty is an insuperable barrier of access to treatment. Ultimately, I claim that while poverty is an integral component to lack of access to affordable antiretrovirals, this in and of itself does not prove that patents are *not* integral to lack of access to affordable antiretrovirals. Both poverty and patents are integral parts of the limitations to access to affordable antiretrovirals.

This paper proceeds as follows: Part I begins by describing the rationale for strong support for patents in U.S. foreign policy and how this policy differs with the conception of patent protection within the United States. I argue that this view of patents has eclipsed into obscurity the view that patents also ought to be regarded as instruments of public policy giving their holders rights subject to certain conditions. In Part II, I attempt to discern where, if at all, access to HIV/AIDS drugs for indigent populations fits within the United State's national interests. I begin this inquiry by tracing Africa's place in U.S. foreign policy/national interest and then explore the engagement of the Clinton and Bush administrations in responding to increasing concern over the reluctance of the United States to support access to antiretrovirals in sub-Saharan Africa. Finally, in Part III, I contextualize the emergence of poverty as the major barrier to access of HIV/AIDS drugs within the U.S.'s policy of strong patent protection. I then proceed to critically examine the foregrounding of poverty and the distancing of patents

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Joseph Nye, *Changing Nature of World Power*, 105 POL. SCI. Q., 181 (1990). As Susan Strange has argued, "the influence of U.S. laws on patents and property rights in medicine and pharmaceutical research throughout the world demonstrates a structural power that directly affects the life chances—good or bad—of millions of people." Strange, *supra* note 6, at 66.

9. Donald G. McNeil Jr., *Prices for Medicine are Exorbitant in Africa, Study Says*, N.Y. TIMES, June 17, 2000, at A6 (quoting the study by Kirsten Myhr, *Comparing Prices of Essential Drugs Between Four Countries in East Africa and with International Prices*).

in the continuing debate on access to antiretrovirals.

## II. PART ONE: THE STRONG PATENT PROTECTION VIEW DOWNPLAYS THE FACT THAT PATENTS ARE PRIVATE PROPERTY RIGHTS SUBJECT TO SIMILAR CONDITIONS AS ANY TRADE MONOPOLY

Strong patent protection is founded on the view that patents are private property rights that confer unconditional rights over inventions and discoveries. Such rights, it is argued, are not a private delegation of public power.<sup>10</sup> The basis of this strong patent protection view is that such a level of unimpeachable protection is a pre-condition or guarantee that patent holders, such as pharmaceutical companies, reap back their investments in research and development so that they have the incentive to continue investing in research and development for new drugs.<sup>11</sup> On this view, any form of governmental control on the otherwise unconditional rights of patentees would discourage investment in development of new drugs. Strong patent protection is achieved not simply by protecting the property interest in the patent from any form of regulatory control, but also through use of a monopoly period of twenty years within which a patent holder is protected from having competitors sell the patented product.<sup>12</sup>

This view of strong patent protection undervalues the fact that the patent monopoly is granted to an inventor in return for the inventor producing a benefit to the society. In other words, patents have both a private as well as a public essence. To refer to patents only as a form of private property right is therefore to downplay the balance between the interests of the inventor and the public consuming the patented product contemplated in many national jurisdictions.<sup>13</sup> For example, the patent and

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10. John H. Wigmore, *The Patent Monopoly: How It Differs From Trade Monopoly*, 195 J. of Comm. & Comm. 24 (1943) put it best:

[A]ll the citizen's fundamental personal rights represent simply the State's promise to exclude other persons from the thing which is the object of the right, i.e., a grant of a monopoly of use of the thing; that the rights of industrial and intellectual property (patent rights, and trademarks), are herein no different from the other rights . . . Any monopoly may be abused. . . [and that raises a cause for] remedying [the] abuse.

*Id.* For Wigmore, patents were no different from tangible property rights and as such the injunction that the abuse of such a tangible right yielded a remedy, applied equally to patents. *Id.* For supporters of a strong regime of patents, Wigmore's thesis is problematic.

11. Doha Declaration on the Trade-Related Intellectual Property Rights Agreement & Public Health, Mar. 14, 2002, Communication from the United States, IP/C/W/340 1 ¶ 6; *see also*, Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 CHI. J. INT'L L. 47 (2002).

12. Article 33 of the TRIPS Agreement provides that, "[t]he term of protection available [for patents] shall not end before the expiration of a period of twenty years counted from the filing date." TRIPS Agreement, *supra* note 3, at 81.

13. I explore this at length in James Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently With Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 FLA. L. REV. 727, 747-71 (2001).

copyright clause of the Constitution<sup>14</sup> embodies such a balance as interpreted by the Supreme Court. In *Brenner v. Manson*, the Supreme Court held that the “basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.”<sup>15</sup>

In short, referring to patents primarily as private property rights is to overshadow their public essence by overstating their privateness. Such an overstatement of the privateness of patents is exemplified by the enormous limitations placed on the permissibility of overriding patents through compulsory and parallel licensing.<sup>16</sup> Such limitations, which privilege the privateness of patents, is the shield pharmaceutical companies use to preclude any regulatory controls over patents. By keeping the government from regulating patents, perhaps in ways that balance the patent holders rights and those of the users of drugs under patents, patent holders simultaneously justify reaping the maximum possible profit from their patents.<sup>17</sup>

In the domestic context, where the balance tilts too heavily either in favor of intellectual property rights on the one hand, or in favor of the intellectual commons on the other hand, some scholars have argued that the public loses its constitutionally protected right to a vigorous public domain.<sup>18</sup> According to this argument, a vigorous intellectual commons is only possible where the availability of information, knowledge and other raw data, free from monopoly control, is available to the public and the private sector to encourage education, research, new discoveries and free speech.<sup>19</sup> In the context of international intellectual property law, patents are protected as private property rights with a twenty-year monopoly with several procedural safeguards protecting the patentee,<sup>20</sup> but that protection is understood to similarly serve public policy objectives such as the promotion of technological innovation in developing countries. Patents, in essence, are understood to serve to the mutual advantages of both producers and users of

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14. Article 1, Section 8 provides that Congress shall make laws “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors exclusive Right to their respective Writings and Discoveries.” U.S. CONST. art. I, § 8.

15. *Brenner v. Manson*, 383 U.S. 519, 534 (1966).

16. For example, Article 31 of the TRIPS Agreement subjects compulsory licensing to twelve pre-conditions except for public non-commercial use or in situations of national emergencies. TRIPS Agreement, *supra* note 3, at 95-96.

17. As Richard A. Posner argues, “the basic challenge in the fine tuning of intellectual property rights as striking the right balance between the interest in encouraging the production of intellectual property and the interest in promoting its widespread use . . . .” Richard A. Posner, *The Law and Economics of Intellectual Property*, 131 *Daedalus* 5, 11 (2002).

18. See LAWRENCE LESSIG, *THE FUTURE OF IDEAS: THE FATE OF THE COMMONS IN A CONNECTED WORLD*, 180-217 (2001); Keith Aoki, *(Intellectual) Property and Sovereignty: Notes Toward a Cultural Geography of Authorship*, 48 *STAN. L. REV.* 1293 (1996).

19. LESSIG, *supra* note 18, at 180-217.

20. See discussion *infra* Part II.

technological knowledge, to the promotion of social and economic welfare, and to the balancing of rights and obligations.<sup>21</sup>

The Doha Declaration on TRIPS and Public Health recognizes this dialectical character of patents in the following terms: “[W]e recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effect on prices.”<sup>22</sup> Further, the Declaration notes that members recognize that while the TRIPS Agreement confers flexibilities such as the freedom to establish their own regimes of international exhaustion and to engage in compulsory licensing, members are still required to maintain their “commitments in the TRIPS Agreement.”<sup>23</sup> Hence, while the Declaration recognizes the importance of interpreting and construing the TRIPS Agreement in a manner that would allow countries to enable access to essential HIV/AIDS drugs through processes such as compulsory licensing, it nevertheless affirms the importance of patent protection.<sup>24</sup> This balance between the rights of patentees and those of consumers of pharmaceutical products is a far cry from the strong conception of patent protection argued to be embodied in the TRIPS Agreement by the United States.

Pharmaceutical companies and western governments, such as the United States, opposed to a dialectical understanding that would allow even limited exceptions to patent protection for essential drugs, have sought to disentangle the relationship between patents and high prices for such essential drugs by overstating the barriers posed by poverty in limiting access to HIV/AIDS drugs.<sup>25</sup> In this context, the world can rest reassured that the thousands who die of HIV/AIDS every day in sub-Saharan Africa are dying because they are poor, not because they did not have access to expensive drugs.<sup>26</sup>

Therefore, rather than directly defending the exclusivity of patents from regulatory controls, the United States now emphasizes that poverty, not the high price of patented HIV/AIDS drugs, is the explanation for lack of access to these drugs in sub-Saharan Africa.<sup>27</sup> This position shifts the focus from pharmaceutical companies and western governments and instead shines the

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21. TRIPS Agreement, *supra* note 3, at 86.

22. Doha Declaration on the TRIPS Agreement & Public Health, *supra* note 11, at ¶ 3.

23. *Id.* at ¶ 5.

24. *Id.*

25. For example, John L. McGoldrick, Executive Vice President of Bristol Myers-Squibb which holds the patent on Zerit, an AIDS drug, commented that the AIDS pandemic “is not about profits; it’s about poverty and a devastating disease . . . .” Karen DeYoung & Bill Brubaker, *Another Firm Cuts HIV Drug Prices*, WASH. POST, Mar. 15, 2001, at A01.

26. HIV/AIDS kills eight million people a year mostly in sub-Saharan Africa. See James Orbinski & Bernard Pecoul, *G8: Drugs for Neglected Diseases*, available at <http://www.msf.org/content/page.cfm?articleid=05c7e503-7f90-4bdf81fe0ad399cfcf44> (June 24, 2003).

27. Doha Declaration on the TRIPS Agreement & Public Health, *supra* note 11 at ¶ 6.



light on endemic poverty in developing countries. Implicit in this shift is the view that poverty, rather than access to essential drugs, accounts for the fact that less than 2%, or 30,000, of the more than 28.5 million Africans living with HIV/AIDS virus in 2001 have access to life-prolonging patented drugs.<sup>28</sup>

Since 1887, when the United States entered into the Union for the Protection of Industrial Property (Union), in influencing the definition of patents as a private property right, it has managed to do so by overshadowing alternative conceptualizations of a patent that acknowledge simultaneously conceiving patents as instruments of public policy.<sup>29</sup>

The Union established the first modern international patent convention, the International Convention for the Protection of Industrial Property.<sup>30</sup> Chancellor Bismarck of Germany was greatly opposed to the issuance of patents for reasons we shall see shortly.<sup>31</sup> The entry of the United States into the Union in 1887 was therefore regarded as a welcome counterweight to the German-led anti-patent movement.<sup>32</sup> At stake during this first meeting of the Union members was the vision to be embodied in the Paris Convention: Would patents be recognized at all, as the German Chancellor did not want them recognized; or if they were recognized, whether the resulting Convention would be modeled on the view that patents were a form of private property as the United States wanted?<sup>33</sup>

In Germany, Chancellor Bismarck led a group of states of the German Zollverein Customs Union and economists who were worried that the expansion of trade and commerce spurred by the industrial revolution would transform patents into tools of monopolistic and restrictive control from foreign importers.<sup>34</sup> In Germany, an agreement in 1842 had secured the exclusive right of patentees to produce “but not the exclusive right to sell.”<sup>35</sup> This agreement, in essence, protected German manufacturers at the expense of foreign manufacturers. There was, however, a group of trade associations, industrialists and engineers who fought the Bismarck-led anti-patent

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28. UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC 2002 1 (2002).

29. See James Gathii, *The Commoditization of Patents in International Policy: 1887-2003*, LAW & POL'Y (forthcoming 2004).

30. Convention for the Protection of Industrial Property, Mar. 20, 1883, 25 Stat. 1372; see also Heinrich Kronstein & Irene Till, *A Re-Evaluation of the International Patent Convention*, 12 LAW & CONTEMP. PROBS. 765 (1947).

31. Kronstein & Till, *supra* note 30, at 767-68.

32. *Id.* at 766.

33. *Id.* at 766-70.

34. This Union was formed in 1832 with a view to remove all customs as between its membership of thirty-nine states, thirty-five monarchies and four free cities. See <http://www.encyclopedia.com/html/G/GermanC1o.asp> (June 24, 2003).

35. EDITH TILTON PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 14 (1951).

movement.<sup>36</sup> This group proposed to strengthen the German patent system through the establishment of a “uniform patent system for the whole of Germany.”<sup>37</sup>

In Germany, as in the rest of Europe where there was a strong anti-patent movement, those pushing for a strong patent movement eventually prevailed with the adoption of a unified patent law in 1878. According to E.T. Penrose, the weakening of the anti-patent movement “was probably associated with the depression of 1873 and with the increasing nationalism and protectionism which arose in most countries as the century came to a close.”<sup>38</sup>

The anti-patent movement also had its day in Switzerland where proposals to protect industrial property with patents were defeated in both 1866 and in 1882 through the passage of a patent law which excluded the textile and the chemical industry from patent protection.<sup>39</sup> This, in effect, excluded foreign importers from limiting Swiss producers from using their inventions. However, under pressure from Germany, Switzerland agreed to protect German patents or face raised duties on Swiss coal-tar and dyestuffs in Germany.<sup>40</sup>

Briefly then, prior to the Paris Convention on Industrial Property, there was a vibrant debate regarding the necessity of a patent regime crossing national boundaries. Countries such as Germany, which resisted the recognition of patents as granting exclusive rights to their holders, were in the throes of balancing between domestic constituencies with conflicting goals. On the one hand, some constituencies sought to limit the scope of the patent rights to preclude foreign manufacturers from claiming exclusivity over methods or processes they had developed when their products entered Germany. Others wanted reciprocal protection by Germany’s trading partners for the methods or processes they had developed and were available in other countries. With the adoption of the Paris Convention on the Industrial Property in 1883, the anti-patent movement seemed to have withered away, and instead, the stakes of the Convention shifted towards whether patents would be viewed as tools of public policy or as private property rights.

In the United States, the natural law tradition, for the most part, informed the perspective that patents were a form of private property.<sup>41</sup>

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36. Kronstein & Till, *supra* note 30, at 769-70.

37. PENROSE, *supra* note 35, at 15.

38. *Id.*

39. Kronstein & Till, *supra* note 30, at 778-79.

40. PENROSE, *supra* note 35, at 16-17.

41. *Seymour v. Osborne*, 78 U.S. 516, 533 (1870). In *Seymour*, Chief Justice Clifford observed that “inventions secured by letters patent are property in the holder of the patent, and as such are as much entitled to protection as any other property, consisting of a franchise during the term of which the franchise or the exclusive right is granted.” *Id.* This view was affirmed by the Supreme Court severally in the nineteenth and early twentieth centuries. *See also*, Cramp & Sons

Under the natural law tradition, intellectual property rights were justified as natural rights since they were regarded as the product of one's own ideas rather than as a private delegation of a public power.<sup>42</sup> Such a showing in turn precluded others from enjoying those ideas at the expense of their owner. In this manner, the ideas came to be recognized as an exclusive property right. Under such a view, intellectual property rights got their force less from being a social institution created by the state than from their recognition as natural rights.<sup>43</sup>

Such a view of intellectual property rights, therefore, mostly rested on both a deontological as well as a consequentialist foundation. It is deontological to the extent that it appeared to rest on a labor theory of value under which patent rights are justified as a reward for the labor of the patentee. Alternatively, it is acknowledged as a moral right of the inventor. It is consequentialist because the patent right is based on the good consequences of its legal recognition, such as the progress of science and the useful arts.<sup>44</sup> However, consequentialism does not have regard for the moral rightness of the patent or "the social consequence of the denial to others of the right to imitate."<sup>45</sup>

Central to the success of the Paris Convention was the entry of the United States into the Union for the Protection of Industrial Property in 1887.<sup>46</sup> U.S. entry into the Union greatly helped in quashing the Bismarck-led anti-patent movement and the consolidation of the view of patents as private property.<sup>47</sup> The natural rights idea of patents as a form of private property prevailed against not just the objections of the anti-patent posture of Bismarck Germany, but also viz a viz other objectors such as *The Economist* magazine of London whose "spirited campaign against the patent system" was cast in the following terms:

Before . . . [the inventors] can . . . establish a right of property in their inventions, they ought to give up all the knowledge and

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Ship & Engine Bldg. Co. v. Int'l Curtis Marine Turbine Co., 246 U.S. 28 (1918); *James v. Campbell*, 104 U.S. 356 (1881); *Cammeyer v. Newton*, 94 U.S. 225 (1876); *Consolidated Fruit Jar Co. v. Wright*, 94 U.S. 92 (1876); *Brown v. Duchesne*, 60 U.S. 183 (1856).

42. Justice Marshall refuting the view that the patent was a monopoly granted by the state for a temporary period noted: "The public yields nothing which it has not agreed to yield; it receives all which it has contracted to receive. The full benefit of the discovery, after its enjoyment by the discoverer for fourteen [now seventeen] years, is preserved . . ." *Grant v. Raymond*, 31 U.S. 218, 242 (1832).

43. PENROSE, *supra* note 35, at 22.

44. The formulation is used in the patent clause of the U.S. Constitution Article I, section 8: "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . ." U.S. CONST. art. I, § 8. For a discussion of the deontological and consequentialist views, see Dale A. Nance, *Foreward: Owning Ideas*, 13 HARV. J.L. & PUB. POL'Y 757 (1990).

45. PENROSE, *supra* note 35, at 22.

46. Kronstein & Till, *supra* note 30 at 769-70.

47. *Id.*

assistance they have derived from the knowledge and inventions of others. That is impossible, and the impossibility shows that that their minds and their inventions are, in fact, parts of the great mental whole of society, and that they have no right of property in their inventions, except that they can keep them to themselves if they please and own all the material objects in which they may realize their mental conceptions.<sup>48</sup>

These objections to the patent movement were focused on the view that ideas are incapable of ownership and that the dissemination of one person's ideas is a reflection of the collective wisdom of the society.<sup>49</sup> The Economist magazine's objection is teleological to the extent that it argues against the presumption that inventors should be rewarded for the collective genius of society.<sup>50</sup> Instead, it would seem that such a teleological approach suggests that a consequentialist justification of a regime of patents "would only accidentally produce the objectively correct amount of knowledge and aesthetic experience" for a society.<sup>51</sup> Under a teleological approach, therefore, perhaps only the government can objectively determine an appropriate level of knowledge and aesthetic experience and the mechanisms necessary to attain it.

Even under a teleological approach, therefore, there is a recurring question of whether patents over intellectual property are an unjustifiable state created private monopoly in trade, or an acceptable institution just like that of the private property over tangible property. This recurring theme replays itself just as much when the issue is framed in terms of whether patents are either a form of private property or an instrument of public policy.<sup>52</sup> Ultimately, it would seem then that the question posed by patent

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48. *Id.* at 23, n. 8 (quoting THE ECONOMIST, Dec. 28, 1850, at 1434).

49. *Id.*

50. *Id.*

51. Nance, *supra* note 44, at 766.

52. There were several other justifications of the international patent regime at the end of the nineteenth century. The administrative handicaps of patentees from country A getting a patent in country B have been described in the following terms:

When an inventor applied for a patent in his own country he had to disclose the nature of his invention, and the publication of the specification attached to this patent application was held by a few other countries to destroy the newness of the invention for patent purposes. In applying for a patent in several countries an inventor had to draw up applications *conforming to widely different and extremely detailed rules; he had strictly to observe complicated procedures, and he had to do all these things within short periods of time.* In the meantime, *others might learn of his invention through the patent application in his own country and patent the invention themselves, if permitted. Or they might simply use it, thus either destroying its novelty for patent purposes or acquiring a legal right to its use which could not be touched even if the original inventor succeeded eventually in obtaining a patent.* Taxes had to be paid on time . . . Thus, to obtain and maintain patents in foreign countries, a patentee was usually forced to incur the expense of obtaining and maintaining patent agents in each country to defend his interest. *Hence a patent who wished to exploit his invention abroad, or to*

policy since the nineteenth century has been whether to think of patents as either an “institution for the achievement of individual liberty within a social order” or as private property for the “efficient utilization of resources.”<sup>53</sup>

With the advent of the TRIPS Agreement, the view of patents as a form of private property prevailed, as is reflected by the exclusive nature of the rights conferred to patent holders in that agreement.<sup>54</sup> In addition, these rights are further buttressed in a number of ways. First, the World Trade Organization (WTO) has, since 1995, protected patents backed up by a dispute settlement system that is compulsory and binding. This dispute settlement system is capable of sanctioning States that violate the rights protected by this patent regime.<sup>55</sup> Second, the TRIPS Agreement departed from the norm of regulatory diversity underpinning the Paris Convention model under which patent rights were regarded as a national prerogative rather than having international scope.<sup>56</sup> Hence, under the TRIPS Agreement, there is now a minimum international substantive regime of what intellectual property rights protections countries should adopt. The requirements of the TRIPS Agreement give countries little choice regarding the scope and extent of the patent rights they can grant, since the Agreement aims at deep integration rather than regulatory diversity as in the pre-TRIPS period.<sup>57</sup> For example, the flexibility to exclude certain inventions, such as pharmaceuticals, from patent protection vanished. The TRIPS Agreement also puts in place judicial and administrative institutions, procedures, safeguards and remedies that countries must put in place to further secure the

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*obtain a revenue from its exploitation abroad by others, or to prevent others from using his invention to compete with him in foreign markets, had a strong incentive to press for international agreements which would eliminate the difficulties of obtaining protection in countries other than his own.*

PENROSE, *supra* note 35, at 42-43 (emphasis added).

53. Nance, *supra* note 44, at 770.

54. Article 28 of the TRIPS Agreement defines as “exclusive” the following rights patents confer to holders:

(a) where the subject matter of a patent is a product, to prevent third parties not having his consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having his consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. (2) Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

TRIPS Agreement, *supra* note 3, at 94.

55. The World Intellectual Property Organization (WIPO) was thought of as ineffective and is now seen or regarded to have become re-energized since the emergence of the WTO in 1995. See Graeme B. Dinwoodie, *The Architecture of the International Intellectual Property System*, 77 CHI.-KENT L. REV. 993 (2002).

56. See Samuel K. Murumba, *Globalizing Intellectual Property: Linkage and the Challenge of a Justice-Constituency*, 19 U. PA. J. INT’L ECON. L. 435 (1998).

57. Gathii, *supra* note 13, at 761.

rights protected under the treaty.<sup>58</sup> Only those patents that are capable of industrial application are protected.<sup>59</sup> Further, the TRIPS Agreement is non-derogable – countries cannot make reservations without the consent of all signatory state parties, which seems rather difficult to attain.<sup>60</sup>

The high level of patent protection embedded in the TRIPS Agreement is the result of a long and tortured history. In recent times, this success must be understood against the backdrop of a shift in U.S. trade policy in the late 1980's.<sup>61</sup> This shift demonstrated the new view that the U.S.'s comparative advantage lay in its unique ability to produce and transform conceptual notions into intangible flows of idea and money; in short, intellectual property.<sup>62</sup> Gone were the days when the United States had a superior advantage in the production of tangible products. The United States was now in a new era that required a new foreign trade policy.<sup>63</sup> This new thinking was prompted by concerns that countries, especially in Asia, were copying or mimicking U.S. intellectual property rights.<sup>64</sup> These concerns in turn led to a concerted policy towards enhancing the protection of U.S. intellectual property rights that ultimately culminated in the TRIPS Agreement.<sup>65</sup>

One of the most dramatic examples of this policy shift came with the amendments to the 1974 Trade Act in 1984 and 1988 adding section 301<sup>66</sup> and super section 301 respectively. Super section 301 requires the United States Trade Representative to unilaterally, without resorting to the WTO, impose retaliatory trade sanctions on any country in violation of U.S.

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58. TRIPS Agreement, *supra* note 3, at 100-03. Articles 42 (fair and equitable procedures), 43 (evidence), 44 (injunctions), 45 (damages), 46 (other remedies), 47 (right of information), 48 (indemnification of the defendant) and 53 (provisional measures) all relate to judicial enforcement obligations members must have in place as obligations under the TRIPS Agreement. *Id.*

59. *Id.* at 93.

60. *Id.* at 110.

61. JAGDISH BHAGWATI, *THE WORLD TRADING SYSTEM AT RISK* 13-57 (1991).

62. Gathii, *supra* note 13, at 754-59.

63. *Id.*

64. *Id.*

65. *Id.*

66. Trade Act of 1974, 19 U.S.C. § 2242 (2000), *amended by* Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-416, 102 Stat. 1105. Under this section, the United States Trade Representative (USTR) is required within thirty days after the submission of the annual National Trade Estimates (foreign trade barriers) to report to Congress those foreign countries that (1) “deny adequate and effective protection of U.S. intellectual property rights” and (2) those countries under (1) “that are determined by the USTR to be priority foreign countries.” *Id.* The USTR identifies as priorities only those countries “that have the most onerous or egregious acts, policies, or practices that . . . have the greatest adverse impact on the relevant United States products and that are not entering into good faith negotiations or making significant progress in bilateral or multilateral negotiations to provide adequate and effective intellectual property rights” protection. *Id.* In a challenge at the WTO, this notorious legal provision of U.S. law was sustained. *See* World Trade Organization Report of the Panel, *United States—Sections 301-310 of the Trade Act of 1974*, WT/DS152/R ¶ 7.22 (Dec. 22, 1999).

intellectual property rights.<sup>67</sup> These powers have been critical in protecting U.S. intellectual property rights abroad since they were enacted.

Another example is reflected by a preference of a bilateral approach in negotiating international patent agreements by the United States in the 1980's. Rather than pursuing the deadlocked Paris Convention path, the United States began a policy of negotiating bilateral intellectual property agreements, thereby breaking up the solidarity among developing countries in the Paris Convention revision meetings, using its new section 301 powers.<sup>68</sup> This policy of bilateral agreements was eventually fortified by the negotiation of the TRIPS Agreement, which was largely sponsored by a strong industry/government partnership in the Uruguay Round. When large developing countries like India and Brazil balked at the enactment of the TRIPS Agreement, section 301 powers came in handy to whip these countries into line, for they could not afford to lose access to U.S. markets.<sup>69</sup>

As a result, the negotiation of the TRIPS Agreement occurred against the background of a coercive bargaining framework. Such coercion demonstrates the structural power of the United States. As noted above, by structural power I mean the ability of the United States, almost unilaterally, to shape the TRIPS Agreement to the exclusion of equally legitimate countervailing views.<sup>70</sup> In particular, the United States prevailed in defining patents almost as non-derogable private property rights without much scope for derogating from patent protection except for some carefully hedged situations, such as under emergencies.<sup>71</sup>

67. § 2411(a)(1).

68. SUSAN SELL, *POWER AND IDEAS: NORTH-SOUTH POLITICS OF INTELLECTUAL PROPERTY AND ANTITRUST* 132 (1998). Sell notes that by shifting to bilateral intellectual property agreements, negotiators from developing countries were trade officials who have 'more clout' than intellectual property officials who were mostly present in the negotiation of the Paris Convention. *Id.* The U.S. was then able to leverage itself better since trade officials would be able to influence legislative and other changes once they reached agreement with the U.S. *Id.* Sell also notes that prior to the new policy of bilateral agreements, developing countries tended to vote as a block within a coalition labeled the Group of 77. *Id.* at 119-29.

69. Gathii, *supra* note 13, at 730-31.

70. See also STEPHEN KRASNER, *STRUCTURAL CONFLICT: THE THIRD WORLD AGAINST GLOBAL LIBERALISM* 14 (1985) (arguing that regimes are a source of power and intentional efforts to change them necessarily involve power). Other scholars have argued even in such relations of unequal power, power is not unilateral but rather relational particularly because the source of the contested power must be valued by both players for it to be a source of power. See DAVID BALDWIN, *ECONOMIC STATECRAFT* (1985); DAVID A. BALDWIN, *PARADOXES OF POWER* (1989).

71. TRIPS Agreement, *supra* note 3, at 95. Article 31 of the TRIPS Agreement provides the following rigid requirements for deviating from patent protection:

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:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such 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

By contrast, in the United States, compulsory licensing is not subject to exceptions as those that encumber are provided in Article 31 of TRIPS.<sup>72</sup> Under U.S. law, the government does not have to seek a license or negotiate for use of a patent or copyright. Any federal employee can use or authorize the use of a patent or a copyright under 28 U.S.C section 1498 (a).<sup>73</sup> The

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within a reasonable 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;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent "the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply: (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent; (ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the first . . . .

TRIPS Agreements, *supra* note 3.

72. *Id.*

73. 28 U.S.C. § 1498 amended by Pub.L. 94-553, § 105(c), 90 Stat. 2599 (1976); Pub.L. 97-164, Title I, § 133(d), 96 Stat. 40 (1982); Pub.L. 100-702, Title X, § 1020(a)(6), 102 Stat. 4671



right owner is entitled to compensation, but cannot enjoin the government or a third party authorized by the government to prevent use.<sup>74</sup> Use by any contractor, subcontractor, person, firm, or corporation who receives authorization from the federal government to use patents or copyrights is construed as use by the federal government, and cannot be sued for infringement.<sup>75</sup> Further, compensation is not based on lost profits or royalties, but rather on reasonable royalty or, as one court has put it, since compensation is based on eminent domain, the proper measure is “what the owner has lost, not what the taker has gained.”<sup>76</sup>

Efforts to achieve this balance, accepted within the U.S. domestic system, at the international level, is reflected in the Doha Declaration on TRIPS and Public Health referred to in the introduction.<sup>77</sup> This Declaration requires reading the TRIPS Agreement in a manner that balances patent protection with access to pharmaceutical products in the context of WTO members facing public health emergencies.<sup>78</sup> However, the United States has stood in the way of arriving at a compromise that would effectuate the intentions of the Declaration.<sup>79</sup> In addition, the United States has continued to use or threaten the use of its section 301 powers, thereby forestalling any derogation from the strong private property rights protections for patents embodied in the TRIPS Agreement.<sup>80</sup> As such, the United States has employed its power in a manner that has not only transformed the international protection of patents into a regime of strong patent protection, but has also done so in a manner that actually limits the capability of developing countries to use medicines now available to treat the millions of their citizens infected with life-threatening diseases such as HIV/AIDS.

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(1988).

74. § 105(c), 90 Stat. 2599; § 133(d), 96 Stat. 40; § 1020(a)(6), 102 Stat. 4671 (1988).

75. § 105(c), 90 Stat. 2599; § 133(d), 96 Stat. 40; § 1020(a)(6), 102 Stat. 4671 (1988).

76. *Leesona Corp. v United States*, 599 F.2d. 958, 969 (Ct. Cl. 1979). This section, § 1498(a), explicitly provides that it shall not have an extra-territorial effect. *Id.*

77. Doha Declaration on the TRIPS Agreement & Public Health, *supra* note 11, at ¶ 6.

78. *Id.* at ¶ 5. The chapeau of paragraph 5 of the Doha Declaration embraces this balancing approach because the members recognize a number of flexibilities contained therein “while maintaining [their] commitments in the TRIPS Agreement.” *Id.* In addition, paragraph 5(c) gives states the right to determine what constitutes a public health emergency or other circumstance of extreme urgency as part of that flexibility. *Id.*

79. See *infra* Part III.

80. Daya Shanker, *Legitimacy and the TRIPS Agreement*, 6 J. OF WORLD INTELL. PROP. 155, 179-83 (2003).

III. PART II: THE NATIONAL INTEREST IN UNITED STATES FOREIGN POLICY:  
WHERE DOES ACCESS TO ESSENTIAL DRUGS FOR AFRICANS WITH HIV/AIDS  
FIT, IF AT ALL?

*A. The National Interest*

A central focus of the U.S.'s national interest over the last century has been economic expansion and world dominance.<sup>81</sup> The United States has worked to achieve those goals by using its commercial and trading relations as well as its military power.<sup>82</sup> Therefore, while containing the spread of communism and the Soviet empire during the Cold War and while combating terrorism since the attacks of September 11, 2001, expanding America's economic influence remains a national interest.<sup>83</sup> While economics and national security have been central to U.S. foreign policy, the national interest has been vaguely defined in the discourse of the U.S.'s experience and power in the world.<sup>84</sup> The national interest in the post-second World War period was informed by a realism that simultaneously rejected economic accounts of the national interest as Marxist determinism and liberal accounts of the national interest as moralistic, utopian and legalistic.<sup>85</sup> Realist theories "maintain that power is diffused throughout society and [posit] that the state is a neutral arena or arbiter whose policies are determined by competition among multiple 'interest groups . . .'"<sup>86</sup> For these realists, the state is independent of the groups lobbying to influence it "[within] a competitive state system in an anarchic world."<sup>87</sup>

According to this post-second World War realism, the national interest was best protected by an international system whose members were capable

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81. See generally JOYCE & GABRIEL KOLKO, *THE LIMITS OF POWER: THE WORLD AND UNITED STATES FOREIGN POLICY, 1945-1954* 1 (1972); see also JOYCE KOLKO, *AMERICA AND THE CRISIS OF WORLD CAPITALISM* 1 (1974).

82. EUGENE P. TRANI, *DOLLAR DIPLOMACY*, Vol.1 *ENCYCLOPEDIA OF AMERICAN FOREIGN POLICY: STUDIES OF THE PRINCIPAL MOVEMENTS & IDEAS* 268-74 (Alexander DeConde ed. 1978); James Thuo Gathii, *Neo-Liberalism, Colonialism and International Governance: Decentering the International Law of Governmental Legitimacy*, 98 *MICH. L. REV.* 1996, 2014-16 (2000).

83. According to Karan K. Bhatia, Deputy Under Secretary for Industry and Security, U.S. Department of Commerce, "in the post-September 11 world, trade security and export controls are no longer arcane. Rather, they are the stuff of presidential summits and cover stories in major news magazines." OFFICE OF INTERNATIONAL INFORMATION PROGRAMS, *Trade Security Top Concern for U.S. Government*, Dec. 12, 2002, available at <http://www.useu.be/Terrorism/USResponse/Dec1202TradeSecurityBhatia.html>.

84. Joseph S. Nye, Jr., *Redefining the National Interest*, *FOREIGN AFFAIRS*, July 1999, at 22-35; Condoleeza Rice, *Promoting the National Interest*, *FOREIGN AFFAIRS*, Jan., 2000, at 45-62.

85. See generally, HANS J. MORGENTHAU, *IN DEFENSE OF THE NATIONAL INTEREST: A CRITICAL EXAMINATION OF AMERICAN FOREIGN POLICY* (1951). According to Morgenthau, idealism was only relevant to foreign policy to the extent that it could give 'concrete content' and application in society. *Id.* at 34.

86. WILLIAM I. ROBINSON, *PROMOTING POLYARCHY: GLOBALIZATION, U.S. INTERVENTION, AND HEGEMONY* 26 (Cambridge Univ. Press 1996).

87. *Id.*

of preserving order and realizing moral values within the limits of their power.<sup>88</sup> In largely conceiving foreign policy as abstractly agglomerating a disaggregated set of variables to predict state behavior, realists separated the political realm from the social-economic order of international relations.<sup>89</sup> This functional autonomy of the political and economic spheres is both false and misleading. It also disguises the fact that “states [often] serve the interests of those groups and classes which are dominant in society.”<sup>90</sup> Hence, the centrality of economic and military dominance in defining the national interest is not merely a reflection of a superior policy outcome among several alternatives. Rather, as some observers have argued, U.S. foreign policy “reflects the interests of a small elite, which also controls the domestic political economy, and which is generally not accountable to mass constituencies and their interests.”<sup>91</sup> Hence, it is no surprise that realists and their progeny are skeptical or reject humanitarian considerations such as democracy, human rights and charity as central to defining the national interest in and of themselves,<sup>92</sup> except in so far as they are consistent with promoting the core aspects of the national interest.<sup>93</sup>

In addition, realist and neo-realist perspectives of U.S. foreign policy underestimate the many other ways in which power manifests itself. In other words, these schools of thought tend to associate power primarily with what nations do.<sup>94</sup> In doing so, realists and neo-realists often underestimate the diffuse power exercised in international relations through the production and reproduction of practices, rules, habits and dispositions. For example, the crafting of the TRIPS Agreement reflects a specific illustration of the social crafting or construction of a regime governing international relations on patent protection that privileges one form of protection to the exclusion of another. As argued in Part One above, as constructed, the TRIPS Agreement is a form of structural power that portends real consequences for millions of people around the world.

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88. Martti Koskeniemi, *THE GENTLE CIVILIZER OF NATIONS: THE RISE AND FALL OF INTERNATIONAL LAW 1870-1960* 439 (2001) (citing MORGENTHAU, *supra* note 85).

89. MORGENTHAU, *supra* note 85, at 52-56.

90. *Id.* at 26.

91. *Id.*

92. Strobe Talbott, *Democracy and the National Interest*, FOREIGN AFFAIRS, Nov./Dec. 1996 at 47-48 (1996). Talbott explains that if the democratic forms of government wildly prevail in the world community, the U.S. will be safer and more prosperous because “democracies are demonstrably more likely to maintain their international commitment, less likely to engage in terrorism or wreak environmental damage, and less likely to make war on each other.” *Id.* at 48-49. For a skeptical view of the place of humanitarian, as opposed to hard-core national interest goals in U.S. foreign policy, see Condoleezza Rice, *Promoting the National Interest*, *supra* note 84, at 45-62.

93. MICHAEL COX, *U.S. FOREIGN POLICY AFTER THE COLD WAR: SUPERPOWER WITHOUT A MISSION?* 117 (Chatham House Papers 1995).

94. See generally Stefano Guzzini, *Structural Power: The Limits of Neo-Realist Power Analysis*, 47 *Int'l Org.* 443 (1993).

B. Africa: Access to Essential Drugs and the National Interest

In light of the foregoing, one might wonder if access to essential drugs fits at all within U.S. foreign policy. For if the United States has led the effort towards defining the international patent regime in a manner that limits the potential to override patents, one might wonder if there is scope for a policy of facilitating access to essential drugs within U.S. foreign policy. There is, of course, no straightforward answer. Part III below will discuss the U.S. foreign policy view that strong patent protection is consistent with facilitating access to essential drugs. In this Part, the query regarding where, if at all, access to essential drugs fits within the U.S. policy of strong patent protection will begin by examining how sub-Saharan Africa fits within U.S. foreign policy.

First, let us consider where Africa falls within the U.S.'s foreign policy priorities. U.S. foreign policy-making on Africa has been characterized as fragmented among various Executive agencies, all of which in turn interpret U.S. foreign policy in Africa differently, in accordance with each agency's own mandate.<sup>95</sup> These agencies include the U.S. Department of State, the U.S. Department of Defense, the Central Intelligence Agency and the Department of Commerce. The dominance of these bureaucracies in U.S. relations with Africa has resulted in an incoherent and inchoate foreign policy framework.<sup>96</sup> The White House is rarely involved in African foreign policy making unless national security issues are involved.<sup>97</sup> In the post-cold war period, Congress has sought to further U.S. involvement in Africa by strengthening trade ties primarily through the Africa Growth and Opportunity Act, which in 1999 became the first trade and investment legislation focused on Africa considered by the U.S. Congress.<sup>98</sup> Another significant U.S. interest in Africa has been to control and reduce threats to U.S. security arising from terrorism, the spread of extremist Islamic movements, drug trafficking, environmental degradation, and increasingly, the spread of infectious diseases such as HIV/AIDS, Ebola, Tuberculosis

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95. PETER J. SHRAEDER, UNITED STATES FOREIGN POLICY TOWARD AFRICA: INCREMENTALISM, CRISIS AND CHANGE 11-37 (1994).

96. *Id.*

97. John F. Clark, *The Clinton Administration and Africa: White House Involvement and the Foreign Affairs Bureacracies*, 26 J. OF OPINION 8 (1998); see also, Peter J. Shraeder, *Removing the Shackles? U.S. Foreign Policy Toward Africa After the End of the Cold War*, in EDMOND J. KELLER & DONALD ROTHCHILD, AFRICA IN THE NEW INTERNATIONAL ORDER: RETHINKING STATE SOVEREIGNTY AND REGIONAL SECURITY 195-96 (1996).

98. This legislation was justified as necessary to stimulate new investment from small and medium sized U.S. enterprises in Africa. However, its critics point out it is nothing more than a bill of rights for U.S. corporations without regard to the best interests of Africa and Africans. See, Claude Kabemba & Chris Landsberg, *Opportunity or Opportunism? Behind the Africa Growth and Opportunity Act* (Sept. 1998), available at <http://www.cps.org.za/execsumm/polbrief2.htm>. The Africa Growth and Opportunity Act was renewed in the Trade Act of 2002, Pub. L. No. 107-210, 116 Stat. 933 (2002).

and Malaria.<sup>99</sup>

Africa becomes, therefore, a foreign policy priority only when it presents a threat to U.S. security and economic interests.<sup>100</sup> Those advocating greater U.S. assistance to Africa's HIV/AIDS pandemic have framed it as an issue implicating the country's national security. For example, the National AIDS Office of the Bush administration has, for a long time, framed the HIV/AIDS epidemic in Africa primarily as an issue involving strategic security issues of state destabilization and national economic distress.<sup>101</sup> Such a framing ostensibly places the HIV/AIDS pandemic among the U.S.'s foreign policy priorities, although the post-September 11, 2001 focus on terrorism certainly eclipses the threat of the HIV/AIDS pandemic. Framing the epidemic in terms of a national security issue also removes the urgency of dealing with the egregious lack of access to health care and antiretroviral drugs in sub-Saharan Africa. Treatment campaigns are overshadowed within U.S. policy on Africa since designating the HIV/AIDS pandemic as a national security issue relegates the responsibility to the national security bureaucracies of the Executive branch. The effect of this relegation is that it excludes the agencies responsible for foreign assistance development related to programs that have health as part of their mandate from being at the frontline in combating the pandemic.<sup>102</sup>

### C. Access to Antiretroviral Drugs versus Prevention in U.S. Policy

To the extent that the Bush administration has been engaged with the HIV/AIDS pandemic in Africa, the issue of access to antiretroviral drugs has been eclipsed by a preference for prevention as opposed to treatment programs.<sup>103</sup> The rationale in favor of prevention is that those already

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99. Shraeder, *supra* note 95, at 193-201.

100. Indeed candidate George W. Bush could not have been clearer. In an interview conducted by Jim Lehrer of PBS during the campaign, he stated that: "While Africa may be important, it doesn't fit into the national strategic interests, as far as I can see them." John Murphy, *A Businesslike View of Africa*, BALT. SUN, Jan. 15, 2001, at 2A; William Douglas, *Bush Visit to Africa in 2003*, NEWSDAY, June 21, 2002, at A16. Bush's visit to Africa was subsequently cancelled indefinitely in light of a probable war with Iraq. See Elizabeth Becker, *U.S. Official to Discuss Trade; Africa Hopes to Talk AIDS*, N.Y. TIMES, Jan., 11, 2003, at A4 (noting the cancellation of Bush's Africa trip); see also, Robert Tait, *HIV/AIDS Classified as Threat to U.S. Security*, THE SCOTSMAN, May 1, 2000, at 8 (reporting that the Clinton administration had designated the spread of AIDS as a 'major threat to US national security'). Bush toured Africa in the summer of 2003. See Richard W. Stevenson, *Back From Africa: Bush's Promises Will be Watched*, N. Y. TIMES, July 14, 2003, at A4.

101. Scott Evertz, *U.S. Targets Global AIDS Pandemic*, available at <http://usinfo.state.gov/journals/itgic/1201/ljge/gj01.htm> (last visited Sept. 11, 2003).

102. Shraeder, *supra* note 95, at 195.

103. John Donnelly, *Policy on Africa Debated Leaders Say Prevention Should Be the Focus*, BOSTON GLOBE, April 7, 2001, at A6; see also, ASSOCIATED PRESS, *Report Calls for More Money for AIDS Prevention*, N.Y. TIMES, May 14, 2003, at A22 (reporting that the global HIV Prevention Working Group found that fewer than one in five people worldwide who are at risk of being infected by HIV have access to prevention programs).

infected will die anyway. However, as former President Clinton recently argued, the fact that millions are already infected by the virus does “not justify our failure to recognize the moral and practical imperatives to mount a full-throttle treatment program in conjunction with ongoing education and prevention programs.”<sup>104</sup> In the United States, where antiretroviral drugs have been available and accessible for some time now, HIV/AIDS patients are living longer with more dignity, and there is no reason to expect less in Africa.<sup>105</sup> According to former President Clinton:

Some people argue that treatment is less important than prevention; a dollar spent on prevention, they say, goes further in slowing the spread of the disease than a dollar spent on treating someone who already has it. But this is a false choice. Prevention doesn't work unless large numbers of people agree to be tested. They won't agree to be tested if all they will learn is that they are going to die.<sup>106</sup>

Another reason to be skeptical of de-linking treatment and prevention is that by highlighting prevention to the exclusion of treatment, lack of access to antiretroviral drugs for treatment is banished into the background. This bias is equally reflected in the work of well-funded private HIV/AIDS philanthropy groups such as the Bill and Melinda Gates Foundation and the Henry J. Kaiser Foundation.<sup>107</sup> Within U.S. HIV/AIDS policy, which is equally supportive of prevention over treatment, the Bush administration's prevention programs have greatly reduced support for condom distribution, which is far more cost-effective than antiretroviral distribution.<sup>108</sup> Opposition to supporting condom use has been spurred by the Bush administration with the strong support of the Republican controlled Congress that disfavors distribution of condoms and similar reproductive services aimed at arresting the spread of sexually transmitted diseases.<sup>109</sup> Republicans, with support of conservative church groups, oppose financing public health programs, which depart from a religious opposition to

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104. William Jefferson Clinton, *AIDS Is Not a Death Sentence*, N.Y. TIMES, Dec. 1, 2002, at A9.

105. *Id.*

106. *Id.*

107. *Access to HIV Prevention: Closing the Gap, A Report by the HIV Prevention Working Group convened by the Bill and Melinda Gates Foundation and the Henry J. Kaiser Family Foundation*, available at <http://www.gatesfoundation.org/nr/downloads/globalhealth/aids/PWGFundingReportSummary.pdf> (last visited May 20, 2003).

108. Nicholas D. Kristof, *The Secret War on Condoms*, N.Y. TIMES, Jan. 10, 2003, at A23.

109. When Bush's \$15 billion AIDS initiative was approved in the Senate, Congress required that at least a third of the money be devoted to prevention programs. See *House Approves Global AIDS Bill*, CBS News, available at <http://www.cbsnews.com/stories/2003/04/01/politics/main547158.shtml> (last visited May 20, 2003). The Bush administration issued a statement that it would place more emphasis on abstinence relative to treatment. *Id.*

measures such as condom distribution, that in their view promote promiscuity, or abortions which undermine the sanctity of human life.<sup>110</sup> Consistent with these beliefs, the Bush administration has also reduced or stopped support for important family planning programs, including reproductive services like counseling women on abortions or performing abortions.<sup>111</sup> Yet organizations such as the United Nations Family Planning Agency have been very effective in addressing sexually transmitted diseases, using a variety of reproductive health services, in developing countries.<sup>112</sup> However, contrary to the policy preferences of the Bush administration, evidence from Brazil indicates that integrating treatment and prevention saves on cost in part because the number of individuals with the HIV/AIDS virus admitted to hospitals has fallen dramatically.<sup>113</sup>

### 1. African Oil versus the HIV/AIDS Pandemic in U.S. Policy

Besides overshadowing the HIV/AIDS pandemic in general, and Africa in particular, the war on terrorism has put Africa on the U.S.'s foreign policy agenda in another respect, one that also backgrounds the HIV/AIDS pandemic. The uncertainty created by war in Afghanistan and Iraq has had the United States scrambling to ensure that it has a continuous and uninterrupted supply of oil.<sup>114</sup> The United States, under Secretary for African Affairs Walter Kansteiner, has concluded that "African oil is of national strategic interest to us, and it will increase and become more important as we go forward."<sup>115</sup> An African Oil Policy Initiative formed with the specific objective of influencing the White House to turn towards Africa for U.S. oil needs.<sup>116</sup> The Black Congressional Caucus also has

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110. Kati Marton, *Protect Women, Stop a Disease*, N.Y. TIMES, March 1, 2003, at A19. Democrats by contrast argue that use of condoms "is one of the healthy lifestyles . . . along with monogamy, marriage and faithfulness," that the Bush Administration's AIDS initiatives should support. See *Lawmakers Agree on AIDS Bill Details*, N.Y. TIMES, Mar. 17, 2003, at A19.

111. Erica Goode, *Certain Words Can Trip Up AIDS Grants, Scientists Say*, N.Y. TIMES, April 18, 2003, at A10; See Miriam Kagan, *Bush 'Gag Order' Chokes Global Family Planning-NGOs*, CyberDyaryo, Sept. 26, 2003, available at [http://cyberdyaryo.com/features/f2003\\_0926\\_04.htm](http://cyberdyaryo.com/features/f2003_0926_04.htm).

112. Ellen Goodman, *Cutting Off Women to Spite China*, BOSTON GLOBE, July 25, 2002, at A11. Secretary of State Colin Powell has been reluctant to buy into this pro-prevention without treatment approach. See Marsha Mercer, *Global Impact of AIDS Commands Attention*, TAMPA TRIB., May 1, 2002, at 11; Coates, et al., *HIV/AIDS is an 'Unprecedented Danger' Neglected in Bush's State of the Union Address* (Feb. 1, 2002), at <http://www.afronets.org/archive/200202/msg00000.php>; Ceci Connolly, *Bush Aides Defend AIDS Policies from Council Criticism*, WASH. POST, Mar. 15, 2002, at A13.

113. Clinton, *supra* note 104.

114. Carl Mortished, *U.S. Presses Africa to Turn on the Tap of Crude Oil*, LONDON TIMES, July 29, 2002, at 36.

115. *Id.*

116. Mike Crawley, *With Mideast Uncertainty, US Turns to Africa for Oil*, CHRISTIAN SCI. MONITOR, May 23, 2002, at 07.

sought to persuade the Bush administration to import more oil from Africa.<sup>117</sup> Although some analysts suggest that oil may improve Africa's fortunes in U.S. foreign policy after all,<sup>118</sup> it is not clear that it will necessarily lead to strengthening U.S. funding towards treatment. In fact, the turn to African oil simply reaffirms the centrality of trade and commercial interests within U.S. foreign trade policy. If oil is becoming increasingly central to U.S./African relations, it seems that there is far less of a chance that the United States will advocate challenging patents to facilitate access to antiretrovirals to Africa.

## 2. Pharmaceutical Company Profits versus AIDS Patients in U.S. Policy

The conclusion that the United States would disfavor overriding patents to facilitate access to essential drugs is best demonstrated by American response to South Africa with regard to protection of patent rights. In 1997, South Africa passed an amendment to its Medicines and Related Substances Act, authorizing the use of compulsory licensing and parallel importing to provide low cost medications to South Africans in need.<sup>119</sup> Over 30% of the South African population is infected with HIV.<sup>120</sup> With the high mortality and morbidity rate, the enactment of this law signaled some willingness on the part of the government to begin laying a framework for facilitating access to antiretrovirals.<sup>121</sup> This Act was never implemented, in large part because of aggressive actions by the United States government and the multinational pharmaceutical industry.<sup>122</sup> The United States added South Africa to the infamous section 301 watch list, under which countries that the United States Trade Representative (USTR) reports to have violated patents granted in the United States are subject to trade sanctions prior to a determination of violation under the TRIPS Agreement.<sup>123</sup> In essence, as noted earlier, section 301 authorizes the use of unilateral trade sanctions as a

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117. Jo Ann Zuniga, *Black Caucus Members Get Energy Tours*, HOUS. CHRON., July 2, 2001, at A21.

118. James Dao, *In Quietly Courting Africa, White House Likes Dowry*, N.Y. TIMES, Sept. 19, 2002, at A1.

119. Medicines & Related Substances Control Act 101 of 1965 amended by Medicines and Related Substances Control Amendment Act 90 of 1997 (S. Afr.); see also Zackie Achmat, *We Can Use Compulsory Licensing and Parallel Imports: A South African Case Study*, at <http://www.sewer.law.wits.ac.za/cals/OLPalp/tac/license.shtml>. (last visited June 10, 2003); Anthony Stoppard, *Health-South Africa: Drug Companies Drop Lawsuit Against Government*, INTER PRESS SERV., available at <http://www.aegis.com/news/ips/2001/IP010413.html> (Apr. 19, 2001).

120. Jenni Fredriksson & Steve Berry, *South Africa HIV/AIDS Statistics*, available at <http://www.avert.org/safricats.htm> (last updated Oct. 21, 2003).

121. Jonathan Michael Berger, *Tripping Over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity*, 17 CONN. J. INT'L L. 157, 157 (2002).

122. Rosalyn S. Park, *The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 MINN. J. GLOBAL TRADE 125, 136-39 (2002).

123. See *infra* Part I.



retaliatory measure by the United States.<sup>124</sup> To further illustrate the U.S.'s support for a policy of strong patent protection is the fact that an additional factor informing the USTR's citation of South Africa under section 301 was South Africa's support of a proposal at the World Health Organization to add HIV/AIDS drugs to the WHO's essential medicines list.<sup>125</sup> The USTR report on South Africa also bore a striking resemblance to the February 16, 1999, Pharmaceutical Research and Manufacturers Association (PhRMA) submission to the USTR, urging the USTR to take action against South Africa for taking action inconsistent with the protection of U.S. intellectual property rights.<sup>126</sup>

Following these actions, the U.S.-South Africa bi-national panel, which both then Vice President Al Gore and Deputy President Thabo Mbeki co-chaired, became the forum that produced a framework for resolving South Africa's listing by the USTR under section 301.<sup>127</sup> As a result, and in light of his connections to the pharmaceutical industry, especially in terms of the funding of his 2000 presidential bid, Gore became a target for AIDS activists seeking to reform U.S. policy towards developing nations facing the HIV/AIDS pandemic.<sup>128</sup> Leading this group of activists was HealthGAP, a coalition group comprised of various activist groups.<sup>129</sup> HealthGAP took advantage of the added publicity Gore was receiving as a result of his run for the Presidency in an attempt to bring the issue of access to HIV/AIDS drugs in South Africa to the forefront of the media.<sup>130</sup> The activists went to Tennessee and disrupted Gore's campaign, chanting and carrying banners that read: "GORE'S GREED KILLS".<sup>131</sup> This protest spurred a series of similar demonstrations throughout Gore's campaign, which had the desired result of bringing the issue of access to affordable essential antiretroviral drugs to the attention of not only the media, but to the U.S. administration as well.<sup>132</sup>

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124. *Id.*

125. For the USTR's report listing South Africa under § 301 dated April 30, 1999, see <http://www.ustr.gov/releases/1999/04/99-41.html> (last visited June 10, 2003).

126. See <http://www.phrma.org/issues/nte/safrica.html>; James Love, *Annotated USTR 301 Report Against South Africa*, available at <http://lists.essential.org/pharm-policy/msg00078.html> (last visited June 10, 2003).

127. Bob Davis, *Gore Hopes New AIDS Pact Will Help Shake Protesters*, WALL ST. J., August 12, 1999, at A24.

128. For a closer look at South Africa's own attempts to address the HIV/AIDS pandemic using a rights framework, see James Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 FL. J. INT'L L. 278-95 (2002).

129. For more information on HealthGAP, see <http://www.healthgap.org>. (last visited June 10, 2003).

130. Davis, *supra* note 127, at A24.

131. Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT'L L.J. 481, 503 (2002).

132. *Id.*

As a result of the media attention, U.S. Trade Representative Charlene Barshefsky announced on September 17, 1999, that an agreement was reached with South Africa that would lead to their removal from the section 301 watch list.<sup>133</sup> On December 1 of that same year, President Clinton announced that the United States would change its trade policies to support greater access to medications for developing nations facing an AIDS crisis.<sup>134</sup> In an Executive Order signed on May 10, 2000, President Clinton stated that the United States would not seek the revocation or revision of any intellectual property law in sub-Saharan African nations, so long as they promote access to HIV/AIDS medication or treatments.<sup>135</sup> This Executive Order, however, required sub-Saharan African countries to provide adequate and effective intellectual property protection as a precondition for increasing access to HIV/AIDS drugs.<sup>136</sup> This condition reflects how U.S. foreign policy of increasing access to antiretroviral drugs gives shelter to the priority of strong patent protection. On the one hand, there is a willingness to succumb to pressure and to acknowledge that patents do not trump public health. Conversely, there is continuity in insisting that any access to essential medicines should not compromise providing adequate and effective intellectual property protection.<sup>137</sup>

Vice-President Gore managed to marshal support within the administration for more money for HIV/AIDS initiatives for Africa and highlighted the importance of the issue by participating in Security Council's focus on public health and Africa in the month of January 2000. However, these initiatives did little to grapple with the issues of whether patents were in any way related to the access and affordability of HIV/AIDS drugs.<sup>138</sup>

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133. See Press Release, Department of Trade and Industry, *Joint Understanding Between the Governments of South Africa and the United States of America* (Sept. 17, 1999), at <http://www.polity.org.za/govdocs/pr/1999/pr0917b.html> (last visited June 11, 2003); see also Simon Barber, *US Remains Hostile to South Africa Drugs Act*, BUS. DAY, Sept. 27, 1999, at 4; Black Radical Congress, *Activists Lock Gore Out of His Office, Criticizing SA AIDS, Drugs Deal*, AFR. NEWS SERVICE, Aug. 25, 1999, at <http://www.freerepublic.com/forum/a37c4c4fe58fa.htm>.

134. Barber, *supra* note 133, at 4. This did not, however, soften support within PhrMA and Congress for taking a tough line on South Africa. *Id.*

135. See Exec. Order No. 13,155, 65 Fed. Reg. 30,521, 30,522 (May 10, 2000).

136. *Id.*

137. Gathii, *supra* note 13, at 752-63.

138. Correspondents in New York and Geneva, *US Vows \$228 million for AIDS War*, THE AUSTRALIAN, Jan. 12, 2000, at 8; James Gerstenzang & Maggie Farley, *Vows to Intensify AIDS Battle Disease: U.N. Security Council for First Time Addresses World Health Issue. U.S. Hopes to Double Funding to \$325 Million to Counter 'Security Threat*, L.A. TIMES, Jan. 11, 2000, at 9; Sam Allis, *Holbrooke Puts UN Focus on Africa's Wars, Aids Epidemic*, BOSTON GLOBE, Jan. 23, 2000, at A1.

### 3. Lobbying the U.S. for Greater Empathy Before President Bush's 2003 State of the Union Address

The tactics and efforts of activists to bring attention to U.S. policy of strong patent protection and the HIV/AIDS crisis did not diminish with Gore's presidential hopes. The current Bush administration has faced many of the same criticisms, as was demonstrated in 2002 at the XIV International Aids Conference in Barcelona.<sup>139</sup> Although the Bush administration continued the Executive Orders signed by President Clinton, the Bush White House has not been spared its share of criticism for doing less than is called for to address the global HIV/AIDS pandemic.<sup>140</sup> At the 2002 Aids Conference in Barcelona, U.S. Health and Human Services Secretary Tommy Thompson was shouted down by pro-treatment/anti-U.S. activists who stormed the stage when he rose to address the conference.<sup>141</sup> The United States was also accused of misrepresenting and being "miserly" with their contributions to the Global Fund for AIDS, Tuberculosis and Malaria.<sup>142</sup> The amount the fund has raised so far is around \$2.8 billion, well short of the stated \$10 billion needed to bring AIDS under control.<sup>143</sup> The criticisms aimed at the United States are a result of the fact that it contributes less per capita than other leading industrialized countries, and it counts some bilateral assistance as contributions to the fund, thereby overstating U.S. support towards addressing the global HIV/AIDS pandemic.<sup>144</sup>

In essence, U.S. policy regarding the balancing of consumer rights with producers' intellectual property rights, both domestically and globally, has been influenced by the policy of strong intellectual property rights protection. The concessions that the United States has been willing to make have come under enormous public pressure by groups like HealthGAP and ACTUP, thereby confirming that breaking patents to facilitate access to HIV/AIDS patients is not a U.S. foreign or domestic policy priority. At the domestic level, this policy of strong patents protection at any cost is evidenced in a variety of judicial decisions that have expanded the scope of patent protection beyond explicit Congressional mandate to encompass

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139. Geoff Dyer, *Activists Attack US Stance on Fighting AIDS*, FIN. TIMES, available at [www.ft.com](http://www.ft.com) (July 9, 2002).

140. In February 2001, Joseph Papovich, the U.S. Trade Representative for Intellectual Property Rights, stated that President Bush was "not considering a change in the present 'flexible policy' on compulsory licensing of drugs by AIDS-stricken countries." GRAEME DINWOODIE ET AL., INT'L INTEL. PROP. L. & POL'Y 436 (2001).

141. Sanjay Gupta, *Bush's Thompson Booed at AIDS Conference*, at <http://www.cnn.com/2002/ALLPOLITICS/07/09/thompson.aids.conference> (July 9, 2002).

142. David Brown, *Disease Fund Says Money Needs Grow; Global Effort Against AIDS, TB, Malaria May Need \$20 Billion in 2007*, WASH. POST, Oct. 12, 2002, at A2.

143. CBS News, *U.S. Under Fire At AIDS Conference*, at <http://www.cbsnews.com/stories/2002/07/08/health/main514417.shtml> (July 9, 2002).

144. *Id.*

genetically created life forms<sup>145</sup> and business methods.<sup>146</sup> There has been a surge in the recent past of legislative proposals to reclaim the balance between the rights of patent holders and users of patented products.<sup>147</sup> Some have focused on making prescription drugs affordable but such proposals have faced the uphill task of the pharmaceutical lobby and support in Congress. For example, a recent bill entitled the *Greater Access to Affordable Pharmaceuticals Act of 2002* sought to recognize the benefits that generic drugs offer to consumers by providing for accelerated approval of generic drug applications, as well as allowing a drug to be considered a bio-equivalent of a listed drug so long as tests show that the effects have no significant difference.<sup>148</sup> Although passed by the then democratic-controlled Senate, the bill did not make it in the Republican controlled House. However, in July 2003, the House passed its own version of the bill, sending it back to the Senate.<sup>149</sup> Earlier, on October 21, 2002, not long before the 2002 mid-term elections, the White House reversed course on its opposition to the initiative of speeding up generic drug entry into the market.<sup>150</sup> On that day, President Bush announced a proposed rule that would prohibit brand-name pharmaceutical companies from getting multiple 30 month stays before their drugs run out of patent protection, thereby delaying entry of cheaper generic drugs on the market.<sup>151</sup> Though the President did eventually intervene to accelerate entry of drugs into the generic market, Congress in effect shied away from this arrangement, thereby opening this area to further complex litigation that may reverse this gain for prescription drug consumers.<sup>152</sup>

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145. For example, in *Diamond v. Chakrabarty*, the Supreme Court expanded the scope of intellectual property rights in the absence of express congressional authorization by holding that non-naturally occurring manufacture (or genetically created micro-organisms or life forms) qualify as patentable subject matter. *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980).

146. For example, in *State Street Bank and Trust Co. v. Signature Fin Group*, the scope of patentable subject matter was extended to include a business method. *State Street Bank and Trust Co. v. Signature Fin. Group*, 149 F.3d 1368 (Fed. Cir. 1998). The federal circuit Court of Appeals observed, “the mere fact that a claimed invention involves inputting numbers, calculating numbers, outputting numbers, and storing numbers, in and of itself, would not render it nonstatutory subject matter, unless . . . its operation does not produce a ‘useful, concrete and tangible result.’” *Id.* at 1374 (citing *In re Alappat*, 33 F.3d 1526, 1557 (Fed. Cir. 1994)). According to Richard Posner, such lowering of the threshold of patentability has resulted in too many resources “being sucked into the creation of new biotechnology, computer software, films, pharmaceuticals, and business methods . . .” Posner, *supra* note 17, at 12.

147. See, e.g., S. 812/H.R. 5311, 107th Cong. (2002); H.R. 5272, 107th Cong. (2002).

148. S.812.

149. ASSOCIATED PRESS, *House Backs Drug Imports to Cut Costs*, INT’L HERALD TRIBUNE, July 26, 2003, available at <http://www.ihf.com/articles/104127.html>.

150. *President Takes Action to Lower Prescription Drug Prices*, Oct. 21, 2002, available at <http://www.whitehouse.gov/news/releases/2002/10/20021021-2.html>.

151. Vonronica Kolidakis, *President Bush Announces FDA Proposal To Speed Access to Generic Medicines*, U.S. L. WEEK, Oct. 29, 2002, at 2282-83.

152. *Id.*

The dangers of collusion between brand name drug companies and generic companies restraining entry of drugs into the generic market still remain.<sup>153</sup> Even in the domestic context, prescription or brand name drug consumers often pay a premium on drugs directly related not only to the U.S. government's policy of strong patent protection, but also to the conduct of the pharmaceutical industry as well.<sup>154</sup>

It has therefore been easier to pass legislation to fund various HIV/AIDS initiatives that do not directly involve compromising patents. For example, in December of 2001, the U.S. House of Representatives passed the Global Access HIV/AIDS Prevention, Awareness, Education, and Treatment Act of 2001,<sup>155</sup> which authorized the appropriation of \$750 million toward the Global AIDS and Tuberculosis Relief Act of 2000<sup>156</sup> and \$50 million for the procurement and distribution of HIV/AIDS pharmaceuticals for developing countries.<sup>157</sup> These humanitarian and charitable initiatives have benefited from some legislators, celebrities and top government officials visits to Africa. These individuals witnessed the AIDS scourge first hand, and have often shifted positions by becoming champions of the anti-AIDS crusade.<sup>158</sup> The most significant shift was that of former Senator Jessie Helms, whose conversion in favor of further U.S. funding for HIV/AIDS initiatives in Africa came after decades of his opposition to foreign aid to the continent when he chaired the Senate Foreign Relations Committee.<sup>159</sup> Senator Helms' change of heart was central to the Bush administration's decision to focus on mother-to-child

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153. See *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 166 F. Supp. 2d 740 (E.D.N.Y. 2001). The court issued the ruling barely a month before the anthrax scare following the terrorist attacks on September 11, 2001 and dismissed Bayer's attempt to forestall a suit against it by Ciprofloxacin consumers alleging antitrust violations. *Id.* The court allowed the case to go to trial after several attempts on Bayer's part to derail such a possibility through litigation. *Id.* Courts have not yet recognized sham litigation as one of the ways in which patent holders seek to immunize themselves from antitrust and patent challenges. James Thuo Gathii, *Consumer and Pharmaceutical Dimensions of Addressing Bio-Terrorism: An Analysis of In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 4 GOV'T, L. & POL'Y J. 46 (2002). Other important prescription drugs in respect of which there have been antitrust challenges include AstraZeneca, Buspirone and Cardizem CD. *Id.* For a further discussion, see *id.*

154. There has been a similar unwillingness to support legislation, such as the Debt Cancellation for HIV/AIDS Response Act of 2001, that linked the HIV/AIDS pandemic in Africa to the debt crisis in Africa. See Press Release, Barbara Lee, Congresswoman, Ninth Congressional District of Columbia (Apr. 29, 2001), available at <http://www.house.gov/lee/releases/01Apr25.htm>; GLOBAL AIDS ALLIANCE, *G7 Leaders are Turning Their Backs on Africa*, June 25, 2002, available at <http://www.globalaidsalliance.org/press250602.html> (last visited Nov. 16, 2003); see also James Wolfensohn, *A War Chest to Fight AIDS*, WASH. POST, April 28, 2001, at A21.

155. Kevin Ivers, *GOP House Passes Comprehensive Global AIDS Legislation*, GA. LOG CABIN, Dec. 11, 2001, available at <http://www.lcrga.com/archive/200112111731.shtml>.

156. *Id.*

157. See Global Access to HIV/AIDS Prevention, Awareness, Education, and Treatment Act of 2001, H.R. 2069, 107th Cong., §§ 4(a)-(c), 7 (2001).

158. Jesse Helms, *We Cannot Turn Away*, WASH. POST, Mar. 24, 2002, at B7.

159. *Id.*

transmission of the virus.<sup>160</sup> A similar shift towards advocating more governmental support for similar initiatives on the part of President Thabo Mbeki of South Africa has given further traction and impetus to this initiative.<sup>161</sup> A visit to the continent by former Treasury Secretary Paul O'Neill and Bono, lead singer of the rock band U2, in May 2002<sup>162</sup> further highlighted the fact that support for more U.S. assistance addressing the HIV/AIDS crisis in Africa would depend, in part, on leaders taking a personal interest in the matter, just as the activists had stirred the administration to begin to more actively get involved.<sup>163</sup> Unfortunately, President Bush not only rejected a Congressional appropriation bill containing a provision backed by Senator Jessie Helms which provided \$500 million U.S. assistance to support HIV/AIDS programs around the world, but Senate Republicans also 'killed' "a bill agreed on unanimously in the House and Senate, that would have provided \$4 billion over two years to fight global AIDS."<sup>164</sup>

#### 4. U.S. Support for Strong Patent Protection over Access to Essential Drugs at the WTO

These gestures of diplomatic empathy at the domestic level come alongside U.S. intransigence that patents should not be broken both at home and at the WTO. This intransigence was most recently epitomized in the debate at the TRIPS Council in preparation for the Doha Ministerial Conference at the end of 2001.<sup>165</sup> The United States ultimately acceded to signing the Doha Declaration on TRIPS and Public Health, as a political, not a legally binding instrument<sup>166</sup> which recognizes the importance of interpreting the TRIPS Agreement in a manner that balances the rights and obligations of producers and consumers of intellectual property rights.

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160. Editorial, *Will Helms' Conversion Brings \$500 Million for AIDS*, NEWSDAY, Mar. 29, 2002, at A38.

161. *Confronting AIDS*, COURIER-JOURNAL, May 21, 2002, at 8A.

162. ASSOCIATED PRESS, *AIDS Crisis Angers O'Neill, Bono*, CHI. TRIB., May 25, 2002, at 4; Reuters, *'Odd Couple' Decries Soweto AIDS Revelations*, TORONTO STAR, May 25, 2002, at A33.

163. Activists criticized the Bush administration Mother-to-Child initiative because the assistance would be channeled bilaterally as opposed to through the Global Fund to fight AIDS, TB and Malaria. See Jim Lobe, *Activists Slam Bush AIDS Initiative*, June 19, 2002, available at <http://www.aegis.com/news/ips/2002/ip020611.htm>. According to the activists, the administration was worried that the Fund would use the money to buy the patented drugs from generic companies in the third world rather than from the patent holding companies in the west. *Id.*

164. Editorial, *More Than Words to Fight AIDS*, N.Y. TIMES, Dec. 16, 2002, at 26; see also PHYSICIANS FOR HUMAN RIGHTS PROJECT, *Bush Decision to Reject Emergency Funds for Global AIDS Fight is Shameful Medical Group Says*, available at <http://www.phrusa.org/campaigns/aids/release081302.html> (last visited Aug. 13, 2002).

165. James Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291 (2002).

166. *Id.*

However, the United States made the following arguments mostly consistent with its view of strong patent protection.<sup>167</sup> First, strong intellectual property protection would be the best guarantee for affordable HIV/AIDS drugs to enter the market.<sup>168</sup> Second, the United States argued that a separate TRIPS and Public Health declaration was unwarranted because developing and least developed countries had not proved that the TRIPS Agreement limited access to essential medicines.<sup>169</sup> Third, the United States argued that the TRIPS Agreement already granted flexibility to developing and least-developed countries in terms of longer transition periods in the treaty for their compliance.<sup>170</sup> Although the Doha Declaration on TRIPS and Public Health was eventually passed unanimously, it reflects U.S. foreign policy to the extent that it both reiterates a commitment to the TRIPS Agreement's strong protections of patent rights and acknowledges that these protections "should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."<sup>171</sup>

*D. Cipro and the Anthrax Scare: Testing U.S. Support for Strong Patent Protection at Home*

The following discussion of the U.S. government's response to the anthrax scare and the attendant fears of a bio-terrorist attack created after the terrorist attacks on the United States on September 11, 2001, further demonstrates the reluctance of the U.S. administration to break patents, even when the United States faces a potential public health crisis. As soon as the presence of anthrax spores was discovered in the offices of leading news organizations and in the offices of congressional leaders, there were immediate calls for the amassing of Ciprofloxacin, since it is the widely preferred antibiotic for patients infected with anthrax.<sup>172</sup>

One alternative the government had under federal law, besides subsidizing Bayer to stockpile the drug, was using its eminent domain powers to override the patent by issuing compulsory licenses to generic companies to manufacture the drug.<sup>173</sup> The government considered, but did

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167. *Id.*

168. Cecilia Oh, *U.S. Opposed to Moves to Address Public-Health Concerns About TRIPS*, THIRD WORLD NETWORK ONLINE, at <http://www.twinside.org.sg/title/twr131f.htm> (last visited June 10, 2003).

169. Gathii, *supra* note 165, at 297.

170. *Id.* at 296-97.

171. Declaration on the TRIPS Agreement and Public Health, WTO WT/MIN(01)/DEC/2 (Nov. 20, 2001), available at [http://www.wto.org/english/thewto\\_e/minist\\_e/mi\\_n01\\_e/mindecl\\_trips\\_e.pdf](http://www.wto.org/english/thewto_e/minist_e/mi_n01_e/mindecl_trips_e.pdf) (last visited Nov. 16, 2003).

172. See Gathii, *supra* note 153, at 46-49.

173. Section 1498(a) of 28 U.S.C. provides that the US government does not have to seek a license or negotiate for use of a patent or copyright. 28 U.S.C. § 1498 amended by Pub.L. 94-553, §

not invoke this power. Instead, it entered into an agreement with Bayer, under which it agreed to subsidize Bayer's production of 1.2 billion Ciproflaxacin (Cipro) pills for stockpiling.<sup>174</sup> This stockpile would, according to Health and Human Services Secretary Tommy Thompson, be adequate to protect at least 10 million Americans on a two-pill regimen for sixty days in the event of a bio-terrorist attack.<sup>175</sup> Under this agreement between the government and Bayer, Bayer initially agreed to lower the retail price of Cipro from \$4.50 a pill to \$1.89 a pill.<sup>176</sup> Eventually, Bayer agreed to further lower the price of a pill to 95 cents.<sup>177</sup> For its initial order of 100 million pills, the U.S. government therefore agreed to pay Bayer \$95 million.<sup>178</sup>

Notwithstanding Bayer's concession to lowering the price of the drug, observers have noted that the government shortchanged American taxpayers, since "Indian companies sell a generic version of the same drug for less than 20 cents."<sup>179</sup> In other words, American consumers would have been better off if the government invoked its eminent domain powers and issued compulsory licenses to generic manufacturers who would produce Ciproflaxacin at a lower cost and in greater quantities as a safeguard against a bio-terrorist threat.<sup>180</sup> Hence, critics of the federal government have argued that it sacrificed public health at the alter of intellectual property rights, by allowing Bayer to continue to be the sole supplier of Ciproflaxacin.<sup>181</sup>

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105(c), 90 Stat. 2599 (1976); Pub.L. 97-164, Title 1, § 133(d), 96 Stat. 40 (1982); Pub.L. 100-702, Title X, § 1020(a)(6), 102 Stat. 4671 (1988). Any federal employee can use or authorize the use of a patent or a copyright. *Id.* The right owner is entitled to compensation, but cannot enjoin the government or a third party authorized by the government to prevent the use. *Id.* Any contractor, subcontractor, person, firm, or corporation who receives authorization from the federal government to use patents or copyrights cannot be sued for infringement. *Id.* Compensation is not based on lost profits or royalties, but rather on reasonable royalty or, as one court has put it, since compensation is based on eminent domain, the proper measure is 'what the owner has lost, not what the taker has gained.' *Leesona Corp.*, 599 F.2d. at 969. This section explicitly provides that it shall not have extra-territorial effect. *Id.*

174. See Timothy J. Burger, *Feds Push Bayer to Boost Cipro Stockpile*, N.Y. DAILY NEWS, Oct. 20, 2001, at 8 (reporting that Secretary Tommy Thompson had rejected an assertion by Senator Chuck Schumer "that the government would save money by using its legal power to authorize other manufacturers to use Bayer's patent on Cipro.").

175. U.S. DEP'T OF HEALTH AND HUMAN SERVS., HHS, BAYER AGREE TO CIPRO PURCHASE, Oct. 24, 2001, available at <http://www.hh.gov/news/press/2001pres/20011024.html>.

176. *Id.*

177. *Id.*

178. *Id.*

179. Russell Mokhiber & Robert Weissman, *The Cipro Rip-Off and the Public Health*, at <http://www.zmag.org/sustainers/content/2001-12/02mokhiber-weissman.cfm> (Dec. 2, 2001).

180. See Letter from Ralph Nader and James Love to Tommy Thompson Regarding Ciprofloxacin, DHHS Secretary, (Oct. 18, 2001) (on file with author).

181. See also David Olive, *It's Sad Sight to See Ottawa Ready to Give in to Bayer on Drug*, TORONTO STAR, Oct. 23, 2001, at E03 (providing a similar story in Canada). For a more recent editorial, see Ramon Castellblanch, *Selling Out Seniors To Protect Drug Industry Profits*, THE HARTFORD COURANT, Oct. 14, 2002, available at <http://www.biohope.org/>



There is yet another consideration that factored into the U.S.'s refusal to issue compulsory licenses over Cipro. The United States does not want to undermine the legitimacy of its negotiating position with developing countries over whether the World Trade Organization treaty, TRIPS, allows these countries to override patents which would enable them to effectively address the HIV/AIDS pandemic.<sup>182</sup> The United States has consistently opposed the efforts of developing countries to override patent protection that would legally allow them to produce generic equivalents of the patented drugs used in the treatment of HIV/AIDS patients.<sup>183</sup> Towards the end of 2002, the U.S.'s objections at the TRIPS Council foreclosed an agreement regarding whether to permit countries with no manufacturing capacity, who are suffering health emergencies such as HIV/AIDS, from engaging countries with a manufacturing base in order to produce essential medicines on their behalf.<sup>184</sup> This scuttled negotiations on paragraph 6 of the Doha Declaration on TRIPS and Public Health. Paragraph 6 had left for further deliberation the question of whether countries without manufacturing capacity, but experiencing the HIV/AIDS pandemic, can take advantage of the flexibility of overriding patents ostensibly agreed on in the Declaration.<sup>185</sup> The United States was frustrating agreements on this issue at a time when the Central Intelligence Agency was warning that the AIDS pandemic continues to spread in Africa and beyond in ways that heighten U.S. security risks.<sup>186</sup> In sum, safeguarding patents has been a top priority

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media/article\_print.cfm?articleid=3109.

182. Gathii, *supra* note 165, at 315.

183. Cecilia Oh, *Developing countries call for action on TRIPS at Doha WTO Ministerial Conference*, at <http://www.twinside.org.sg/title/twr131d.htm> (last visited June 10, 2003).

184. HEALTH GAP, *Thanks to U.S. bullying, no deal this year on access to medicines at the WTO. Poor countries prevent U.S. re-write of the Doha agreement on public health*, available at [http://www.globaltreatmentaccess.org/content/press\\_releases/02/122002\\_HGAP\\_WTO\\_US\\_exp.html](http://www.globaltreatmentaccess.org/content/press_releases/02/122002_HGAP_WTO_US_exp.html) (Dec. 20, 2002).

185. Faizel Ismail, *The Doha Declaration on TRIPS and Public Health and the Negotiations in the WTO on Paragraph 6 – Why PhRMA Needs to Join the Consensus!*, 6 J. WORLD INTELL. PROP., 393, 395 (2003). However, note that reports just prior to the final edit of this article indicate that the U.S. has backed off its opposition to a compromise solution at the WTO that would ensure access to essential drugs for millions infected with the HIV/AIDS virus. See Elizabeth Becker, *In Reversal, U.S. Nears Deal on Drugs for Poor Countries*, N.Y. TIMES, Aug. 28, 2003, at A1. Note however that the Cancun Ministerial talks about how the agreement on Paragraph 6 would have been ratified broke down. *Id.*

186. *More Than Words to Fight AIDS*, N.Y. TIMES, December 16, 2002; INT'L CENTRE FOR TRADE AND SUSTAINABLE DEV., *WTO Fails To Meet TRIPs [sic] & Health Deadline Due To US Opposition*, BRIDGES UPDATE (Jan. 2, 2003), available at [http://www.ictsd.org/ministerial/cancun/TRIPs\\_update.htm](http://www.ictsd.org/ministerial/cancun/TRIPs_update.htm). This article reports that:

Negotiations on TRIPs [sic] and health broke down in the early hours of 21 December over the US' refusal to accept the Chairman's proposed disease coverage for the para. 6 solution, i.e. "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics" as set out in para. 1 of the Doha Declaration . . . . In a last-minute attempt to reach a deal, the US suggested the inclusion of a footnote that would expand its previously proposed list of diseases from three (HIV/AIDS, malaria and tuberculosis) to

for the United States and, as such, efforts to address the HIV/AIDS crisis have had to contend with the inflexibility of this attachment to the exclusivity of pharmaceutical patents.

### 1. 2003: U.S. \$15 Billion for Fighting HIV/AIDS

In his 2003 State of the Union address to Congress, President Bush announced an unprecedented initiative on the part of the United States to support the global effort to combat the HIV/AIDS pandemic.<sup>187</sup> This \$15 billion initiative would provide AIDS drugs for two million people infected with the virus, care for 10 million AIDS patients and orphans, and provide education to prevent the epidemic from spreading further.<sup>188</sup> This widely applauded plan<sup>189</sup> was eventually approved by the Senate on May 16, 2003 when it voted to appropriate just over \$3 billion in the first installment of this five year initiative.<sup>190</sup> However, President Bush's 2004 budget only proposes to spend less than half of that amount in twelve African countries and two in the Caribbean.<sup>191</sup> The Bill, as passed, also requires that a third of the money go to programs to promote abstinence until marriage.<sup>192</sup>

The reasons for increased U.S. support in combating the HIV/AIDS pandemic is the result of a variety of events including activist pressure and the shifting attitudes of U.S. government leaders about the overwhelming need to support efforts to curb the crisis.<sup>193</sup> The plan has, however, been criticized for compromising rather than working with the Global Fund to Fight AIDS, TB and Malaria since the money would be spread wider and faster and for introducing religious priorities that limit addressing

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23 and "other epidemics of comparable gravity and scale", [sic] including those that might arise in the future. Developing countries, however, rejected this proposal, arguing that it would restrict the mandate given by the Doha Declaration, which refers more generally to "measures to protect public health" (para. 4). They also rejected a proposal by the EU that the US could make a statement to the effect of its proposed footnote, which would then be supported by the TRIPs [sic] Council Chair as the framework for implementing the solution.

*Id.*

187. Rachel L. Swarns, *African Nations Applaud Bush Plan to Fight AIDS Epidemic*, N.Y. TIMES, Jan. 29, 2003, at A19.

188. *Id.*

189. *Id.*; Rachel L. Swarns, *Free AIDS Drugs in Africa Offer Dose of Life*, N.Y. TIMES, Feb. 8, 2003, at A1; Sheryl Gay Stolberg & Richard W. Stevenson, *The President's Proposals: AIDS Policy; Bush AIDS Effort Surprises Many, But Advisors Call It Long Planned*, N.Y. TIMES, Jan. 30, 2003, at A1.

190. Sheryl Gay Stolberg, *Senate Approves AIDS Bill, Pleasing White House*, N.Y. TIMES, May 17, 2003, at A13.

191. *Id.*

192. *Id.*; see also Sheryl Gay Stolberg, *The World: A Calling to Heal; Getting Religion on AIDS*, N.Y. TIMES, Feb. 2, 2003, at A1.

193. Mike Allen & Paul Blustein, *Unlikely Allies Influenced Bush to Shift Course on AIDS Relief*, WASH. POST, Jan. 30, 2003, at A01.

transmission of HIV/AIDS through condom use among other criticisms.<sup>194</sup> Most important, the critics have observed that to the extent that the new initiative will buy drugs from brand name companies rather than encourage cheaper generics, the expense will limit the number of people that it can benefit.<sup>195</sup>

President Bush cloaked the new initiative in the mantra of compassion and morality.<sup>196</sup> Indeed, as President Bush said in an address on Global HIV/AIDS the day after his state of the Union address:

This is a historic year for America . . . We have a chance to achieve peace. We have a chance to achieve a more compassionate world for every citizen. America believes deeply that everybody has worth, everybody matters, and everybody was created by the almighty. And we're going to act on that belief, and we'll act on that passion.<sup>197</sup>

The fact that the United States was, at the time, strongly supporting military action in Iraq notwithstanding opposition to war policy across the world might have factored into the making of this gesture. Although Bush administration officials are said to have denied that "politics" had anything to do with the announcement, they acknowledged that it might have "beneficial ripple effects, especially in helping burnish the country's image abroad."<sup>198</sup> Further, these Bush administration officials are said to have hoped that the announcement of the initiative at a time when the administration was moving rightward in its "economic policy, judicial nominations and other issues," would "remind moderate voters of Bush's claim to be a compassionate conservative."<sup>199</sup>

Ultimately, whatever motivation the Bush administration had in supporting this new initiative, the support indicates that there is more concern and commitment than ever before in doing something about the HIV/AIDS pandemic. That said, there continues to be a strong continuity in U.S. support for strong pharmaceutical patents even with increased U.S. assistance to combat the pandemic. As we have noted earlier, foreign

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194. See Sabin Russell, *Fears, Cheers Over Bush AIDS Pledge: Plan Shortchanges Global Fund, Activists Say*, S.F. CHRON., Jan. 30, 2003, at A5; *AIDS Plan Offer Hope; But Some Activists Worry Global Funds May Not Reach Victims*, NEWSDAY (NY, Nassau and Suffolk ed.), Jan. 30, 2003, at A39.

195. Jim Lobe, *Activists Slam Bush AIDS Initiative*, available at <http://www.aegis.com/news/ips/2002/ip020611.html> (June 19, 2002) (making a similar point).

196. Stolberg & Stevenson, *supra* note 189, at A1.

197. George W. Bush, *President Speaks on Fighting Global and Domestic HIV/AIDS*, available at [www.whitehouse.gov/news/releases/2003/01/20030131-4.html](http://www.whitehouse.gov/news/releases/2003/01/20030131-4.html).

198. Mike Allen & Paul Blustein, *Unlikely Allies Influenced Bush to Shift Course on AIDS Relief*, WASH. POST, Jan. 30, 2003, at A1.

199. *Id.*

assistance to support HIV/AIDS prevention and treatment is consistent with the U.S.'s policy of strong patent protection. First, a focus on prevention as a priority eclipses the need for treatment. The second treatment campaigns are predicated on buying the expensive antiretrovirals rather than on manufacturing cheaper generic equivalents to spread the resources to benefit as many people as possible. Indeed, almost at the same time the administration was announcing this initiative to increase funding to combat HIV/AIDS, it had just managed to scuttle a growing consensus at the WTO on balancing patent protection with consumer interests in the context of HIV/AIDS, TB, malaria and other similar diseases.<sup>200</sup>

While at home, the United States has used the foreign assistance it gives in combating the HIV/AIDS pandemic to camouflage the link between its support for strong patents protection and low access to essential drugs. At the WTO, the United States has been slowly, but surely, consolidating the view that poverty, not patents, is the reason that makes drugs unaffordable and inaccessible to those who need them in developing countries.

#### IV. PART III: POVERTY – THE LATEST FAD IN THE U.S.'S POLICY OF STRATEGIC AMBIGUITY

##### *A. The Discovery of Poverty: From the IIPE 2000 Study to the Attaran/Lee Gillespie 2001 Paper*

In line with its policy of strong patent protection, the latest explanation given by the United States for lack of access to HIV/AIDS drugs in sub-Saharan Africa is poverty.<sup>201</sup> In its initial submission to the TRIPS Council regarding a solution to paragraph 6 of the Doha Declaration on TRIPS and Public Health, (which left the question of whether countries with no manufacturing capability could authorize those with manufacturing capability to make essential drugs that were still under patent available to address a public health emergency), the USTR relied on the 2001 World Health Organization's *Macroeconomics and Public Health* report to argue that poverty, rather than patents, was the major factor inhibiting access to "needed medicines at any price."<sup>202</sup> The premise of this position is that there is no necessary relationship between the cost of and access to patented drugs since millions of Africans with HIV/AIDS could not afford these drugs even if their prices were substantially lowered. In essence, Africans are too poor to afford the drugs even if their prices were dramatically lowered.

The first soundings of the move to de-link negligible access to essential drugs from strong patents protection did not, however, come from the U.S. administration. Rather, they came from the International Intellectual

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200. See Doha Declaration on TRIPS & Public Health, *supra* note 11, at ¶ 6.

201. *Id.*

202. *Id.* The submission further noted that for "any TRIPS-related solution there would still involve a cost." *Id.*

Property Institute, (IPPI), a pro-intellectual property think tank based in Washington DC that was established in 1999.<sup>203</sup> In a report issued in 2000, IPII examined the prevalence of the HIV/AIDS pandemic in Africa in the context of three other major considerations. First, it analyzed the response of the international community and in particular, the levels of foreign assistance provided by western countries such as the United States.<sup>204</sup> Second, it examined the availability of patent regimes across the African continent. Third, it examined the number of patented HIV/AIDS drugs in these countries.<sup>205</sup> The conclusions of this study seemed rather benign when compared to subsequent work that built upon this initial work and concluded that poverty was a primary barrier.<sup>206</sup> Unlike subsequent work, this 2000 IPII report concluded that access to essential drugs involves “numerous and complex issues, including health care infrastructure, international pricing mechanisms, financing, debt, tariffs and patents.”<sup>207</sup>

In fact, the report specifically concluded that the TRIPS Agreement was “not an impediment to the distribution of HIV/AIDS pharmaceuticals” for at least three reasons.<sup>208</sup> First, the TRIPS Agreement was not in force in “a majority of sub-Saharan Africa countries.”<sup>209</sup> Second, the TRIPS Agreement “permits sufficient flexibility for countries to avoid negative effects.”<sup>210</sup> Third, “most drug companies have not obtained patents widely in Africa.”<sup>211</sup> Hence, rather than elevate poverty as the primary barrier to access of HIV/AIDS drugs, the report emphasized that the real issue “is that of adequate financing of the overall health system and the development of health care infrastructures.”<sup>212</sup> The report therefore remained open for further research to establish whether or not patents and the TRIPS

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203. The IPII describes itself as “an international developing organization and think tank dedicated to promoting sustainable economic growth in all countries through the use of healthy intellectual property systems . . . .” INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE, at <http://www.iipi.org> (last visited June 10, 2003).

204. INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE, PATENT PROTECTION AND ACCESS TO HIV/AIDS PHARMACEUTICALS IN SUB-SAHARAN AFRICA (2000).

205. *Id.*

206. Lee Gillespie-White, was the Executive Director of IPII and one of the authors of the PATENT PROTECTION AND ACCESS TO HIV/AIDS PHARMACEUTICALS IN SUB-SAHARAN AFRICA. *Id.* She teamed up with Amir Attaran a year later to write the article that gave poverty the spotlight as the leading barrier to access to essential medicines. See Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa*, 286 JAMA 1886, 1886-92 (2001).

207. INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE, *supra* note 204, at 2.

208. *Id.* at 3.

209. *Id.*

210. *Id.*

211. *Id.*

212. *Id.*

Agreement played any role with regard to access to affordable drugs.<sup>213</sup>

Lee Gillespie-White, one of the contributors to the IPI report, and Amir Attaran, affiliated with Center for International Development and the Kennedy School of Government at Harvard, conducted a further survey relying on responses from drug companies.<sup>214</sup> Unlike the 2000 IPI study, which examined a number of patented HIV/AIDS drugs alongside donor funding and availability of patent protections in sub-Saharan Africa, the Gillespie-White/Attaran study was much narrower, primarily focusing on the relationship between patents and access to drugs.<sup>215</sup> Some of its conclusions coincided with those of the 2000 IPI study. For example, Gillespie-White/Attaran study confirmed that patent protection was not extensive in Africa.<sup>216</sup>

The Gillespie-White/Attaran study also made several assumptions, particularly regarding the reliability of patent status data from patent holders and licensees,<sup>217</sup> concluding that “pharmaceutical research and development will always require the incentive of patentability in poor countries . . . [since] the entire African pharmaceutical market, at 1.1% is commercially negligible, as is the market share of antiretroviral drugs sold to the poorest of the third world.”<sup>218</sup> The report notes that there are non-patent barriers to access to antiretrovirals, including insufficient financing, lack of political will among countries, poor medical care and infrastructure, regulatory barriers, and high sales taxes and tariffs, among other inhibitions.<sup>219</sup>

Perhaps the most significant assumption the paper makes is that the annual cost of a full regiment of antiretroviral treatment per-patient, per year, is United States \$1,200,<sup>220</sup> although they acknowledge prices for some antiretroviral combinations range anywhere between \$350 and \$1,000 outside the United States.<sup>221</sup> This, the authors conclude, puts treatment out of reach for many of Africa’s economies whose annual health budgets spend \$8 or less per person.<sup>222</sup> Hence, the conclusion that “even if health budgets were radically expanded and all waste and corruption banished, Africa’s impoverished economies could never afford more than a few percent of the cost of treatment and this is true even if antiretroviral drug prices continued

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213. INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE, *supra* note 204, at 2.

214. Attaran & Gillespie-White, *supra* note 206, at 1886-92.

215. *Id.*

216. *Id.* at 1887.

217. *Id.* at 1887, 1889-90.

218. *Id.* at 1890.

219. *Id.*

220. Attaran & Gillespie-White, *supra* note 206, at 1891.

221. *Id.*

222. *Id.*

to decline significantly, which is unlikely.”<sup>223</sup> Gillespie-White and Attaran therefore conclude that the “extreme dearth of international aid finance, rather than patents, is most to blame for the lack of antiretroviral treatment in Africa.”<sup>224</sup>

Since the publication of the Gillespie-White/Attaran study, pharmaceutical companies,<sup>225</sup> press reports, and the USTR’s office in particular,<sup>226</sup> have much more loudly used the legitimacy given to poverty as a barrier to access to antiretrovirals to distance patents as inhibiting such access.<sup>227</sup> A press report in a South African paper even went so far as to conclude that “[i]f developing country governments are serious about resolving the issue [of access to antiretrovirals], they should be encouraging greater protection of private property, the rule of law and other market-based reforms.”<sup>228</sup> The statement that most supported such a conclusion in the Gillespie-White/Attaran paper had the caveat that although patents might create market conditions “in which it could become lucrative to patent antiretroviral drugs more widely in future,”<sup>229</sup> even where patents do exist in sub-Saharan Africa, there was still a need to have an infusion of foreign assistance based on the recognition that “countries ought to respect patent laws, but that patent holders reciprocally supply medicines to the global poor without profit, but also without loss.”<sup>230</sup>

### B. Limits of the Gillespie-White/Attaran Poverty Thesis

There are several limitations inherent in the Gillespie-White/Attaran thesis. First, Gillespie-White and Attaran make a circular argument. For

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223. *Id.*

224. *Id.*

225. This endorsement by the pharmaceutical industry is perhaps best exemplified by a press release issued by PHRMA (the pharmaceutical industry lobby) soon after the Attaran/Gillespie-White paper. See PHRMA, *Health Care in the Developing World: Intellectual Property and Access to AIDS Drugs*, available at <http://www.phrma.org/ip.access.aids.drugs.html> (last visited June 10, 2003). On Attaran’s link to the pharmaceutical company world and his criticism of access to essential medicines activists and advocates, see *Big Pharma’s Favorite Academics and Opinion Makers*, available at <http://www.cptech.org/ip/health/pharmadefenders.html> (last visited August 17, 2002).

226. It is reported that the USTR’s office cited the Attaran & Gillespie-White paper at the Doha Ministerial meeting to make the argument that it was poverty, and not patents, that prevented access to essential medicines. See E-mail from Asia Russell to the essential medicines listserve of the Consumer Project on Technology, *USTR at TRIPS Council Special Meeting* (Sept. 19, 2001), available at <http://lists.essential.org/pipermail/ip-health/2001-September/001858.html>.

227. See also Julian Morris & Richard Tren, *A ‘Free Market’ Point of View*, available at <http://www.pharmaceuticalpatents.com/opinions.asp?ID=13> (last visited May 27, 2003).

228. Julian Morris et al., *Patents Not Real Villain in Blocking Access to Drugs*, Nov. 9, 2001, available at <http://www.businessday.co.za/bday/content/direct/1,3523,965575-6096-0,00.html> (last visited June 10, 2003).

229. Attaran & Gillespie-White, *supra* note 206, at 1891.

230. *Id.*

example, they find that patents are not a major issue inhibiting access to antiretrovirals because poverty is a more important factor.<sup>231</sup> But, then, they take for granted that the cost of these drugs is an immovable baseline. It is implicit in their argument that nothing can be done about the drug prices other than in terms of increasing donor assistance.<sup>232</sup> In essence, the goose that lays the golden eggs must be protected from governments seeking to override patent rights. Second, Gillespie-White and Attaran assume that the only “reciprocal” obligations pharmaceutical companies have towards poor countries is that of voluntarily reducing prices of expensive antiretrovirals and no more.<sup>233</sup>

I have several reservations regarding the aforementioned arguments and claims advanced by Attaran and Gillespie-White. First, recent research undertaken by the World Bank demonstrates that the WTO’s new commitments, such as TRIPS, impose expensive implementation costs that undermine poverty reduction and growth, especially in the least developed countries.<sup>234</sup> To that extent, the link between lack of access to HIV/AIDS drugs to poverty, or lack of donor support, must necessarily account for the fact that the very implementation of new regimes of intellectual property protection do not positively contribute towards the eradication of poverty, but rather serve to undermine anti-poverty programs being implemented in these countries.

In addition, the Gillespie-White & Attaran assumption that adoption of patent regimes would necessarily create market conditions under which access to antiretrovirals would be enhanced underestimates the fact that the economic programs that accompany such shifts in protection of intellectual property protection also call for contractionary macro-economic policies, which reduce public spending on areas such health and the imposition of user-fees.<sup>235</sup> For example, in its 1993 World Development Report entitled *Investing in Health*, the World Bank recommended that patients should pay user fees for health, with the exception of a limited range of essential services.<sup>236</sup> However, the report does not acknowledge that there was a “disastrous” resurgence of tuberculosis in China in direct and almost

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231. *Id.*

232. Interestingly, Attaran and Gillespie-White noted that “poor countries have only the last resort of compulsory licensing . . . which both TRIPS and the Paris Convention legitimately allow them to do so.” *Id.* at 1891. However, the authors seem to suggest that compulsory licensing is not an option until 2005, when the TRIPS Agreement comes into force in developing countries. *Id.* Even then, the authors suggest the issue of access would only be restricted to access to new medicines—presumably those patented after 2005. *Id.*

233. *Id.*

234. See J. Michael Finger & Philip Schuler, *Implementation of Uruguay Round Commitments: The Development Challenge*, 24 *WORLD ECON.* 511 (2000), available at <http://www.worldbank.org/research/trade>.

235. For an extensive authoritative expose of such policies, see JOSEPH E. STIGLITZ, *GLOBALIZATION AND ITS DISCONTENTS* (2002).

236. WORLD BANK, *INVESTING IN HEALTH*, WORLD DEVELOPMENT REPORT 58 (1993).



immediate response to the reintroduction of user fees for TB tests.<sup>237</sup> Evidence shows dramatic declines in hospital visits in countries undertaking these reforms particularly for pre and anti-natal care, preventative tests and infant deliveries.<sup>238</sup> In large-scale commercial farming areas, the introduction of user fees coincided with a 64% drop in patient registration at health clinics.<sup>239</sup> If such programs have the effect of discouraging the poor to take preventive steps to avoid tuberculosis, clearly they would have a similar effect with HIV/AIDS, especially because it is associated with cultural and social stigma, more so than tuberculosis.<sup>240</sup>

Second, there is much that is unknown in countries that have only recently upgraded their intellectual property systems in conformity with the WTO's intellectual property rules. Specifically, it is difficult to establish with certainty whether there have been changes in activity patterns that affect prices of HIV/AIDS drugs, either upwards or otherwise.<sup>241</sup> Such a determination would be critical since a premise of strong patent protection is that such protection would create market conditions under which more research and development would be undertaken to make drugs more readily available. The difficulty of establishing such activity patterns is evidenced by the fact that the TRIPS Agreement is not yet formally binding in most of sub-Saharan Africa until 2005. It is therefore an overstatement to presume that the adoption of patent regimes would necessarily create market conditions under which antiretrovirals would be more readily available even before the TRIPS Agreement is actually implemented. Indeed, Attaran and Gillespie-White acknowledge that after 2005, patents will likely impede access to antiretrovirals AIDS medications.<sup>242</sup>

In addition, recent research on retail-pricing patterns of patented antiretrovirals in East Africa shows their actual availability, as opposed to access, varies greatly from country to country.<sup>243</sup> This, in and of itself, would make it hard for anyone to conclude, without additional verifiable evidence, that cost or poverty is as significant an issue barring access to antiretrovirals given that they are often not even available although patented. More importantly though, where the drugs were available, there was a wide

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237. Marc Epprecht, *Investing in Amnesia, or Fantasy and Forgetfulness in the World Bank's Approach to Healthcare Reform in Sub-Saharan Africa*, 31 J. DEV. AREAS 337, 343-44 (1997).

238. *Id.*

239. *Id.* at 344.

240. For an excellent analysis of the cultural and stigma issues related to the HIV/AIDS pandemic, see SIDDHARTH DUBE, *SEX, LIES AND AIDS* (2000).

241. Robert B. Sherwood, *Global Prospects for the Role of Intellectual Property in Technology Transfer*, 42 IDEA: J.L. & TECH., 27, 34 (2002).

242. Attaran & Gillespie-White, *supra* note 206, at 1886-92.

243. See McNeil, *supra* note 9, at A6.

price divergence within the region for the same drug.<sup>244</sup> For example, for the same antiretroviral, there was a price divergence of 35-100% between the lowest and the highest price.<sup>245</sup> This seems rather odd, since such variation cannot be attributed to variations in per capita income. Further, the same study found that antiretrovirals such as aciclovir and nevirapine, were twice as expensive in Kenya as in Norway,<sup>246</sup> and zidovudine was 35% more expensive in Tanzania than in Norway.<sup>247</sup> The conclusions of studies such as these should serve as a caution to linking poverty to lack of access to drugs for if pharmaceutical pricing is “about the law of the jungle,” price levels, and not merely poverty, are key to access to these drugs.<sup>248</sup> These disparities mean that a Tanzanian worker would have to earn 500 hours of wages to get a course of first-line tuberculosis treatment, compared to the one-hour of wages necessary for a Swiss worker.<sup>249</sup> Needless to say, although poverty is not a static phenomenon, it seems foolhardy to argue that it is the major deterrent to access when pricing of the drugs does not seem to reflect just the cost of research and development, but also ancillary and inflated costs that cannot be justified even under market conditions.<sup>250</sup>

Third, the premise that the cost of drugs or poverty is as big a factor inhibiting access to AIDS medications as Gillespie-White & Attaran and their supporters claim is frighteningly consistent with the non-responsiveness of Western countries towards humanitarian disasters in Africa. Indeed, the HIV/AIDS pandemic is not the first time that millions of Africans have died.<sup>251</sup> For example, over 30,000 people lost their lives daily during the genocide in Rwanda in the early 1990’s as the world watched.<sup>252</sup> Today, 5,000 people die every day in the Democratic Republic of Congo and

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244. *Id.*

245. *Id.*

246. Nevirapine, which prevents mother to child transmission of the HIV/AIDS virus, costs \$430 per 100 units in Norway (although there is hardly any market for it), and \$874 in Kenya, where the need is desperate. *Id.*

247. McNeil, *supra* note 9, at A6.

248. *Id.*

249. *Id.*

250. *See, e.g., Profiting From Pain: Where Prescription Drug Dollars Go*, FAMILIES USA, July 2002, at 1.

251. *See, e.g., IRIN, Kenya: Focus on Lack of Access to HIV/AIDS Drugs*, available at [http://www.irinnews.org/AIDSreport.asp?ReportID=1429&SelectRegion:East\\_Africa](http://www.irinnews.org/AIDSreport.asp?ReportID=1429&SelectRegion:East_Africa) (last visited June 10, 2003) (UN Office for the Coordination of Humanitarian Affairs making certain observations on simple and rather inexpensive ways that the government has failed to take in the registration of AIDS drugs that might make them more accessible quickly and affordably).

252. Samantha Power, *Bystanders to Genocide: Why the United States Let the Rwanda Tragedy Happen*, ATLANTIC MONTHLY, Sept. 2001, at 84-108; Thomas W. Lippman, *Albright Embarks on Africa Tour; She Acknowledges U.S., Allies Mishandled Rwanda Crisis*, WASH. POST, Dec. 10, 1997, at A28; Lynne Duke, *Frustration and Envy Over the West's Rapid Response*, WASH. POST, May 7, 1999, at A31; *see also* Richard B. Bilder, *Kosovo and the "New Interventionism": Promise or Peril?*, 9 J. TRANSNAT'L L. & POL'Y 153, 163 (1999).

countless others throughout sub-Saharan Africa die with little or no response from the West.<sup>253</sup> The world has learned to watch tragedy in Africa and do little or nothing about it. President Clinton's attempts at apologizing for doing little about the well-publicized genocide in Rwanda when he visited Kigali for only about an hour says a lot about what needs to change concerning U.S. foreign policy towards Africa generally, and the HIV/AIDS epidemic particularly: more than window-dressing and appearances is what is needed.<sup>254</sup>

Fourth, attempts by the Bush administration to address the HIV/AIDS epidemic in Africa primarily as an issue involving strategic security, state destabilization, and national economic distress removes the urgency of dealing with the egregious lack of access to health care, as well as to AIDS drugs in sub-Saharan Africa. This is a human and not simply a strategic foreign policy issue. Even with the \$15 billion five-year initiative launched by President Bush, only 2 million in twelve African and two Caribbean countries of the more than 29 million in need of access to HIV/AIDS care and support in sub-Saharan Africa and the Caribbean, including drugs, will be serviced.<sup>255</sup> The good news is that those of the 2 million people who will benefit from treatment under the initiative launched by President Bush will be a big increase from the fewer than 30,000 people who by the end of 2001 were estimated to be benefiting from antiretroviral drugs in sub-Saharan Africa.<sup>256</sup>

Happily too, advances in access to care and drugs in resource limited settings make it possible now, more than ever before, to ensure that a larger number of Africans, who comprise over 70% of those infected globally,<sup>257</sup> are reached.<sup>258</sup> The WHO's guidelines, seeking to have a three-in-one pill,<sup>259</sup> together with its treatment guidelines once such drugs are available, are based on an analogous experience in the United States, where the introduction of the triple-therapy in 1996 led to a 70% decline in AIDS

253. Nicholas D. Kristof, *What Did You Do During the African Holocaust?*, N.Y. TIMES, May 27, 2003, at A25.

254. ASSOCIATED PRESS, *President Clinton Apologizes* (March 25, 1998), available at <http://www.rudyfoto.com/ClintonApology.html>.

255. Deb Riechmann, *Bush Signs Bill to Help Fight AIDS Abroad*, YAHOO NEWS, May 27, 2003, at [http://news.yahoo.com/news?tmpl=story2&u=/ap/20030527/ap\\_on\\_go\\_pr\\_wh/bush\\_aids](http://news.yahoo.com/news?tmpl=story2&u=/ap/20030527/ap_on_go_pr_wh/bush_aids).

256. UNAIDS, *supra* note 28, at 23.

257. Berger, *supra* note 121, at 158.

258. See WHO, *3 Million HIV/AIDS Sufferers Could Receive Anti-Retroviral Therapy by 2005*, at <http://www.who.int/inf/en/pr-2002-58.html> (July 9, 2002).

259. Such a pill could combine AZT (Zidovudine), 3 TC (lamivudine) and a third drug such as nevirapine, abacavir, or efavirenz depending on the particular patient. John S. James, 'Trizivir' Approved: Three Existing Drugs in One, 355 AIDS TREATMENT NEWS, Nov. 17, 2000, available at <http://www.aegis.com/pubs/atn/2000/ATN35503.html>. Other drugs on the WHO's essential drugs list includes didanosine, indinavir, lopinavir, nelfinavir, ritanovir low dose, saquinavir and stavudine. *Id.*

deaths.<sup>260</sup> New research and the hope of new drugs also continue to abate fears of drug resistance.<sup>261</sup>

In addition and quite significantly contrary to the Gillespie-White & Attaran paper, which together with the Macroeconomics and Health report discussed below are cited as the leading studies supporting the proposition that poverty is the largest barrier of access to AIDS drugs,<sup>262</sup> most of the drugs on patent in Africa are not “practical as first-line treatments” in most of sub-Saharan Africa because of the need for constant monitoring as well as cumbersome dietary requirements.<sup>263</sup> Further, the AZT/3TC combination, which is the “most practical and sought after” treatment, is patented in thirty-seven out of fifty-three countries while nevirapine, a leading non-nucleoside used for preventing mother-to-child infection, is patented in twenty-five out of fifty-three countries.<sup>264</sup> In those countries, the Attaran & Gillespie-White study, when read against evidence of falling prices of generic triple-therapies, only confirms the high correlation between patents for brand-name drugs and high prices, which a more recent study tends to confirm.<sup>265</sup> When the cost of these drugs drops, African employers, particularly corporations, might be better able to buy them for their employees with HIV/AIDS.<sup>266</sup> In addition, more Africans, as well as governments in the continent, might extend coverage to more and more

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260. Donald G. McNeil, Jr., *WHO Moves to Make AIDS Drugs More Accessible to Poor Worldwide*, N.Y. TIMES, Apr. 23, 2002, at F7.

261. Theresa Agovino, *New AIDS Drug Raises Hopes, Fears*, (Aug. 22, 2003) available at [http://www.immunecentral.com/templates/info\\_template.cfm/6181/77/31](http://www.immunecentral.com/templates/info_template.cfm/6181/77/31).

262. Attaran & Gillespie-White, *supra* note 206, at 1886-92.

263. Press Release, Joint Statement by Oxfam, Treatment Action Campaign, Consumer Project on Technology (CPT), Médecins Sans Frontières (MSF) and Health GAP, *Patents Do Matter in Africa According To NGOs* (Oct. 17, 2001), at <http://www.accessmed-msf.org/prod/publications.asp?scntid=171020011428553&contenttype>.

264. *Id.*

265. Joan-Ramon Borrell & Jayashree Watal, *Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries*, CENTER FOR INT’L DEV. AT HARV. UNIV. WORKING PAPER NO. 92 (May 2002). The article concludes in part:

On the one hand, patents may constrain access to new drugs through less competition and higher prices. On the other hand, patents may promote access to new therapies by encouraging innovators to launch new drugs in low and middle-income countries. The net effect is theoretically ambiguous and, therefore, it is an empirical matter to evaluate. Our main finding is that patent rights do have a negative effect on unsubsidized access to HIV/AIDS drugs. Between 1995 and 1999, switching all HIV/AIDS drugs from a patent regime to a no patent regime would have actually increased access to therapy by 30%. However, we also find that the negative impact of patents on access differs strongly over time, and across countries with different income levels. Patents hurt access most in the early period from the date the drug is launched in the US, and in the countries of our sample with the relatively higher per capital income levels.

*Id.* at 2.

266. Brook K. Baker, *Brief Analysis of Macroeconomics and Health: Investing in Health for Economic Development*, available at <http://lists.essential.org/pipermail/ip-health/2001-December/002547.html> (last visited June 10, 2003).

people since lower prices will stretch foreign assistance and corporate health programs further since lower drug prices might mean increased volumes of the drugs would be affordable.<sup>267</sup>

Further, until relatively recently, the Bush administration has equivocated on the AIDS issue. For example, in early February 2001, Bush Chief of Staff, Andrew Card, announced that the administration would close the National AIDS policy office opened by President Clinton.<sup>268</sup> Soon thereafter, responding to criticism regarding this move, the administration announced that it would not close the office and that its commitment to the HIV/AIDS problem was a focus at the White House.<sup>269</sup> Although this was a domestic policy office, this early indecision in the administration is also reflected in its HIV/AIDS policy abroad. In April 2001, when President Bush announced his new director of the White House Office of National AIDS Policy, the office's expanded mandate was designated as incorporating the "international and national security aspects of the pandemic."<sup>270</sup> In other words, U.S. foreign policy would link its programs on combating the pandemic to national security.<sup>271</sup> This conceptualization of the pandemic was rather narrow and myopic since it gave little focus to the grave human dimensions of the pandemic particularly in sub-Saharan Africa. Little wonder then that, on the eve of the Presidential Advisory Council on HIV/AIDS meeting in mid-March 2002, a coalition of Non-Governmental Organizations (NGO) took issue with the administration's record on addressing the epidemic within the United States.<sup>272</sup> The NGO found the administration's response lacking in comprehensiveness, coordination, funding and leadership, even while increasing numbers of U.S. citizens are getting infected.<sup>273</sup> The NGO report noted that the greatest increases in infection were among African Americans and Latinos, who make up an

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267. *Id.*

268. *White House to Keep Offices on AIDS, Race Relations* (Feb. 7, 2001), at <http://www.cnn.com/2001/ALLPOLITICS/stories/02/07/wh.aids/>; Christopher Heredia, *White House AIDS, Race Relations Bloopers: Bush Says Offices Will Stay Open, After Top Aide Said They'd Close*, S.F. CHRON., Feb. 8, 2001, at A3.

269. Heredia, *supra* note 268, at A3.

270. Scott Evertz, *U.S. Targets Global AIDS Pandemic*, available at <http://usinfo.state.gov/journals/itgic/1201/ijge/gj01.htm> (last visited Aug. 28, 2003).

271. This seems to be confirmed by the White House in its September 2002 report entitled THE WHITE HOUSE, *The National Security Strategy of the United States of America* (Sept. 2002) Under Chapter IV, entitled, "Work With Others to Defuse Regional Conflicts," the policy documents stated in part "[I]n Africa, promise and opportunity sit side by side with disease, war, and desperate poverty. This threatens both a core value of the United States-preserving human dignity-and our strategic priority-combating global terror." *Id.* at 10.

272. *AIDS Report Card for the Bush Administration, Submitted by a national coalition of AIDS organizations*, (Mar. 13, 2002), available at <http://www.lambdalegal.org/cgi-bin/iowa/documents/record?record=1024>.

273. *Id.*

estimated 70% of new HIV infections.<sup>274</sup> Indeed, in the United States, the NGO report noted that HIV/AIDS was “disproportionately impacting women of color and men who have sex with men, and increasingly on older Americans and low-income persons.”<sup>275</sup>

The WHO’s Commission on Macroeconomics and Health, which was chaired by economist Jeffrey Sachs, has also argued that the United States can do better by increasing foreign aid to significantly increase access to HIV/AIDS drugs among other public health goals in developing countries.<sup>276</sup> The report observes that if the United States increased its foreign aid budget from its current levels of less than one-tenth of 1.1% of the U.S.’s GNP to two-tenths of 1%, an extra \$10 billion would be available for disease control, primary school education, clean water and other important needs in developing countries such as those of sub-Saharan Africa.<sup>277</sup> The report in essence notes that a tiny share of rich-country income would translate into eight million lives saved each year in poor countries.<sup>278</sup> Should the United States have the political will to raise its foreign aid budget to such an amount, it would in turn become a significant bargaining advantage with the European Union and Japan to get even more money towards this end. As UN Secretary General Kofi Annan has suggested, the Global AIDS Fund would need \$7 billion from the United States to be effective.<sup>279</sup> It seems that such a goal is clearly within the reach of the international community with proper leadership from the United States.<sup>280</sup> The U.S. initiative pledging \$15 billion over five years is a big first step in that direction. Although this is a significant pledge, it is by no means enough to win the battle against HIV/AIDS as Jeffrey Sachs noted in response to the initiative.<sup>281</sup>

From the perspective that the Bush administration had previously only promised a mere \$500 million to the Global AIDS Fund and had failed to support Congressional efforts to raise funding levels<sup>282</sup> and eventually

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274. *Id.*

275. *Id.*

276. REPORT OF THE COMMISSION ON MACROECONOMICS AND HEALTH, MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT 11-12 (2001).

277. *Id.*

278. COMM’N ON MACROECONOMICS AND HEALTH, WHO, MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT (2001); see also Dan Rather, *Why Do We Sleep as AIDS Epidemic Continues*, HOUSTON CHRON. (March 2, 2002), available at [www.chron.com/cs/CDA/printstory.htm?editorial/outlook/1279183](http://www.chron.com/cs/CDA/printstory.htm?editorial/outlook/1279183); Jimmy Carter & Bill Gates, Sr., *Pennies a Day Can Stop Spread of AIDS*, L.A. TIMES (April 7, 2002), at M5, available at [www.latimes.com/news/opinion/commentary/la-000024730apr07.story?co](http://www.latimes.com/news/opinion/commentary/la-000024730apr07.story?co).

279. COMM’N ON MACROECONOMICS AND HEALTH, *supra* note 278.

280. C. Payne Lucas, *The Strength to Kill AIDS Lies Within U.S.*, NEWSDAY, Aug. 13, 2002, at A27.

281. *Bush Begins Trip To Five African Countries*, U.N. WIRE, July 7, 2003, available at [http://www.unwire.org/UNWire/20030707/449\\_6231.asp](http://www.unwire.org/UNWire/20030707/449_6231.asp).

282. In early June 2002, President Bush is said to have called Senator Frist, who had

blocked congress' appropriation of the \$500 million, the \$15 billion initiative is very welcome.<sup>283</sup> However, like the \$500 million initiative, which was narrowly targeted to fourteen countries and for mother-to-child transmission, the \$15 billion initiative is limited to twelve African and two Caribbean countries.<sup>284</sup> It is also laced with limitations on condom use as already noted above.<sup>285</sup> Its long-term viability is also doubtful since it is tied to the unpredictable cycle of yearly appropriations in Congress. Hopefully, unlike the miniscule \$500 million initiative,<sup>286</sup> the \$15 billion initiative will end the Bush administration's "shell-game" of re-designating existing levels of bilateral support to please the world, rather than significantly shifting policy towards addressing the epidemic and to provide leadership on this issue to the world.<sup>287</sup>

Finally, one must doubt the Bush administration's commitment to a global HIV/AIDS policy when pharmaceutical companies are some its biggest supporters and when the White House and the Republican controlled House of Representatives and the Senate have stood in the way of legislation to ensure affordable access to prescription drugs here in the United States. However, this observation ought to be measured against the fact that in July 2003, the House of Representatives did pass a bill allowing importation of drugs to address the rising costs of prescription drugs.<sup>288</sup> In addition, we must not forget that the Bush administration chose to buy out Bayer on the Ciproflaxacin drug to deal with the bio-terrorist threat related to anthrax.<sup>289</sup> The Bush administration did this in order to avoid compromising its position on refusing to allow developing countries to use compulsory or parallel licensing to address the HIV/AIDS pandemic.<sup>290</sup> In sum, the Bush

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proposed increasing levels of U.S. funding to the Global AIDS Fund to \$600 million and asked him to "offer a much lower figure." See Press Release, HEALTH ACTION AIDS (June 7, 2002); *Senate Failure on Global AIDS Fund*, available at <http://www.phrusa.org/campaigns/aids/release060902.html>. Senate Majority Leader Bill Frist returned from a ten day tour of Africa (the trip took place August and September, 2003) amidst criticism that he had held back approval of the money promised by Bush for AIDS in Africa in his 2003 State of the Union address. See HEALTHGAP, *Activists Denounce AIDS Funding Excuses: Senate Must Act to Fund Promised \$3 Billion—with at least \$1 billion for the Global Fund* (Sept. 11, 2003), available at <http://www.oneworld.net/article/view/67265/1/>.

283. Press Release, *supra* note 282.

284. Jim Lobe, *Activists Slam Bush AIDS Initiative*, INTER PRESS SERVICE (June 19, 2002), at <http://www.aegis.com/news/ips/2002/IP020611.html>.

285. Stolberg, *supra* note 190, at A13.

286. Salih Booker & William Minter, *Aid - Let's Get Real*, NATION (July 18, 2002), available at <http://www.thenation.com>.

287. Salih Booker, *Bush Plays Shell Game With African Lives* (June 24, 2002), available at <http://www.fpi.org> and <http://www.africaaction.org>.

288. ASSOCIATED PRESS, *House Backs Drug Imports to Cut Costs* (July 26, 2003), available at <http://www.iht.com/articles/104127.html>.

289. HHS PRESS OFFICE, *supra* note 175.

290. See James Thuo Gathii, *Balancing Patent Rights and Affordability of Prescription*

administration, like the Clinton administration before it, has given in grudgingly and minimally to widening access to HIV/AIDS drugs abroad at the urging of activists. Presently, the war against Iraq and the unpopularity of the United States around the world seemed to occasion a rethinking of the administration's policy on the global HIV/AIDS pandemic. It would seem that by announcing the \$15 billion initiative right before the then impending attack on Iraq with enormous international disapproval and no U.N. Security Council authority, the United States was assuaging the international community under the threat of its diminished stature. Though a welcome policy shift, the \$15 billion initiative is perhaps best understood in this context. After all, there has been no simultaneous concession made to weakening the barriers of strong patent protection to access to essential drugs.

## V. CONCLUSIONS

By beating the drumbeat of poverty, pharmaceutical companies and Western governments, such as the United States, that are opposed to making exceptions to patent protection to facilitate access to HIV/AIDS drugs to indigent populations while arguing that this is consistent with the provisions of the TRIPS Agreement, have sought to marginalize the issue of access to antiretrovirals by suggesting that solutions lie largely outside the patent regime. In this context, the world can rest reassured that the thousands who die of HIV/AIDS every day in sub-Saharan Africa are dying because they are poor, not because they did not have access to drugs. Yet, the policy of strong patent protection prevents widespread access of antiretroviral drugs to treat HIV/AIDS.

Although the direct actions of HIV/AIDS activists targeted towards leading figures of both the Clinton and Bush administrations, and notwithstanding the organized efforts of a coalition of developing country governments at the WTO has led to more humanitarian assistance towards alleviating the pandemic, the policy of strong patent protection persists. I have argued that poverty is one of the latest fads that the Bush administration has begun to deploy, particularly at the WTO, with a view to distancing the extent to which patents bar access to essential drugs. I have further demonstrated that there are many reasons to be skeptical about the emphasis that poverty has received in identifying bottlenecks of access to antiretrovirals. A major reason for such skepticism is that the poverty fad distances the attention or focus on patents and pricing in Africa. This is most evidenced by the fact that although all the members of the WTO unanimously acceded to the passage of the Doha Declaration on TRIPS and Public Health,<sup>291</sup> which recognized that the TRIPS Agreement contemplates

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*Drugs in Addressing Bio-Terrorism: An Analysis of In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 13 ALB. L.J. SCI. & TECH. 651 (2003).

291. *Africa: You Talk, We Die*, Sept. 30, 2003, available at [http://www.sas.upenn.edu/African\\_Studies/Urgent\\_Action/apic-093003.html](http://www.sas.upenn.edu/African_Studies/Urgent_Action/apic-093003.html).



a balance between the rights and interests of consumers and producers of intellectual property rights, there is yet to be even one instance of a country in Africa utilizing this flexibility to facilitate access to affordable antiretrovirals, such as through compulsory licensing. This seems to strongly suggest that the U.S.'s view of strong patent protection supported by many TRIPS-plus sanctions, such as section 301, has transformed pharmaceutical patents into impregnable private property rights. That strong patent protection, therefore, seems to enjoy an unassailable persistence, even in the face of one of the most serious public health crises of the last century, in my view, reflects lopsidedness favoring pharmaceutical profits over the lives of millions of Africans dying without dignity unnecessarily.

The variety of ways in which patents have been removed from the equation of access to essential medicines, as exemplified in the inflexibility of the U.S.'s support of strong patent protection, reflects not only the asymmetrical nature of power in international relations, but also the structural power of strong patent protection on the most vulnerable populations of the global economy. The discourse of charity and humanitarianism accompanying the uncompromising support of patents at any cost simply disguises the U.S.'s priorities in ensuring that multinational pharmaceutical companies acquire markets for their drugs without any threat to their profitability, even in the face of heart-wrenching human need.