



# **Shocking the Conscience of the World: International Norms and the Access to AIDS Treatment in South Africa**

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Shocking the Conscience of the World:  
International Norms and the Access to AIDS Treatment in South Africa

An Essay Presented

by

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to

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In partial fulfillment of the requirements

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ABSTRACT

This paper examines the emergence and institutionalization of a new international norm supporting greater access to lifesav

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### **Shocking the Conscience of the World: International Norms and the Access to AIDS Treatment in South Africa**

South Africa has the largest number of people living with HIV/AIDS in the world.<sup>1</sup> More than 95% of people infected with HIV live in the developing world, including more than 25 million in sub-Saharan Africa.<sup>2</sup> By the end of 1999, an estimated 4,100,000 people, or just under 20% of the South African population were

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<sup>1</sup>See AIDS in Africa Website (visited Apr. 20, 2002) <<http://www.avert.org/aafrica.htm>>.

<sup>2</sup>See European Parliament Resolution on Access to Drugs for HIV/AIDS Victims in the Third World, Paragraph A, 2001 O.J. (44) 343, 300-30, *available at* Eur-Lex (visited Apr.15, 2002) <<http://europa.eu.int/eur-lex/en/archive/2001/c.34320011205en.html>> [hereinafter European Parliament Resolution].

estimated to be living with HIV or AIDS.<sup>3</sup> In 1999, an estimated 250,000 people died of AIDS in South Africa.<sup>4</sup> Each 15-year-old in South Africa has a 50% risk of becoming infected and dying from AIDS,<sup>5</sup> and 1,600 people contract HIV each day in the country.<sup>6</sup> Anti-retroviral drugs have already reduced the number of AIDS deaths in Europe and the USA by 75%, but the price of these drugs keeps these medicines out of reach of millions of infected people, notably in Africa.<sup>7</sup>

In response to this looming health crisis, the South African government made legislative changes in 1998 that allowed more flexibility in the rules governing the domestic production of generic AIDS drugs and importation of foreign generic AIDS drugs. The purpose of these changes was to reduce the price of drugs so that they could become more affordable for the South African population.

Although the United States initially opposed amendments, the U.S. government came to eventually accept them, albeit in a conditional manner. This presented a “turning point in U.S. policy toward the global HIV/AIDS pandemic.”<sup>8</sup> A worldwide coalition of pharmaceutical companies, which initially responded to the legislative changes by suing the South African government in a South African court, dropped their lawsuit and reduced prices for several AIDS drugs. Over time, the positions of both the United States government and the pharmaceutical companies changed in response to an “unparalleled global coalition” supporting greater access to AIDS drugs.<sup>9</sup> This sentiment was articulated through widespread efforts and campaigns – by NGOs, international organizations, as well as in the media.

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<sup>3</sup>See AIDS in Africa Website (visited Apr. 20, 2002) <<http://www.avert.org/subadults.htm>>. The figures are estimates at the end of 1999, published by UNAIDS in the Report on the Global HIV/AIDS Epidemic June 2000. They include all people with HIV infection, whether or not they have developed symptoms of AIDS, alive at the end of 1999. The figures are estimates based on several sources of information, rather than exact counts of infections.

<sup>4</sup>See AIDS in Africa Website (visited Apr. 20, 2002) <<http://www.avert.org/subadeaths.htm>>. The figures are the estimates at the end of 1999, published by UNAIDS in the Report on the Global HIV/AIDS Epidemic June 2000. The figures are estimates based on a number of different sources of information, rather than exact counts of infections.

<sup>5</sup>See European Parliament Resolution, *supra* note 2, at para. B.

<sup>6</sup>See George Ayittey, *AIDS Scourge Saps Africa's Vitality*, The Financial Gazette, Apr. 18, 2002, available in LEXIS, Nexis Library, ALLNEWS file.

<sup>7</sup>See European Parliament Resolution, *supra* note 2, at para. C.

<sup>8</sup>J. Stephen Morrison, *U.S. Policy Towards HIV/AIDS in Africa: Momentum, Opportunities, and Urgent Choices*, in *Africa Policy in the Clinton Years: Critical Choices for the Bush Administration* 18, 13-33 (J. Stephen Morrison et al. eds., 2001).

<sup>9</sup>See Amit Sen Gupta, Jana Swasthya Abhiyan (Peoples Health Movement), India, *A Long Road to Travel: Declaration on TRIPS at Doha* (visited Mar. 1, 2002) <<http://lists.kabissa.org/pipermail/pha-exchange/2001-December/000092.html>>.

International reactions to the HIV/AIDS crisis in South Africa played a key role in the emergence and institutionalization of a new norm. This new norm can be stated as follows: even at the expense of the pharmaceutical companies' profits, developing countries should be allowed to adjust their own domestic legal regimes to allow for generic production or the importation of generics in order to make lifesaving pharmaceuticals affordable for their population. While initially rejected by pharmaceutical companies and some industrialized countries, the norm began to find acceptance over the span of less than ten years.

In the first pivotal negotiations on global access to HIV/AIDS drugs at Geneva, Switzerland in 1991 pharmaceutical companies refused to budge on the issue of patent protection.<sup>10</sup> They also did not want to lower drug prices, and argued that it was the responsibility of governments to ensure that those in need received necessary treatments. The talks ended in 1993.<sup>11</sup> Less than ten years later, pharmaceutical companies were willing to assume a different position. In 2000, five major pharmaceutical companies issued a joint statement with the UN, in which they acknowledged that "affordability is an issue in developing countries."<sup>12</sup> In 2001, the international community affirmed this commitment when over 140 countries gathered together at the World Trade Organization meetings in Doha, Qatar and approved a declaration that allows countries to override pharmaceutical patents to gain faster, cheaper access to medicines in certain situations, as when poor nations want access to patented drugs.

This paper examines the emergence and institutionalization of this new norm supporting greater access to lifesaving drugs for developing countries, particularly for HIV/AIDS drugs in sub-Saharan Africa. The first section enumerates the basic components of norm theory, which originates in political science. While political scientists have examined the emergence of international norms, such as the normative consensus against the use of landmines, this paper focuses on the international norm that developing countries should be allowed to

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<sup>10</sup>See Barton Gellman, *An Unequal Calculus of Life and Death*, Wash. Post, Dec. 27, 2000, at A1 [hereinafter *Unequal Calculus*].

<sup>11</sup>See *Unequal Calculus*, *supra* note 10, at A1.

<sup>12</sup>See *id.* at A1



adjust their own domestic legal regime to allow for generic production or the importation of goods in order to make lifesaving pharmaceuticals affordable for their population. The second section summarizes the basic international legal framework for the protection of intellectual property rights and attempts to reconcile the norm with existing international laws. The third section examines the legislative changes South Africa made in response to its HIV/AIDS crisis; the legislative response was the country's attempt to institutionalize the norm in its domestic laws. The fourth and fifth sections analyze the response to these changes by the U.S. government and a worldwide coalition of pharmaceutical companies; the U.S. and the pharmaceutical companies challenged the basis for the norm's adoption and sought the withdrawal of the law. The final sections will demonstrate that, while the norm has been institutionalized in various forms, political obstacles within South Africa as well as other practical factors have prevented its full internalization, and many segments of the population are still without affordable HIV/AIDS drugs. Furthermore, developing countries continue to face various obstacles to making legislative changes necessary to reduce drug prices.

## I. Application of Norm Theory to the Debate on Drug Prices

Norm theory provides a useful theoretical tool to understand how ideas and moral assessments can lead to political change in the international arena, including the significant shift in the international arena regarding access to HIV/AIDS drugs. Political scientists define norms as standards regarding appropriate or proper behavior. Norms embody a quality of "oughtness" or "shared moral assessment."<sup>13</sup> They "prompt justifications for action, and leave an extensive trail of communication among actors that we can study."<sup>14</sup> The key norm in this discussion is the belief that developing countries should be allowed to create flexible legal

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<sup>13</sup>Martha Finnemore and Kathryn Sikkink, *International Norm Dynamics and Political Change*, 52 *International Organizations* 887, 891 (Autumn 1998).

<sup>14</sup>*Id.* at 892.

regimes that allow generic domestic production or importation of foreign generic drugs in order to reduce the cost of pharmaceuticals needed by their population.

Scholars have proposed a three-stage process for understanding norms: norm emergence, broad norm acceptance or a “norm cascade”, and norm internalization. In the first stage of norm emergence, norm entrepreneurs “attempt to convince a critical mass of states (norm leaders) to embrace new norms.”<sup>15</sup> They call attention to issues or even “create” issues by using language that names, interprets, and dramatizes them. They face firmly embedded norms and frames that create alternative perceptions of both appropriateness and interest. Norm promoters construct “cognitive frames” that, when successful, “resonate with broader public understandings and are adopted as new ways of talking about and understanding issues.”<sup>16</sup> All norm promoters at the international level promote their norms through an organizational platform.<sup>17</sup>

Activist nongovernmental organizations have been the primary norm entrepreneurs who have marched, lobbied, editorialized, and even sued in order to increase public attention on the issue of public access to drugs. The primary organizations have included Doctors Without Borders, the Consumer Project on Technology, which was founded by Ralph Nader in 1995,<sup>18</sup> and the Global Treatment Access Campaign, which is a consortium of organizations including a South African organization called Treatment Action Campaign, ACT UP/New York, and the International Gay and Lesbian Human Rights Commission.<sup>19</sup> These activist organizations have used a variety of tools to increase awareness as well as to influence the political process. The website of the Consumer Project on Technology, which is located at [www.cptech.org](http://www.cptech.org), for example, contains an exhaustive collection of articles, official documents, and commentary regarding the pricing debate.

These norm promoters faced firmly embedded norms in the arguments offered by pharmaceutical companies. The companies have argued that infringement on their patent rights will reduce the quality and quantity of

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<sup>15</sup>*Id.* at 900.

<sup>16</sup>*Id.* at 897.

<sup>17</sup>*Id.* at 899.

<sup>18</sup>*About the Consumer Project on Technology* (visited April 1, 2002) <<http://www.cptech.org/about.html>>.

<sup>19</sup>*Global Treatment Access Campaign Website* (visited April 1, 2002) <<http://www.globaltreatmentaccess.org>>.

much-needed research and development efforts. They have also asserted that even if the cost of drugs were reduced, most countries do not have the infrastructure, personnel, and funding needed to properly distribute them and to instruct people on how to use them,<sup>20</sup> and that prevention, rather than medication, is the only genuine solution to the AIDS crisis. The pharmaceutical companies had superior resources to voice these counter-norms. They had closer connections with key U.S. government officials, as well as the money needed to lobby for needed action, to conduct high-end media campaigns, and to bring suit in South African court. In spite of the superior financial resources of the pharmaceutical companies, the activist groups were successful in helping to influence the ultimate outcome of the bilateral tug-of-war between the United States and South Africa regarding patent protection of pharmaceuticals. Norm entrepreneurs in the activist groups were vocal opponents of the U.S. government actions opposing the law, as well as the lawsuit brought by pharmaceutical companies against the government of South Africa. The norm entrepreneurs ended up capturing the attention of the press, international organizations, and politicians, and the norm became institutionalized in various government statements and international documents.

Institutionalizing a norm is a critical step between the first and second stage of international norm dynamics. The first two stages are divided by a “tipping point”, at which a critical mass of relevant state actors adopt the norm. For an emergent norm to move to the second stage, it must become institutionalized in specific sets of international rules and organizations. By clarifying what, exactly, the norm is and what constitutes violation, institutionalization contributes to the possibility of norm cascade, the second stage in norm development.<sup>21</sup>

The second stage is characterized by a more dynamic of imitation as the norm leaders attempt to socialize other states to become norm followers. More countries begin to adopt the norm even without domestic pressure for change. Norm cascades occur through a process of “international socialization” intended to in-

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<sup>20</sup>See Susan King Finston, *Patents, Poverty, and Public Health: Two Perspectives on the Treatment of AIDS in Africa*, 1 *Global Perspectives: A Forum on Business in Transition and Emerging Markets* 16, 18 (Winter 2002).

<sup>21</sup>See Finnemore and Sikkink, *supra* note 13, at 900.

duce norm breakers to become norm followers.<sup>22</sup> In the international scene, socialization involves diplomatic praise or censure, either bilateral or multilateral, which is reinforced by material sanctions and incentives. This process of “international socialization” occurred in the negotiations between developing and developed countries in the WTO meetings, during which the countries agreed to sign the Doha Declaration. In the third stage of norm internalization, norms have a “taken-for-granted quality” and “no longer are a matter of public debate.”<sup>23</sup> They become so widely accepted that conforming with the norm becomes automatic. This paper argues that while the norm of increased access to AIDS drugs has completed the first two stages of emergence and institutionalization, it has yet to realize the third stage of norm internalization. The main proponents of the alternative norm, the pharmaceutical companies, did not face a complete loss. The international statements that clarified and stated the new norm left considerable latitude for pharmaceutical companies to preserve some of their patent rights. Furthermore, those international statements are general enough to allow for future debate and change. Finally, domestic actors within South Africa have failed to take steps necessary to radically improve access.

## II. International Framework for the Protection of Intellectual Property

The Trade Related Intellectual Property Rights Agreement (“TRIPS”), the broadest international intellectual property agreement, was signed as part of the Uruguay Round of the GATT on April 15, 1994.<sup>24</sup> The TRIPS negotiations reconciled the dramatically different interests of industrialized and developing countries.

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<sup>22</sup> See *id.* at 902.

<sup>23</sup> See *id.* at 904.

<sup>24</sup> See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round, 33 I.L. M. 81 (1994) [hereinafter TRIPS Agreement].

In general, the United States and other industrialized countries favored the creation of international standards for the protection of intellectual property, while developing countries argued that intellectual property should be a matter of solely domestic concern.

#### A. International Legal Regime Prior to TRIPS

The two main intellectual property agreements preceding TRIPS were the Paris Convention for the Protection of Industrial Property and the Berne Convention on Copyrights. Originally adopted in 1883 and subsequently modified in 1967, the Paris Convention for the Protection of Industrial Property protected a variety of industrial property, including the rights of patent holders.<sup>25</sup> The Paris Convention, however, did not impose obligations on a member country to protect the rights of foreigners if the member country did not grant protection to its own nationals.<sup>26</sup> As a result, member countries could easily circumvent the Convention's requirements by universally withholding protection of intellectual property.<sup>27</sup>

Originally adopted in 1887 and most recently modified in 1971, the Berne Convention for the Protection of Literary and Artistic Works established protection for the rights of copyright owners' technical and creative material.<sup>28</sup> Like the Paris Convention, the Berne Convention was criticized for its limitations, including the failure to devise provisions for empowering intellectual property holders to enforce their rights and resolve disputes.<sup>29</sup>

Both the Paris Convention and the Berne Convention were administered by the United Nations-affiliated World Intellectual Property Organization ("WIPO"), which was established by the Stockholm Convention

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<sup>25</sup>See Frank Romano, International Conventions and Treaties, 536 PLI/Pat 545, 557 (1998), *cited in* Naomi Bass, *Note: Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21<sup>st</sup> Century*, 34 Geo. Wash. Int'l L. Rev. 191, 195 n. 18-20 (2002).

<sup>26</sup>See *id.*

<sup>27</sup>See *id.*

<sup>28</sup>See Romano, *supra* note 25, at 552.

<sup>29</sup>See *id.* at 553.

of 1967.<sup>30</sup> WIPO failed, however, to create an effective regime for the protection of intellectual property,<sup>31</sup> which led industrialized countries, such as the United States, to seek the inclusion of intellectual property issues at the Uruguay Round negotiations of the General Agreement on Tariffs and Trade (“GATT”).<sup>32</sup> The position of the United States was strongly influenced by the pharmaceutical industry. Pharmaceutical industry groups played a key role in advising the United States Trade Representative (“USTR”) throughout the negotiations on TRIPS.<sup>33</sup> They argued that patent protection was important for two key reasons: first, industry representatives contended that inadequate patent protection cost U.S. manufacturers billions of dollars in annual sales.<sup>34</sup> Second, they argued that strong intellectual property protections would promote economic development; patent rights would benefit developing countries by encouraging foreign and domestic investment in research and by enabling high technology companies to engage in technology transfer with them.<sup>35</sup>

Developing countries strongly favored WIPO negotiations over revisions to international intellectual property obligations.<sup>36</sup> Until 1989, countries such as India, Brazil, Argentina, and Thailand had opposed even the inclusion of the issue of intellectual property on the multilateral trade negotiating agenda because, they argued, the subject of intellectual property rights was not a trade issue.<sup>37</sup> Domestic laws on intellectual property should not be linked with trade, they insisted, and countries should be permitted to develop their

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<sup>30</sup> See Theresa Beeby Lewis, *Patent Protection for the Pharmaceutical Industry: A Survey of Patent Laws of Various Countries*, 30 Int’l Law. 835, 841-42 (1996).

<sup>31</sup> See Bass, *supra* note 25, at 195.

<sup>32</sup> See Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. Pa. J. Int’l Econ. L. 1069, 1078 (1996).

<sup>33</sup> See Robert Weissman, *Patent Plunder: TRIPping the Third World*, Multinational Monitor, at 8 (Nov. 1990).

<sup>34</sup> See Al Wyss, *Patent Protection Winning New Round*, Chemical Marketing Rep., Mar. 19, 1999, at SR 22 (citing many of the studies used by the industry), *cited in* Weissman, *supra* note 32, at 1086 n. 95.

<sup>35</sup> See Richard T. Rapp and Richard P. Rozek, *Benefits and Costs of Intellectual Property Protection in Developing Countries*, J. of World Trade, Oct. 1990, at 75, 77-81.

<sup>36</sup> See Craig Edgar, Note, *Patenting Nature: GATT on a Hot Tin Roof*, 34 Washburn L. J. 76, 98 n. 54 (1994).

<sup>37</sup> See Gupta, *supra* note 9.

intellectual property laws in accordance with their own stage of economic development and technological progress.<sup>38</sup> Developing countries feared that laws providing strong patent protection would threaten the ability of developing countries to “catch up” to already-developed countries, such as Japan and Canada, whose economic development greatly benefited from weak patent protection of technology.<sup>39</sup> According to developing countries, it was unfair to impose a uniform patent structure upon all countries of the globe, irrespective of their stage of development.<sup>40</sup>

## B. Overview of TRIPS

In spite of opposition from developing countries, TRIPS was passed during the GATT negotiations. Expanding upon existing obligations under the Paris Convention, the Berne Convention, and WIPO, TRIPS establishes minimum protection standards for copyrights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits, and undisclosed information including trade secrets and test dates.<sup>41</sup> TRIPS is a major departure from preexisting conventions on intellectual property rights in that it contains detailed provisions on enforcement: the Agreement stipulates specific obligations related to evidence, injunction, damages, counterfeiting, and penalties for infringement.<sup>42</sup> Member states, and not private parties, can address non-compliance with TRIPS obligations under the multilateral procedures established by the Dispute Settlement Understanding.<sup>43</sup>

TRIPS sets forth the minimum standards to be applied by all members of the WTO. Member countries cannot, in the specific areas and issues covered by the Agreement, confer a lower level of protection than provided under the Agreement.<sup>44</sup> At the same time, members cannot be obliged to provide “more extensive”

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<sup>38</sup>See *id.*

<sup>39</sup>See *id.*

<sup>40</sup>See *id.*

<sup>41</sup>See Carlos M. Correa, Intellectual Property Rights, the WTO, and Developing Countries: The TRIPS Agreement and Policy Options 1 (2000).

<sup>42</sup>See Correa, *supra* note 41, at 2.

<sup>43</sup>See *id.*

<sup>44</sup>See Correa, *supra* note 41, at 8.

protection.<sup>45</sup> In accordance with Article 1 of the Agreement, “Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provision of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”<sup>46</sup>

Developing countries negotiated with industrialized countries for a transitional arrangement, under which developing countries would have additional time until which TRIPS obligations became applicable.<sup>47</sup> Developing countries have five years after the date of entry into force of the WTO Agreement to apply the obligations relating to intellectual property protection. The obligations concerning national and most-favored nation treatment become applicable one year after the date of entry into force of the WTO Agreement.<sup>48</sup> A further five years is contemplated for countries that are bound to introduce patent protection in areas of technology not so protected in their territory on the general date of application of the TRIPS Agreement for these countries.<sup>49</sup>

Despite the arguments of developing countries, the final TRIPS Agreement ultimately did contain U.S.-style patent laws.<sup>50</sup> Signatories to TRIPS must provide patent protection for inventions “in all fields of technology.”<sup>51</sup> An exception to this is that patent need not be granted for “diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.”<sup>52</sup> Although this phrase could be construed to mean that drugs need not be protected by patents, Article 70(8) of TRIPS requires member countries to set up a means of collecting applications for pharmaceutical patents. The rights granted under patents include the

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<sup>45</sup>TRIPS Agreement, *supra* note 24, at art. 1.

<sup>46</sup>*Id.*

<sup>47</sup>*See* Correa, *supra* note 41, at 9.

<sup>48</sup>*See* TRIPS Agreement, *supra* note 24, at art. 65.2

<sup>49</sup>*See id.* at art. 65.4.

<sup>50</sup>*See* Weissman, *supra* note 32, at 1096.

<sup>51</sup>TRIPS Agreement, *supra* note 24, at art. 27(1).

<sup>52</sup>TRIPS Agreement, *supra* note 24, at art. 27(3)(a).



right to prevent third parties from making, using, offering for sale, selling, or importing the product without the consent of the patentee.<sup>53</sup>

However, there are a number of exceptions and loopholes that give countries substantial leeway, although not as much as they had before TRIPS, to experiment with different patent schemes.<sup>54</sup> The two loopholes that have figured prominently in the debate over access to pharmaceuticals are ones that provide for parallel imports and compulsory licensing.

### C. TRIPS Provisions on Parallel Imports

Parallel importing occurs when a distributor buys a product in a country where it is sold at a low price, with or without pa

Parallel importers normally sell the product for less than the patentee.<sup>56</sup> The issue of parallel imports generated lots of disa

Some commentators believe that because TRIPS fails to address the issue of parallel licensing, it is therefore permissible un

The relevant provisions of TRIPS that pertain to parallel imports are Article 6 and Article 28:Article 6:

Article 6 of TRIPS says that “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”<sup>59</sup> The phrase “exhaustion of patent rights” refers to the practice of parallel

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<sup>53</sup>TRIPS Agreement, *supra* note 24, at art. 28(1)(a).

<sup>54</sup>See Weissman, *supra* note 32, at 1096.

<sup>55</sup>See Alexander J. Stack, *TRIPS, Patent Exhaustion and Parallel Imports*, 1 J. of World Intell. Prop., 657, 666-667 (1998).

<sup>56</sup>See David Perkins, et al., *Exhaustion of Intellectual Property Rights*, 574 PLI/Pat. 41, 46 (1999).

<sup>57</sup>See Claude E. Barfield and Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 Fordham Intell. Prop. Media & Ent. L. J. 185, 190 (1999).

<sup>58</sup>See Duane Nash, *South Africa's Medicines and Related Substances Control Amendment Act of 1997*, 15 Berkeley Tech. L.J. 485, 494 (2000).

<sup>59</sup>TRIPS Agreement, *supra* note 24, at art. 6.

importing. According to the doctrine of exhaustion, a patentee has no right to control the use or resale of goods that he has put on the market or has allowed a licensee to market.<sup>60</sup> Since Article 6 specifies that nothing in TRIPS addresses this issue, it suggests that the decision of whether to permit parallel importing is left to each individual country. If a country decides that the first sale of a product anywhere in the world exhausts the rights of a patentee, then parallel importing is allowed. However, if a country decides that the first sale of a product within the country in which it is patented exhausts the patentee's rights, then parallel importing is not allowed.<sup>61</sup>

#### Article 28:

However, there is considerable debate about the meaning of Article 6. Article 28 of TRIPS is often used to shed light on the meaning of Article 6.<sup>62</sup> Under Article 28, a patentee has exclusive right under TRIPS "to prevent third parties not having his consent from acts of: making, using, offering for sale, selling or importing."<sup>63</sup> This provision might be construed to limit parallel importing, but a footnote to this provision says that it is subject to provisions of Article 6. Therefore, the exclusive right of importation in Article 28 is limited by the principle of international exhaustion. Interpreting Articles 6 and 28 in conjunction, whenever a patentee's rights are exhausted in any country, he has lost the right to prevent importation by a non-authorized party.<sup>64</sup>

### **D. TRIPS Provisions on Compulsory Licenses**

Compulsory licenses are permitted under TRIPS under certain conditions. Compulsory licensing occurs when a country tha

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<sup>60</sup>Correa, *supra* note 41, at 81.

<sup>61</sup>*See id.*

<sup>62</sup>*See* Rosemary Sweeney, *Comment: The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Coalition*, 9 Pac. Rim L. & Pol'y 445, 456 (2000).

<sup>63</sup>TRIPS Agreement, *supra* note 24, at art. 28.

<sup>64</sup>*See* Correa, *supra* note 41, at 84.

<sup>65</sup>Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349 (1993), reprinted

Article 31 Compulsory licenses are permissible under TRIPS under some situations. Article 31, which is entitled “Other Use Before compelling a patent-holder to license his rights to generic manufacturers in exchange for monetary compensation, a g The right holder must be paid adequate remuneration taking into account the economic value of authorization.”<sup>68</sup> The compulsory license should be authorized “predominantly for the use of the domestic market of the Member authorizing Article 31 specifies that any compulsory license is limited to the purpose for which it is authorized,<sup>70</sup> is non-exclusive,<sup>71</sup> and is non-assignable.<sup>72</sup> Article 31, however, does not explicitly define the qualifying events that justify the application of c According to Article 31(b), the requirement of obtaining authorization from the patent holder can be waived in the case of In such a situation, however, the patent holder should be notified “as soon as reasonably practicable.”<sup>75</sup> In the case of publi Compulsory licensing presents a unique opportunity for countries encountering national health crises such as AIDS to manu There are a number of other articles in TRIPS under which developing countries could create more flexible patent regimes: Article 30 Article 30 potentially provides very broad exceptions to the patent requirements of TRIPS. It permits members to There are three limitations to this provision: exceptions must be “limited.”<sup>80</sup> Second, the exceptions cannot “unreasonably And third, the exception must not “unreasonably prejudice the legitimate interests of the patent owner.”<sup>82</sup> Article 27 Article 27 permits exclusion from patentability where necessary to protect public health and the environment.<sup>83</sup>

in International Intellectual Property Law, (Anthony D’Amato & Doris Estelle Long, eds., Kluwer Law International 1997) at 357 n. 6.

<sup>66</sup>TRIPS Agreement, *supra* note 24, at art. 31.

<sup>67</sup>*Id.*, at art. 31(b).

<sup>68</sup>*Id.*, at art. 31(h).

<sup>69</sup>*Id.*, at art. 31(f).

<sup>70</sup>*Id.*, at art. 31(c).

<sup>71</sup>*Id.*, at art. 31(d).

<sup>72</sup>*Id.*, at art. 31(e).

<sup>73</sup>Karl Vick, *African AIDS Victims Losers of a Drug War*, Wash. Post, Dec. 4, 1999, at A 18, *cited in* Bass, *supra* note 25, at 199 n. 53.

<sup>74</sup>TRIPS Agreement, *supra* note 24, at art. 31(b).

<sup>75</sup>*Id.*

<sup>76</sup>*Id.*

<sup>77</sup>See Vivian Hoffman, *Health Groups Say Poor Nations Need Access to Generic Drugs*, Boston Globe, Nov. 27, 1999, at A15.

<sup>78</sup>TRIPS Agreement, *supra* note 24, at art. 8, para. 1.

<sup>79</sup>*Id.* at art. 30.

<sup>80</sup>*Id.*

<sup>81</sup>*Id.*

<sup>82</sup>*Id.*

<sup>83</sup>TRIPS Agreement, *supra* note 24, at art. 27, para. 2.

However, the denial of patentability must be linked to a denial of commercial exploitation.<sup>84</sup> This provision, commonly known

#### E. Summary

In sum, TRIPS does *not* contravene a norm favoring increased access to life-saving drugs. Arguably, its provisions allow for parallel imports and compulsory licensing, which have been used successfully in the past to lower the price of drugs. However, although TRIPS does not explicitly contradict a norm favoring increased access to drugs, many countries have not successfully invoked TRIPS provisions to reduce drug prices. This is because the U.S. government, heavily influenced by pharmaceutical interests, has used trade pressures on developing countries, thereby limiting the extent to which developing countries can make liberal use of TRIPS provisions to reduce drug prices. The United States has also argued for a very restrictive interpretation of these provisions.

Thailand's experience illustrates this point. Thailand's 1992 Amendments provided patent protection for all pharmaceutical drugs for the first time in the country's history, but provided liberal opportunities for compulsory licensing and parallel importing.<sup>86</sup> According to commentators, these amendments were *legal* under TRIPS; however, the United States pressured the country to pass 1999 amendments, which narrowed opportunities for compulsory licensing and virtually eliminated parallel importing.<sup>87</sup> These amendments were made in response to U.S. pressure for fear that the Thai government would lose access to the U.S. market, Thailand's principal export market.<sup>88</sup>

Prior to the South African crisis, international norms favored access to life-saving drugs, but the patent rights of pharmaceuticals, and the receptiveness of the U.S. government to these concerns, greatly limited the influence these norms had on actual outcomes.

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<sup>84</sup> *Id.*.

<sup>85</sup> See Weissman, *supra* note 32, at 1101.

<sup>86</sup> See Sweeney, *supra* note 62, at 449 n. 36-38.

<sup>87</sup> See *id.* at 462.

<sup>88</sup> See *id.*

### III. South Africa's Legislative Response to the HIV/AIDS Crisis

#### A. Background

South Africa has the largest number of people living with HIV/AIDS in the world.<sup>89</sup> By the end of 1999, an estimated 4,100,000 people, or 19.94% of the South African population were estimated to be living with HIV or AIDS.<sup>90</sup> In 1999, an estimated 250,000 people died of AIDS in South Africa.<sup>91</sup>

There are multiple roots of the HIV/AIDS crisis in South Africa. After Nelson Mandela came to power in South Africa, his party, the African National Congress, made a variety of legal reforms.<sup>92</sup> However, the country's patent laws were left intact.<sup>93</sup> This strong system of patent protection left South Africa at a disadvantage in treating people with HIV/AIDS, as its economy was too small to provide jobs that would enable people to afford costly medicines.<sup>94</sup> The country's patent laws were too strong for the country to easily manufacture cheap, generic AIDS medicines, as countries like Brazil, India and Thailand have been able to do.<sup>95</sup> Furthermore, partly due to the difficulties of administering the state using a bureaucratic apparatus inherited from the apartheid regime, the ANC government failed to adequately respond to the HIV/AIDS crisis when it was in an incipient stage.<sup>96</sup> Others factors, such as the reluctance of the country's leaders to candidly address the scope of the problem greatly contributed to the problem. Mandela himself was reluctant to publicly address the AIDS/HIV crisis and never uttered the word "AIDS" in public while he was president.<sup>97</sup> President Thabo Mbeki, who was elected to succeed Mandela in 1999, has raised controversy by

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<sup>89</sup> See AIDS in Africa Website, *supra* note 1.

<sup>90</sup> See AIDS in Africa Website, *supra* note 3.

<sup>91</sup> See AIDS in Africa Website, *supra* note 4.

<sup>92</sup> See Jon Jeter, *Global Issues Dog S. Africa on AIDS*, Wash. Post, Apr. 20, 2001, p. A01 [hereinafter *Global Issues Dog S. Africa*].

<sup>93</sup> See *id.*

<sup>94</sup> See *id.*

<sup>95</sup> See *id.*

<sup>96</sup> See Jon Jeter, *S. Africa's Advances Jeopardized by AIDS*, Wash. Post, July 6, 2000, p. A01.

<sup>97</sup> See Andrew Maykuth, *Companies Challenge Influx of Generic AIDS Drugs*, Philadelphia Inquirer, Mar. 7, 2001, available in LEXIS, Nexis Library, NEWS File.

publicly denying that HIV causes AIDS as well as questioning the effectiveness of AIDS medications. Mbeki has also championed government research into a bogus AIDS cure called Virodene.<sup>98</sup>

#### B. 15(C) of the Medicines and Related Substances Act

In an attempt to “rationalise the use of our limited resources and to thereby

extend the reach of our health services,” the South African government embarked on a review of drug policy in 1996. This review resulted in the finalization of amendments to the Medicines and Related Substances Act (“Medicines Act”) in October 1997. South Africa’s patent laws are codified in the Medicines and Related Substances Act. The amendments to the Medicines Act addressed a range of issues, including the streamlining of registration and regulation procedures, the creation of secure and efficient methods of distribution, and the “rational” prescribing and dispensing of drugs.<sup>99</sup> On December 12, 1997, President Mandela signed the amendments into law.<sup>100</sup> Under Section 15(C) of the Medicines and Related Substances Control Act, “the minister [of health] may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public,” and in particular may, under Section 15(C)(a) do the following:

notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent<sup>101</sup>

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<sup>98</sup>*See id.*

<sup>99</sup>South Africa Comments to WHA Executive Board on Drug Strategy (visited March 10, 2002) <<http://lists.essential.org/pharm-policy/msg00005.html>> [hereinafter South Africa Comments].

<sup>100</sup>Consumer Project on Technology, Appendix B: Time-line of Disputes over Compulsory Licensing and Parallel Importation in South Africa, Version 1.03 (August 5, 1999) (visited Apr. 12, 2002) <<http://www.cptech.org/ip/health/sa/sa~timeline.txt>> [hereinafter Timeline of Disputes].

<sup>101</sup>Text of Amendment 15(C) to South Africa’s Medicines and Related Substances Act, (visited Mar. 10, 2002) <<http://lists.essential.org/pipermail/pharm-policy/2001-January/000607.html>> [hereinafter Text of Amendment 15(C)].

Various scholars, the U.S. Congress, and some European countries have interpreted this provision to allow for compulsory licensing, as well as a full-scale infringement of patent rights.<sup>102</sup> The media has also taken this viewpoint. Some interpret this provision as giving the Minister the power to permit compulsory licensing of pharmaceuticals, so long as the product was initially marketed by the owner or with the owner's consent, but without any other express limitation.<sup>103</sup> They read this provision as empowering the Minister of Health to "compel a particular drug's patentholder to license another company to produce its drugs, if that can be done cheaper than buying them from the patentholder," provided the drug was initially marketed by the patentee or with the patentee's consent, and the drug does not have other expressed restrictions.<sup>104</sup>

However, others read 15(C)(a) in a more limited fashion. According to South Africa's Minister of Health at the time, Dr. Nkosazana Zuma, 15(C)(a) is aimed at permitting parallel imports of medicines.<sup>105</sup> The contentious part of Section 15(C)(a) is the statement that pharmaceutical patent rights "shall not extend to acts in respect of such medicine which has been put *onto the market*" (emphasis added). Interpreted literally, this law denies patent holders any benefits of patent protection once they begin to sell their drugs onto the market and allows the Minister of Health to authorize production of a drug that is an exact copy of the patented product. This means that the Minister of Health can choose to abrogate patent rights whenever the Minister deems it to be in the best interest of the public's health.

According to James Love, an activist with the organization Consumer Project on Technology, the Minister and Directors of Health have indicated that earlier proposals for compulsory licensing were considered, but were later dropped from the regulations. According to Love, the new proposed regulations for the African

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<sup>102</sup>Donald G. McNeil, Jr., *South Africa's Bitter Pill for World's Drug Makers*, N.Y. Times, Mar. 29, 1998, at Section 3, page 1.

<sup>103</sup>See Nash, *supra* note 58, at 492.

<sup>104</sup>See Rosalyn S. Park, *Note: The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 Minn. J. Global Trade 125, 136 n. 80 (2002).

<sup>105</sup>See McNeil, *supra* note 102, at 1.

Medicines Act, announced on June 4, 2001, also do not provide for compulsory licensing, or for other ways to authorize the import of generic equivalents of drugs protected by patent in South Africa.<sup>106</sup> However, it is clear that some have interpreted 15(C)(a) to allow for compulsory licensing. Some officials within the South African government have expressed this view as well. In comments made by South Africa to WHA Executive Board on Revised Drug Strategy, the government “passed legislation to enable South Africa to parallel import pharmaceuticals and to allow for the issuing of non-exclusive compulsory licenses.”<sup>107</sup> On balance, 15(C)(a) *does* seem to empower the government of South Africa to issue compulsory licenses, although it is not clear why the drafters of the legislation did not use more precise language.

Section 15(C)(b) of the new law explicitly reverses the prohibition on parallel imports contained in the 1978 Patents Act of South Africa. It allows the minister to do the following:

prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported.<sup>108</sup>

Under this section, “a medicine which is available abroad” and which is “identical to one registered by the same manufacturer in South Africa” need not be the subject of a separate registration and may therefore be imported and sold in competition with the medicine which is the subject of the local registration.<sup>109</sup> This

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<sup>106</sup>Statement by James Love (visited April 1, 2002) <<http://www.cptech.org/ip/health/sa/>>.

<sup>107</sup>See South Africa Comments, *supra* note 99.

<sup>108</sup>Text of Amendment 15(C), *supra* note 101.

<sup>109</sup>See Tony Hooper, Peter Davies, *The Medicines and Related Substances Control Amendment Bill (B30-97) and Its Effect on Intellectual Property Rights* <<http://www.spoor.co.za/lib/genericdrugs.html>>, cited in David Benjamin Snyder, *Comment: South Africa's Medicines and Related Substances Control Amendment Act: A Spoonful of Sugar or a Bitter Pill to Swallow?*, 18 Dick. J. Int'l L. 175, 187 n. 83 (1999).



provision is aimed at increasing local price competition and lowering prices by allowing parallel importation, or the importation of drugs from other countries where they are cheaper. This section also allows the Minister of Health to threaten to begin parallel importation of a manufacturer's drugs from other countries if the local prices do not conform with rates abroad.<sup>110</sup>

### C. Legality of 15(C) under TRIPS

Many commentators believe that these legislative changes are legal under TRIPS. While there is divided opinion as to whether 15(C)(a) refers to compulsory licensing or parallel imports, this paper will interpret 15(C)(a) as a compulsory licensing provision. This interpretation is fitting because most commentators, including journalists and academics, have read 15(C) to allow for compulsory licensing. Also, 15(C)(b) is clearly a parallel importing provision, and thus if 15(C)(a) refers to parallel importing instead of compulsory licensing, then the legality of 15(C)(a) would be addressed anyway in the discussion of the legality of 15(C)(b) under TRIPS.

The compulsory licensing provision of the Medicines Act is not invalid per se under TRIPS. The Act's provision is less restrictive than TRIPS, and it does not specifically address the conditions required under TRIPS' compulsory licensing provision. However, the Act's ambiguous wording could be construed to be both in accordance with or in conflict with TRIPS. If, for instance, the Minister of Health interprets the Act within the context of TRIPS, and abides by the conditions described in Article 31 of TRIPS, then the compulsory license would not violate TRIPS. If, however, the Minister of Health enforced a compulsory licensing provision in the absence of any prior attempt to obtain the license on reasonable commercial terms, without a licensing fee, or without the possibility of judicial review, then the compulsory license would be valid under the Act but would violate TRIPS.<sup>111</sup>

<sup>110</sup>See Jacob Dlamini, Erwin Defends Drugs Law, Suggests WTO Intervention, *Bus. Day (S. Afr.)*, Oct. 22, 1997, at 2, *cited in* Snyder, *supra* note 109, at 187 n. 86.

<sup>111</sup>See Nash, *supra* note 58, at 494.

TRIPS fails to explicitly permit parallel importing, although some commentators believe that TRIPS permits this practice of purchasing goods in a foreign market and later reselling them in the domestic market. In the absence of a clear statement on parallel importing, the Act's provision on parallel importing is legal under TRIPS. Parallel importing remains an entirely domestic legal concern and the South African government is free to enact any parallel importation scheme that it chooses.<sup>112</sup>

Thus, provided the Minister of Health issues compulsory licenses within the restrictions set forth in the TRIPS Agreement, then neither the compulsory licensing provision nor the parallel imports provision of the Medicines Act violates TRIPS. Both can be interpreted to be consistent with TRIPS, as TRIPS allows for compulsory licensing under Article 31, parallel imports under Article 6, as well as some flexibility with patent laws under Articles 8, 27, and 30.

#### IV. The United States Response to 15(C) of the Medicines Act

There were two aggressive international responses to 15(C) of the Medicines and Related Substances Act. One was the direct application of U.S. government pressure on the South African government to change the law or to limit its scope. The other was a lawsuit brought by nearly 40 pharmaceutical companies in a South African court against the South African government. Both these responses were related. The pharmaceutical companies were influential in determining the response of the U.S. government, and the U.S. withdrawal of its original opposition to 15(C) contributed to the withdrawal of the pharmaceutical companies' lawsuit. This section will focus on each response separately in order to understand and describe the effects of international

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<sup>112</sup>*See id.*

pressures on the relevant actors. The U.S. response was not the only diplomatic response to the law. Other countries, such as some in Western Europe, also applied diplomatic pressure against the law. This section, however, will focus on the U.S. response because of the disproportionate influence of the U.S. government on South Africa.<sup>113</sup>

### A. Opposition to the Law

The response to the lawsuit on the part of pharmaceutical companies and the U.S. government was swift. Pharmaceutical companies contacted legislators as well as the United States Trade Representative (“USTR”) to apply pressure on South Africa to change the law to comply with pharmaceutical patents. Congress responded to these pressures. In early 1999, for instance, Rep. Rodney P. Frelinghuysen (R.-N.J.) sponsored a successful effort to cut off aid to South Africa until the State Department submitted a report on the government’s “assiduous, concerted campaign” to repeal the South Africa law.<sup>114</sup> Congress made future aid to South Africa dependent on the Secretary of State’s issuance of a report summarizing U.S. government efforts to work with South Africa to have the Act repealed.<sup>115</sup> Public Law 105-277 from the 105<sup>th</sup> Congress provided that:

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<sup>113</sup>See United States Department of State, U.S. Government Efforts to Negotiate the Repeal, Termination, or Withdrawal of 15(C) of the South African Medicines and Related Substances Act of 1965 (visited Apr. 15, 2002) <<http://www.cptech.org/ip/health/sa/stdept-feb51999.html>> [hereinafter State Department Report] (finding that “European Governments preferred to let the US Government take the lead in demarching the South African Government on pharmaceutical patent protection” but that “French President Chirac raised France’s concerns during his July 1998 state visit to South Africa and the Swiss and German presidents also raised the issue privately with Deputy President Mbeki”).

<sup>114</sup>See Barton Gellman, *Gore in Conflict of Health and Profit*, Washington Post, May 21, 2000, at A1 [hereinafter *Gore in Conflict*].

<sup>115</sup>See Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, 112 Stat. 2681, 2681-155 (1998). Cited in Nash, *supra* note 58, at 496.

None of the funds appropriated under this heading may be made available for assistance for the government of South Africa, until the Secretary of state reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(C) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997.<sup>116</sup>

The U.S. position towards the law, cogently expressed in a State Department report, was that the law was inappropriately

The report conceded that South African government officials gave assurances that "there was no intention to use the author

Nevertheless, the report found that "provisions of 15(C) authorize action clearly inconsistent with South Africa's obligation

The statement also asserted that "under the terms of the TRIPS agreement, disputes related to parallel importation are no

The report stated that a broad-based coalition of federal government agencies were engaged in a campaign against the law:

*All relevant agencies of the U.S. Government* – the Department of State together with the Department of Commerce, its U.S. Patent and Trademark Office (USPTO), the Office of the United States Trade Representative (USTR), the National Security Council (NSC) and the Office of the Vice President (OVP) – have been engaged in an assiduous, concerted campaign to persuade the Government of South Africa (SAG) to withdraw or modify the provisions of Article 15(C) that we believe are inconsistent with South Africa's obligations and commitments under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights. (emphasis added)<sup>121</sup>

Attempts by the pharmaceutical industry to voice their concerns to USTR,

which began even before formal passage of the law, also began to pay off. On April 30, 1998, the USTR designated South Africa a Special 301 "watch list" country during USTR's annual review of intellectual property protection.<sup>122</sup> Section 301 threatens trade sanctions against any trade partner that fails to provide "adequate and effective protection of intellectual property rights" or denies "fair and equitable market access to United States persons who rely upon intellectual property protection."<sup>123</sup> The USTR must list

<sup>117</sup>See State Department Report, *supra* note 113.

<sup>118</sup>See *id.*

<sup>119</sup>See *id.*

<sup>120</sup>See *id.*

<sup>122</sup>See Patrick Bond, Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians, 29 Int'l J. Health Services, 765, 771 (1999).

<sup>123</sup>Trade Act of 1974, Pub. L. No. 93-618, 301-09. 88 Stat. 1978, 2041 (1975) (amended by Omnibus Trade and Competi-

such suspect countries within thirty days of issuing its yearly National Trade Estimate Report and must subsequently investigate these countries.<sup>124</sup> Investigation of a country can also be precipitated at the request of an interested party, often a trade group that claims its intellectual property rights have been violated in the country in question. Countries are classified as 1) priority watch countries (for the most egregious violations; 2) priority watch list countries (for lax protection of intellectual property); or 3) watch list countries (for minor violations). Investigations are intended to lead to negotiations, but USTR may increase import duties or impose other restrictions on imports if a priority country does not later its intellectual property policies.<sup>125</sup>

The USTR decision to designate South Africa a “watch list” country was based largely on the impact of 15(C) “not only in the South African market but also due to its global precedent and the undermining of WTO principles.”<sup>126</sup> The USTR report dated April 30, 1999 included the following: “South Africa’s Medicines Act appears to grant the Health Minister ill defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights.”<sup>127</sup> The report called on the South African government to do the following:

We call on the Government of South Africa to bring its [intellectual property rights] regime into full compliance with TRIPS before the January 1, 2000 deadline . . . and clarify that the powers granted in the Medicines Act are consistent with its international obligations and will not be used to weaken or abrogate patent protection.<sup>128</sup>

In the previous year, trade officials at the USTR had already placed South Africa on a “watch list” of countries known to disregard intellectual property rights. The State Department, USTR, and the Department of Commerce also decided to withhold preferential tariff treatment for certain South African exports. On June

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tiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107, 1164 (codified in scattered sections of 19 U.S.C. (1988)). Cited in Sweeney, *supra* note 62, at footnote 129.

<sup>124</sup>19 U.S.C. 2412(b)(2)(A).

<sup>125</sup>19 U.S.C. 2242(b)(2)(B), (f)(2)(A).

<sup>126</sup>See State Department Report, *supra* note 113.

<sup>127</sup>See United States Trade Representative, 1999 Report of the United States Trade Representative <<http://www.ustr.gov/releases/1999/04/99-41.html>>. Cited in Nash, *supra* note 58, at 495 n. 61.

30, 1998, the White House announced that four items, for which South Africa had requested preferential tariff treatment under the Generalized System of Preferences (“GSP”) program, would be held in abeyance pending “adequate progress on intellectual property protection in South Africa.”<sup>129</sup> The United States adamantly opposed the Medicines Act’s deference to the South African Health Minister, condemning the Minister’s “sweeping authority to abrogate patent rights for pharmaceuticals.”<sup>130</sup>

During the August 1998 U.S.-South Africa Binational Commission meetings in Washington, Vice President Gore made intellectual property protections of pharmaceutical patents a key issue in his discussions with Deputy President Thabo Mbeki. They agreed on a government-to-government negotiated solution, and the USTR was chosen to lead the U.S. government’s negotiation efforts.<sup>131</sup> Suspended GSP benefits would be restored as the negotiations made progress.<sup>132</sup>

During the fall of 1998, the South African parliament drafted and considered a new medicines law that would replace the existing Medicines Act, including the amendments that the United States found to be objectionable. In spite of U.S. objections to 15(C) of the Act, the parliament passed a bill with provisions identical to 15(C) in November 1998.<sup>133</sup>

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<sup>129</sup>See State Department Report, *supra* note 113. See also Sweeney, *supra* note 62 (explaining that under the GSP, the President has discretion to grant duty-free treatment to “any eligible article from a beneficiary developing country. Among other things, the president considers whether the beneficiary developing country is providing adequate and effective means under its laws for foreign nationals to secure, to exercise, and to enforce exclusive rights in intellectual property.”)

<sup>130</sup>See Gary G. Yerkey, *USTR Says South Africa Agrees to Provide WTO-Consistent Patent Protection for Drugs*, 16 Int’l Trade Rep (BMA) 1541, 1541 (Sept. 22, 1999).

<sup>131</sup>See *Gore in Conflict*, *supra* note 114.

<sup>132</sup>See State Department Report, *supra* note 113.

<sup>133</sup>See *id.*

## B. Change in the Position of the United States Government

The United States government's position was clear: it opposed the amendments and wanted the South African government to change them or at least to clarify that they would be administered in a manner that complies with TRIPS. However, from the beginning of the latter half of 1998 and accelerating into 1999, "a surge of activism" emerged in Congress and the administration that would change U.S. trade policy and elevate U.S. rhetorical and financial commitments to battling HIV/AIDS overseas.<sup>134</sup> This policy change occurred partly in response to widespread public and international support for the developing nation's efforts to increase access to drugs.

While initially Gore represented the interests of pharmaceutical companies in negotiations with the South African government, he was among the earliest to break with the position of the pharmaceutical lobby.<sup>135</sup> There were signs that senior policymakers within the Clinton administration were focusing more on the AIDS issue and were coming to favor wider access to HIV/AIDS drugs, even at the expense of intellectual property rights.<sup>136</sup> Internal debates on how to approach the South African legislation were arising, and the coalition within the U.S. government opposing 15(C) of the Medicines Act was beginning to disintegrate. In March 1999, for instance, the USTR, backed by Commerce and State, proposed to escalate the dispute with South Africa to the "priority watch list." A step closer to formal sanctions, this designation is regarded as punitive in itself because it sends a no-confidence signal to foreign investors.<sup>137</sup> Gore, however, combined forces with the National Security Council staff and public health authorities to squash that proposal.<sup>138</sup>

There was recognition within the U.S. government that its position on compulsory licensing was not reflected in TRIPS. At meetings in Geneva sponsored by activist organizations Consumer Project on Technology and

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<sup>134</sup>Morrison, *supra* note 8, at 19.

<sup>135</sup>*See Gore in Conflict*, *supra* note 114, at A1.

<sup>136</sup>*See id.*

<sup>137</sup>*See id.*

<sup>138</sup>*See id.*

Doctors Without Borders, Lois Boland, representing the U.S. Patent and Trademark Office, acknowledged that the government's position on compulsory licensing exceeded the minimum requirements set forth under TRIPS:

The fact that [the USG] view is not reflected in the TRIPS agreement, in the multilateral context, is fully acknowledged. In our bilateral discussions, we continue to regard the TRIPS agreement as an agreement that establishes minimum standards for protection and, in certain situations, we may, and often do, ask for commitments that go beyond those found in the TRIPS agreement.<sup>139</sup>

In June of 2000, the United States and South Africa achieved a settlement on the dispute. Under this settlement deal, South Africa agreed to implement the TRIPS agreement. A statement issued by the South African Department of Trade and Industry clarified the position of the South African government:

It is the express position of the South African Government that, in the implementation of provisions of the Medicines Act - which permits parallel importation and compulsory licensing of patents for pharmaceuticals - it will honour its obligations under the TRIPS Agreement.<sup>141</sup>

The USTR announced that it would consult with the U.S. Secretary for Health and Human Services on intellectual property-related trade claims to see its opinion on health considerations.<sup>142</sup> According to a public statement issued by the USTR:

...the two governments have identified common ground with respect to South Africa's implementation of its so-called Medicines Act ...the United States very much appreciates South Africa's assurance that, as it moves vigorously forward to bring improved health care to its citizens, it will do so in a manner consistent with international commitments and that fully protects intellectual property rights ...this will enable U.S. to set aside this issue from our bilateral trade agenda. Moreover, once GSP is re-authorized by Congress, new GSP benefits granted to South Africa in June 1998 will be implemented.<sup>143</sup>

In connection with this announcement, the USTR removed South Africa from its Section 301 "watch list."

This announcement followed the USTR's decision, under pressure from Vice President Gore, to reduce

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<sup>140</sup>See *Gore in Conflict*, *supra* note 114.

<sup>142</sup>The Protection of Intellectual Property and Health Policy, Office of the United States Trade Representative, USTR Press Release 99-97, Dec. 1, 1999, *cited in* Frederick M. Abbott, *Report: TRIPS in Seattle: The Not-So-Surprising Failure and the Future of the TRIPS Agenda*, 18 Berk. J. Int'l Law 165, 172 n. 39 (2000).



pressure on South Africa because of its liberal parallel importing and compulsory licensing provisions.<sup>144</sup>

### C. Examining the Impetus for Change

Norm entrepreneurs — consumer interest groups and public health advocates — played a critical role in prompting the about-face in the U.S. government's position. In the first stage of norm emergence, norm entrepreneurs and their organizations usually strive to “secure the support of state actors to endorse their norms.”<sup>145</sup> In accordance with norm theory's assertion that “to challenge existing logics of appropriateness, activists may need to be explicitly ‘inappropriate,’”<sup>146</sup> AIDS activists used dramatic protest tactics in order to capture the attention of the Clinton administration and to influence the U.S. policy change.

In June 1999, for instance, AIDS activists began tormenting Gore's campaign with showers of printed “blood money” and banners charging “Gore's Greed Kills.”<sup>147</sup> The same week that Clinton administration withdrew its two years of objections to the law, Gore announced his candidacy for presidency. At this particular speech in Carthage, Tennessee, AIDS activists used guerilla tactics to infiltrate the crowd with noisemakers and banners, and they repeated the performance for the following two days after Gore announced his candidacy.<sup>148</sup> Some allege that this settlement between USTR and South Africa was a result of highly visible protest tactics that placed political pressure on Gore at a sensitive political moment, immediately prior to his declaration of candidacy for the president.<sup>149</sup> While it is not clear whether the protests led directly to the change in U.S. policy — Gore officials assert the change was motivated by principles and not political whim<sup>150</sup> — it is clear that norm entrepreneurs strategically used democratic techniques of protest and deliberation to pressure government officials to adopt their norm. Gore's campaign officials were taking the opinions

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<sup>144</sup>See Abott, *supra* note 142, at 173.

<sup>145</sup>See Finnemore and Sikkink, *supra* note 13, at 900.

<sup>146</sup>See *id.* at 897.

<sup>147</sup>See *Gore in Conflict*, *supra* note 114, at A1.

<sup>148</sup>See *id.*

<sup>149</sup>See *id.*

<sup>150</sup>See *id.*

of activists into consideration. At one of Gore's speeches in New Hampshire, Gore's campaign manager Donna Brazile plunged into the crowd of protestors and asked Paul Davis of ACT-UP Philadelphia for his phone number.<sup>151</sup> Activists, including Davis and others, later held back-to-back meetings at the White House and at Gore 2000 headquarters.<sup>152</sup> Also, NGO activities played a critical role in framing the issue to bring the issue of public health into the forefront of the debate. USTR Representative Charlene Barshefsky acknowledged that NGO activism spurred a change in attitudes: "Largely it was the activities of ACT-UP and the AIDS activists that galvanized our attention [to the fact] that there was an absolute crisis," she said. Until then, Barshefsky asserted, "In years past, this [pharmaceutical] issue was treated purely as a trade issue and not an intellectual property rights issue."<sup>153</sup>

The U.S. government's policy change was also a response to changing sentiments amongst its domestic population, who were learning more about the HIV/AIDS crisis due to increased coverage by the major media. Domestic polls revealed support among the American population for expanded international HIV/AIDS programs.<sup>154</sup>

#### **D. Institutionalization of the Norm in U.S. Policy Towards South Africa**

Norm entrepreneurs' vigorous efforts to bring public attention to the severity of the HIV/AIDS crisis, as well as broad coverage of the situation in South Africa in the media, prompted a change in U.S. policy, and the norm of wide access to drugs quickly became institutionalized in U.S. statements and laws. According to norm theory, institutionalization of the norm in specific rules contributes to the possibility of a norm cascade, which is the second stage in norm theory, by "clarifying what, exactly, the norm is and what constitutes

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<sup>151</sup> *See id.*

<sup>152</sup> *See id.*

<sup>153</sup> *See id.*

<sup>154</sup> Morrison, *supra* note 8, at 21.

violation.”<sup>155</sup>

At a speech President Clinton made at the December 1999 WTO meeting in Seattle, for instance, he said that the United States will “implement... trade policies in a manner that ensures . . . the poorest countries won’t have to go without medicine they so desperately need.”<sup>156</sup> The Clinton administration institutionalized the norm, not only in its political rhetoric, but also in its laws.

On May 10, 2000, Clinton signed Executive Order 13155, entitled “Access to HIV/AIDS Pharmaceutical and Medical Technologies.” E.O. 13155 was one of the clearest signs of the institutionalization of the norm in U.S. law. The E.O. provides the following:

In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies<sup>157</sup>

This means that sub-Saharan African countries are protected from U.S. trade retaliation. The E.O. enumerated two conditions for this protection: first, the law must promote access to HIV/AIDS pharmaceuticals or medical technologies; second, the law or policy must provide adequate and effective intellectual property protection consistent with TRIPS.<sup>158</sup> However, the U.S. government retains the capacity to express concerns about such laws or policies and to consult or with the foreign government on whether such laws or policies meet the conditions of the E.O. Furthermore, the order does not prohibit the government from invoking the WTO dispute settlement procedures to examine whether any such law or policy is consistent with TRIPS.<sup>159</sup>

Clinton later stated that this order does not undermine the protection of pharmaceutical patent rights.<sup>160</sup>

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<sup>155</sup>See Finnermore and Sikkink, *supra* note 13, at 900.

<sup>156</sup>Victoria Slind-Flor, *Doctors’ Group seeks IP Changes*, The Recorder, Jan. 5, 2000; Frank Ching, *Eye on Asia: Drug Patents vs. Human Rights*, Far E. Econ. Rev., Feb 17, 2000, available at 2000 WL-FEER 8518035.

<sup>158</sup>See Exec. Order No. 13155, *supra* note 157.

<sup>159</sup>See *id.*

<sup>160</sup>See Emily Miao, *TRIPS Agreement Impacts Pharmaceutical Sector: Not All Members, Especially Developing Nations Feel the Benefits of Increased Trade*, Nat’l L.J., Jul. 24, 2000, at C11, cited in John A. Harrelson, *Note: TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 Wid. L. Symp. J. 175, 186 (2001).

This was a clear articulation of the new norm as well as a major change in U.S. policy. The United States had previously used trade sanctions to successfully pressure Thailand to change its law, and had attempted to use such sanctions to persuade South Africa.<sup>161</sup> In the State Department report on the South African law issued one year before in February 1999, the State Department warned that intellectual property violations by the South African government would be met with further trade sanctions: “Should there be an actual violation of any U.S. pharmaceutical patent right (e.g., patent abrogation) this Administration will respond forcefully in accordance with appropriate *trade remedy* legislation (emphasis added).”<sup>162</sup> Indeed, it was common practice for the U.S. government to use Section 301 and GSP preferences to pressure developing countries to increase intellectual property protections,<sup>163</sup> but E.O. 13155 was committing the U.S. to take a different course in South Africa. After years of using trade sanctions to pressure South Africa to strengthen its intellectual property laws, the U.S. government had now promised to refrain from using such pressures. When the United States first responded to 15(C) of the Medicines and Related Substances Act, it acknowledged that its position was based on standards higher than those contained in TRIPS, and that, even if compulsory licensing and parallel imports were legal under TRIPS, the United States was free to argue for a higher standard. The U.S. position was that TRIPS set forth only a minimum standard which, in this context, the United States was free to surpass. In E.O. 13155, however, Clinton set forth a different version of the U.S. position. He called for compliance with the minimum standards contained in TRIPS—nothing more and nothing less.

In early 2001, the Bush administration agreed to follow Clinton’s policy. In spite of the request of the Pharmaceutical Research and Manufacturers of America (“PhRMA”) that the government file a Section 301 case against South Africa, the Bush administration removed South Africa from the Section 301 “watch list” stating that the United States will not initiate sanctions against developing countries combating the AIDS

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<sup>161</sup> See Sweeney, *supra* note 109, at 460.

<sup>162</sup> See State Department Report, *supra* note 113.

<sup>163</sup> See Sweeney, *supra* note 109, at 459.

epidemic.<sup>164</sup> Several interest groups supported this position; for example, the AFL-CIO wrote the USTR a letter in March 2001 to urge the USTR to resist PhRMA's request to place South Africa on the "watch list."<sup>165</sup> Officials announced that the Bush administration would not seek trade sanctions against developing countries that try to force down the price of patented anti-AIDS drugs by legalizing the importation or manufacture of generic versions. The administration announced that it would not try to punish such countries even if American drug makers complain or United States patent laws are broken, provided that the country adheres to TRIPS.<sup>166</sup> In an informal statement by USTR officials on February 20, 2001:

The HIV/AIDS crisis is a terrible tragedy for countries, families and individuals. USTR is not considering a change in the present flexible policy. Consistent with our overall effort to protect America's investment in intellectual property, USTR will seek to contribute to Administration efforts to work with countries that develop serious programs to prevent and treat this horrible disease.<sup>167</sup>

## V. Response by Pharmaceutical Companies to 15(C) of the Medicines Act

The U.S. response coincided with an aggressive response from the pharmaceutical industry. Just as norm entrepreneurs used various tactics in a concerted campaign to influence the U.S. position on 15(C), they waged a similar campaign regarding the pharmaceutical industry's legal offensive against 15(C). They spread information in the press and on the Internet, collected signatures, and even expressed their opinion to judicial tribunals in order to express norms contrary to those articulated by pharmaceutical companies. And just as the norm entrepreneurs' efforts helped spur an institutionalization of the norm in the United States, their

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<sup>164</sup>Rachel L. Swarns, *AIDS Drug Battle Deepens in South Africa*, NY Times, Mar. 8, 2001, at A1, *cited in* Bass, *supra* note 25, at 212 n. 148-9.

<sup>165</sup>Letter from David Smith, Director, Public Policy Department, AFL-CIO, to Robert Zoellick, United States Trade Representative (Mar. 2, 2001) (visited Apr. 12, 2002) <<http://www.cptech.org/ip/health/sa/aflcio.html>>.

<sup>166</sup>Donald G. McNeil, Jr., *Bush Keeps Clinton Policy on Poor Lands' Need for AIDS Drugs*, NY Times, Feb. 22, 2001, *available in* LEXIS, News Library, NYTimes File.

<sup>167</sup>United States Trade Representative, Statement on HIV/AIDS and Trade Policy, February 20, 2001 (visited Apr. 12, 2002) <<http://lists.essential.org/pipermail/pharm-policy/2001-February/000705.html>>.

efforts to mobilize public sentiment and to spread information increased pressure on the industry to withdraw its legal offensive. Clearly, norm entrepreneurs were changing the landscape of international norms.

### **A. Pharmaceutical Companies vs. the South African Government**

Pharmaceutical companies were concerned about 15(C) even before it formally became law. Beginning in May 1997, prominent figures in the pharmaceutical industry, including Aldridge Cooper of Johnson & Johnson and Harvey Bale of PhRMA, the industry lobby, began writing to USTR's office and Commerce Secretary William Daley to denounce Pretoria's proposed amendments to the Medicines Act.<sup>168</sup> What would become a three-year long legal tussle began in early 1998, when, upon enactment of the Medicines Act, the Pharmaceutical Manufacturers' Association (PMA) of South Africa brought a lawsuit in Pretoria High Court against the South African government on behalf of forty domestic and international pharmaceutical companies, including Alcon Laboratories, Bayer, Bristol-Myers Squibb, Eli Lilly, and Merck.<sup>169</sup> The suit named South Africa as the defendant and alleged that Section 15(C) was unconstitutional on the following grounds: it enabled the Minister of Health to determine conditions for the supply of affordable medicines without setting forth any policy considerations or guidelines; it enabled the Minister of Health to determine the extent to which rights under a patent shall apply irrespective of provisions of the Patents Act; and it enabled the Minister of Health to deprive owners of intellectual property without any provision for compensation to be paid.<sup>170</sup> Lawyers for the drug manufacturers framed the case in terms of intellectual property rights, rather than access to AIDS medicines.<sup>171</sup>

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<sup>168</sup>See *Gore in Conflict*, *supra* note 114.

<sup>169</sup>The Pharmaceutical Manufacturers' Association of South Africa, et al. vs. The President of South Africa, et al., In the High Court of South Africa (Transvaal Provincial Division), Case no. 4183/98 (visited April 10, 2002) <<http://www.cptech.org/ip/health/sa/pharmasuit.html>> [hereinafter PMA Lawsuit].

<sup>170</sup>See PMA Lawsuit, *supra* note 169, at Sections 2.1, 2.2, 2.3.

<sup>171</sup>See generally, PMA Lawsuit, *supra* note 169.

Why were the companies opposed to the law? Since the entire continent of Africa constituted only 1.3 percent of the global pharmaceutical market,<sup>172</sup> it is not likely that they were motivated by a desire to maintain profits from the African market. Rather, their underlying fear was that 15(C) would erode its markets in U.S. and Europe, the source of most pharmaceutical profits.<sup>173</sup> Prior to bringing the lawsuit against 15(C), the South African government had been negotiating with Cipla, an Indian drug company, to obtain AIDS drugs at a fraction of the prices currently charged by firms who hold the patents.<sup>174</sup> Pharmaceutical companies feared that cheap generic drugs produced in developing countries could be resold in their Western markets, undermining the industry's entire pricing structure and its ability to fund costly new research.<sup>175</sup> The average cost of developing a new drug is \$500 million to \$880 million.<sup>176</sup> Companies also feared that reducing prices or allowing for production of generics would increase pressure it faced in wealthier markets to reduce the prices of drugs: if customers in America learned that pills that cost \$10,000 for them are available for only \$700 in Africa, many were bound to demand similar discounts from the companies.<sup>177</sup>

The companies also argued that solving the HIV/AIDS crisis in South Africa required much more than improving access to

One of the strongest counter-arguments to the demands for wider access was that since there is no cure for AIDS, the best

B. The First Round of Price CutsThe companies announced two rounds of price cuts in HIV/AIDS drugs during the duration

The first series of price cuts occurred in April and May 2000, at around the same time of Clinton's Executive Order and the

Undoubtedly, the executives who decided to reduce prices were fully aware of the protests occurring in the United States, as

<sup>172</sup>Jim Zarroli, *Drug Companies Balk at Plans to Provide Cheaper Drugs to Developing Nations*, National Public Radio, Weekend Edition, May 6, 2001, available in LEXIS, Nexis Library, NEWS file.

<sup>173</sup>See Maykuth, *supra* note 97.

<sup>174</sup>See *The Price of Africa's Cheap Drugs*, Economist.Com, Mar. 5, 2001, available in LEXIS, Nexis Library, NEWS file.

<sup>175</sup>See Maykuth, *supra* note 97.

<sup>176</sup>John Carey and Amy Barrett, *Drug Prices: What's Fair?*, BusinessWeek, Dec. 10, 2001, at 60, available in LEXIS, Nexis Library, NEWS file.

<sup>177</sup>*The Price of Africa's Cheap Drugs*, *supra* note 174.

<sup>178</sup>See Maykuth, *supra* note 97.

<sup>179</sup>See *id.*

<sup>180</sup>See *The Price of Africa's Cheap Drugs*, *supra* note 174.

<sup>181</sup>See *Unequal Calculus*, *supra* note 10.

<sup>182</sup>See Barton Gellman, *A Turning Point that Left Millions Behind*, Wash. Post, Dec. 28, 2000, at A01 [hereinafter *A Turning*

One month later, five pharmaceutical companies, Bristol-Myers Squibb, GlaxoSmithKline, Merck, Boehringer-Ingelheim, and

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The United Nations played a key role in the formation of the Accelerated Access Initiative. However, the pharmaceutical companies had not always been willing to cooperate with international organizations. For instance, at the first pivotal negotiations about global access to AIDS drugs in Geneva in 1991, pharmaceutical companies said they did not want to lower prices, and that it was the responsibility of governments to ensure that those in need received necessary treatments.<sup>184</sup> These talks ended in 1993. But soon after UN Secretary General Kofi Annan called for new public-private partnerships at an AIDS summit in New York on December 6, 1999, mid-level executives of pharmaceutical companies began drafting a set of principles that could guide an AIDS treatment initiative. Their draft statement set forth five conditions that eventually constituted the core of the Accelerated Access Initiative joint statement that would be issued with the UN in May 2000. The five conditions began with a requirement that recipient countries make an “unequivocal and ongoing political commitment.”<sup>185</sup> International agencies would have to assume responsibility for building up health care infrastructure capable of monitoring patients and their compliance with dosing schedules.

Drugs would be sent only into an “efficient, reliable and secure distribution system” to prevent interruptions of treatment and diversion of products to other markets.<sup>186</sup> The companies were willing to acknowledge that “affordability is an issue in developing countries” if UN agencies agreed that AIDS drug treatment was “a shared responsibility of all sectors of society.”<sup>187</sup> Finally, the firms wanted support from all concerned for “adequate and enforced intellectual property rights” to “provide the prospect of a satisfactory return on

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*Point*].

<sup>183</sup> See *Unequal Calculus*, *supra* note 10.

<sup>184</sup> See *id.*

<sup>185</sup> A *Turning Point*, *supra* note 182.

<sup>186</sup> *Id.*

<sup>187</sup> *Id.*



investment in the high-risk search for new medicines.<sup>188</sup>

The companies were willing to reduce prices; they would not, however, compromise their intellectual property rights, and the preservation of these rights in paragraph 5 were a condition for the initial price reductions. On April 14, 2000, leaders of the five companies and five agencies (UNAIDS, the World Health Organization, United Nations Children Fund or UNICEF, the World Bank, and the United Nations Population Fund) gathered for the first time to discuss the terms of the price reductions. The statement was issued in May, and was similar to the draft statement originally written by pharmaceutical executives.<sup>189</sup>

These announcements were accompanied by press packages and much rhetorical flourish.<sup>190</sup> While the pharmaceutical companies couched the price reductions in the most positive terms, activist groups assessed the reductions with a critical eye. They criticized the programs because the companies failed to make the price disclosures transparent, but instead negotiated variable prices in strict confidence.<sup>191</sup> While these five companies unveiled plans to sell AIDS drugs at substantial discounts to countries in Africa, the companies gave little specific information to the public. During the eight months after the agreement, only one of the 5 companies (Glaxo Wellcome) was willing to disclose the amount of its AIDS medicines discount.<sup>192</sup>

Activists also criticized the Accelerated Access Initiative because the price reductions were not enough to make the drugs widely accessible. Activists noted that even with the lower prices offered by Bristol-Myers and Merck, the cost would still be higher than prices of generic drugs for the three-drug combination commonly used in the developed world to treat people with AIDS and HIV. Bristol-Myers proposed a \$1 a day per-patient price for its two AIDS medicines, Zerit and Videx. Merck announced it would charge \$600 per

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<sup>188</sup> *Id.*

<sup>189</sup> *See id.*

<sup>190</sup> *See, e.g.,* Bristol-Myers Squibb Announces Accelerated Program to Fight HIV/AIDS in Africa, Press Release, Mar. 14, 2001 (viewed March 20, 2002) <[http://www.bms.com/news/press/data/fg\\_press\\_release\\_1446.html](http://www.bms.com/news/press/data/fg_press_release_1446.html)>.

<sup>191</sup> *See A Turning Point, supra* note 182.

<sup>192</sup> *See id.*

year for the protease inhibitor, Crizivan. Together, this was far more than the \$350 a year price offered by generic drug manufacturers that were available in Thailand, India, and Brazil.<sup>193</sup> The eighty percent reduction was still inadequate to make the drugs more affordable to most Africans, said some.<sup>194</sup> World Bank economist, Hans P. Binswanger described the programs as “expensive boutiques...available to the lucky few.”<sup>195</sup> Activists also criticized the limited scope of the Accelerated Access Initiative, and asked why such efforts should be limited to just South Africa.<sup>196</sup>

Norm entrepreneurs in consumer groups and other activist organizations mounted a counter-attack in response to the offensive of the pharmaceutical companies. Instead of framing the issue in terms of intellectual property, they framed the issue in terms of human rights, and they even became directly involved in the lawsuit. As of September 1999, implementation of the law had been suspended pending the resolution of a constitutional challenge in the South African courts. On March 5, 2001, hearings began on the lawsuit brought by PMA against the South African government.<sup>197</sup> In the same month, the Pretoria High Court ruled that it would accept evidence from the South African Treatment Action Campaign and that it would accept the group as a “Friend of the Court.”<sup>198</sup> AIDS activists could join the Government’s side, and the Court acknowledged that in addition to the protection of intellectual property rights, the lawsuit involved matters of public health and social justice.<sup>199</sup> The South African organization, Treatment Action Campaign, filed an affidavit in support of the South African government on April 10, 2001, along with supporting affidavits on topics such as generic substitution, parallel imports, costs of research and development by

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<sup>193</sup>Neeraj Kaushal, *EcoScope: Not by Aid Alone*, Econ. Times, May 16, 2000, at WL 16892773.

<sup>194</sup>*Id.*

<sup>195</sup>*Unequal Calculus*, *supra* note 10.

<sup>196</sup>Karen DeYoung and Bill Brubaker, *HIV Drug Price Cut for Some in Africa*, Wash. Post, Mar. 15, 2001, at A01.

<sup>197</sup>Bass, *supra* note 25, at 212.

<sup>198</sup>High Court Accepts the Right of People with HIV to be Heard, Press Release issued by COSATU, TAC, MSF, OXFAM, and Consumer Project on Technology, Mar. 6, 2001 (viewed April 12, 2002) <<http://lists.essential.org/pipermail/pharm-policy/2001-March/000748.html>>.

<sup>199</sup>*World Affairs Paying for AIDS Facing Outraged Victims in Poor Countries, Big Pharma Cuts the Prices of Lifesaving Drugs*, Newsweek Int’l, Mar. 19, 2001, 2001 WL 8109129.

pharmaceutical companies.<sup>200</sup>

### C. The Second Round of Price Cuts

Pharmaceutical companies announced the second round of price cuts just days after the hearings for the lawsuit began on March 6, 2001. Merck & Co. agreed in March 2001 to sell two of the roughly 15 medicines used to treat HIV at drastically reduced costs. By reducing prices on Crixivan to \$600 per patient per year and \$500 per patient per year for Stocrin, Merck would no longer expect to profit from the sales of these medicines in developing nations.<sup>201</sup> On March 15, 2001, Bristol-Myers Squibb Co. announced that it would sell the two AIDS medicines it manufactures to sub-Saharan countries “below cost” and would not prevent South Africa from ignoring patent rights it held on one of the drugs, Zerit.<sup>202</sup> Bristol-Myers said it would reduce the cost of Videx and Zerit to 15 cents a day for the first and 85 cents a day for the second.<sup>203</sup>

Norm entrepreneurs, whose campaign in support of the South African government placed pharmaceutical companies in the awkward position of defending higher prices for their products, played a key role in instigating these price reductions. For instance, Bristol-Myers’ decided to reduce the price of Zerit in direct response to pressures from Doctors Without Borders and a group of Yale University law students.<sup>204</sup> Initially, Bristol-Myers had argued that it could not bypass the patent on Zerit because of an agreement with Yale University, which developed the drug and licensed the company to manufacture and distribute it. However, in response to pressures from Doctors Without Borders and a group of Yale University law students to make the drug more widely available, the university reached an agreement with the company to “remove any obstacles” on

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<sup>200</sup>Affadavit Filed by the Treatment Action Campaign, April 10, 2001 (viewed April 10, 2002) <<http://www.tac.org.za/archive.htm>>.

<sup>201</sup>Bass, *supra* note 25, at 213 n. 152-156

<sup>202</sup>Jon Jeter, *South Africa Resists Call for AIDS “Emergency”*, Wash. Post, March 15, 2001, at A01.

<sup>203</sup>Accelerated Program to Fight HIV/AIDS in Africa <<http://www.bristol-myers.com/landingdata/index/html.>>, *cited in* Bass, *supra* note 25, 213 n. 156.

<sup>204</sup>*See* DeYoung and Brubaker, *supra* note 196.

patent and price issues.<sup>205</sup> Although Bristol-Myers did not relinquish its patent rights, the company pledged not to challenge the manufacture and sale of generic equivalents in South Africa.<sup>206</sup>

It was clear from the pressure applied to Bristol-Myers and other companies that public support for greater access to drugs was mounting. Despite the attempts of companies to improve their public image, norm entrepreneurs continued to portray the companies as unwilling to sacrifice profits to save human lives. Oxfam called on the United Nations to investigate a possible “gross breach of human rights” in the companies’ attempt to “prevent the South African government from fulfilling its international human rights obligations.”<sup>207</sup> And on April 17, 2001, the international medical aid organization Doctors Without Borders presented the results of a global Internet petition campaign in which 250,000 people from over 130 countries called on the pharmaceutical industry to drop the case. Noteworthy individuals signed the petition, including AIDS researcher Dr. David Ho; the inventor of AIDS drug d4t, William Prusoff, PhD; authors Chinua Achebe and John Le Carré; musicians Quincy Jones and Sarah McLachlan; and Members of Parliament in Canada and in the European Parliament.<sup>208</sup> Doctors Without Borders also joined the South African Treatment Action Campaign and other national and international organizations in condemning the pharmaceutical industry for pursuing a court case blocking legislation aimed at making medicines more affordable in South Africa.<sup>209</sup> Norm entrepreneurs were the most organized and vocal vanguard to voice their opposition to the PMA lawsuit; however, there was growing indication that other influential actors were beginning to join norm entrepreneurs in their opposition to the pharmaceutical companies’ lawsuit. In early March 2001, members of the U.S. Congress announced their opposition to the lawsuit and introduced the Affordable HIV/AIDS

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<sup>205</sup> *Id.*

<sup>206</sup> *Id.*

<sup>207</sup> Oxfam Great Britain, Drug Giants Set to Cause Violation of Human Rights: Oxfam Calls for Urgent Investigation, Press Release, Apr. 11, 2001 (viewed Apr. 12, 2002) <<http://www.oxfam.org.uk/whatnew/press/cutcost6.htm>>.

<sup>208</sup> Public Support for South Africa’s Fight for Affordable Medicines, Doctors Without Borders Website (viewed Apr. 12, 2002) <<http://www.doctorswithoutborders.org/news/2001/accesscelebs.04-2001.shtml>> [hereinafter Public Support for South Africa’s Fight].

<sup>209</sup> Medicines Sans Frontiers-USA, Thousands Sign Global Internet Petition Demanding End to South African Court Case, Press Release, Apr. 17, 2001 (viewed Apr. 12, 2002) <<http://www.doctorswithoutborders.org/pr/2001/04-17-2001.shtml>>.

Medicines for Poor Countries Act, a bill to promote the availability of affordable HIV/AIDS medicines in the countries of sub-Saharan Africa and other developing countries.<sup>210</sup> Congresswoman Maxine Waters (D-CA) personally urged the companies to drop the lawsuit:

It is unconscionable that some of the world's wealthiest corporations are trying to prevent an African country from manufacturing or purchasing their own medicines. These are the very some corporations that have steadfastly refused to make HIV/AIDS medicines available to impoverished people in sub-Saharan Africa at reasonable prices. It is time to let African countries take care of their people.<sup>211</sup>

Government leaders from Denmark, Germany, the Netherlands, and Belgium also expressed their public support for withdrawal of the lawsuit.<sup>212</sup> On March 15, 2001, the European Parliament passed an emergency resolution entitled "Access to medicines for AIDS patients in the Third World" that called on the pharmaceutical companies to withdraw from the case.<sup>213</sup> The Resolution also called on the European Commission to "strengthen the ability of developing countries to resist the pressure to introduce more stringent patent laws than those currently required under the WTO TRIPS Agreement"<sup>214</sup> and also called for a review of the TRIPS Agreement to ensure that rights of developing countries "to obtain the cheapest possible life-saving medicines, whether patented or generic, are guaranteed."<sup>215</sup>

#### D. Pharmaceutical Companies Retreat from the Lawsuit

In the three years since PMA first commenced the lawsuit, companies had reduced prices and attempted to refurbish their much-tarnished public image through costly commercials, advertisements, and diverse

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<sup>210</sup>Congresswoman Waters Denounces Lawsuit by AIDS Drug Companies Against the Government of South Africa; Introduces The Affordable HIV/AIDS Medicines for Poor Countries Act, Press Release, Mar. 7, 2001 (viewed Apr. 12, 2002) <<http://www.house.gov/waters/pr010307.htm>> [hereinafter Congresswoman Waters Denounces Lawsuit]; Coalition Reintroduces Bill to Promote Access to Affordable HIV/AIDS Drugs: Denounce Actions of Pharmaceutical Industry in South Africa, Press Release from U.S. Rep. Schakowsky, Mar. 7, 2001 (viewed Apr. 12, 2002) <<http://www.cptech.org/ip/health/sa/>>.

<sup>212</sup>Public Support for South Africa's Fight, *supra* note 208.

<sup>213</sup>See European Parliament Resolution, *supra* note 2.

<sup>214</sup>*Id.* at para. 4.

<sup>215</sup>*Id.* at para. 6.

humanitarian efforts.<sup>216</sup> In the same three year period, however, activities of groups opposing the lawsuit intensified, and the lawsuit became, in the words of Kevin Watkins of Oxfam, a “public relations disaster” for the companies as moral outrage against the companies increased.<sup>217</sup> Due to efforts of norm entrepreneurs as well as widespread concerns among the public, the media portrayed the companies as losing a battle laden with issues of morality and equality. The Associated Press referred to the case as “an international battle that deeply embarrassed the companies,” and *The New York Times* said the companies were “feeling pressure from a growing chorus of international critics who assailed the high prices of anti-AIDS drugs.”<sup>218</sup> The *Christian Science Monitor* said the pharmaceutical companies had replaced tobacco companies as “the corporate bad guy.”<sup>219</sup>

Recognizing that public opinion was their “ultimate regulator”<sup>220</sup> and that they were losing the public debate, on April 19, 2001, PMA announced that it would drop the lawsuit against the South African government. Just as U.S. policy shifted throughout the early part of 2000, a shift in the position of pharmaceutical companies occurred, largely in response to widespread public sentiment against the companies’ lawsuit. The withdrawal of the suit was motivated less by legal reasons than a desire on the part of the companies to stem the tide of moral opposition and salvage its public reputation.<sup>221</sup>

Negotiations had been underway for several months, and they finally culminated in a settlement that was negotiated between representatives of the industry and the South African government. In withdrawing their suit against Section 15(C) of the Medicines Control Act, the government agreed to implement its laws in compliance with TRIPS and to write regulations putting 15(C) into effect.<sup>222</sup> The government also agreed to embrace the firms as partners in dealing with South Africa’s health problems through the creation of a joint

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<sup>216</sup>See Billie Swift, *The Public Opinion Pendulum*, Risk Management, July 1, 2001, at 8.

<sup>217</sup>*Id.*

<sup>218</sup>*Id.*

<sup>219</sup>Rena Singer, *Drug Firms Yield to Cry of the Poor*, The Christian Science Monitor, April 20, 2001, at 1.

<sup>220</sup>Swift, *supra* note 216.

<sup>221</sup>*Id.*

<sup>222</sup>Simon Barber, *End of AIDS Drugs Case Sees Spotlight Fall on New Arenas*, Business Day, April 25, 2001, available at <<http://www.bday.co.za/bday/content/direct/1,3523,836777-6078-0,00.html>>.

working group with the pharmaceutical industry to examine broader health issues.<sup>223</sup> The government also agreed to consult with the industry on regulations regarding the implementation of the Act.<sup>224</sup> Importantly, the companies can still go back to court to assert their rights on a case-by case basis.<sup>225</sup> Finally, the drug companies agreed to pay the state's court costs.

The pharmaceutical companies had failed in their campaign to reverse the law, as well as in their campaign to win over public opinion. Why were the norms that the pharmaceutical companies articulated less influential than those propounded by activists? Norm theory suggests that “intrinsic qualities about the norm itself” can determine its influence and eventual adoption.<sup>226</sup> According to some political scientists, norms that are clear and specific, rather than ambiguous and complex, are more likely to be effective.<sup>227</sup> Some stress that the substantive content of the norm, rather than its form, are more likely to determine whether it will be successful. Norms that are particularly effective are those involving bodily integrity and prevention of bodily harm for vulnerable or “innocent” groups, especially when a short causal chain exists between cause and effect, and legal quality of opportunity.<sup>228</sup>

The norms espoused by the activists—that HIV/AIDS drugs should be more affordable in order to save millions of lives—were certainly simpler in form than the pharmaceutical companies' insistence that price reductions would erode their research and development funds necessary for developing future drugs. The emotional appeal of the lack of medication causing death was stronger than the emotional appeal of the links between patent infringement, reduction in companies' profit, and slowing innovation of new drugs. The public was much more likely to be moved by the activists' framing of the issue in terms of basic human survival rather than the pharmaceutical companies' concerns with preserving patent protection and research funds.

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<sup>223</sup>Joint United Nations Programme on HIV/AIDS, UNAIDS Welcomes Outcome of South African Court Case, Press Release, April 19, 2001 (visited April 29, 2002) <[http://www.unaids.org/whatsnew/press/eng/pressarc01/SAfrica\\_190401.htm](http://www.unaids.org/whatsnew/press/eng/pressarc01/SAfrica_190401.htm)>.

<sup>224</sup>GlaxoSmithKline, GlaxoSmithKline Welcomes the Settlement of Industry Association Litigation against the South African Government, Press Release, Apr. 19, 2001 (visited Apr. 29, 2002) <[http://corp.gsk.com/press\\_archive/press\\_04192001.htm](http://corp.gsk.com/press_archive/press_04192001.htm)>.

<sup>225</sup>See Barber, *supra* note 222.

<sup>226</sup>

<sup>227</sup>*Id.*

<sup>228</sup>Finnemore and Sikkink, *supra* note 13, at 907.

Only sophisticated populations could fully understand the pharmaceutical companies' arguments, which required some basic understanding of patent law as well as the enormous costs of research and development. PMA's withdrawal was a victory for the South African government and the activist groups. The mood was celebratory and media generally perceived the lawsuit to be a failure on the part of pharmaceutical companies. Activists and international organizations issued press releases celebrating the conclusion of the legal battle, as well as a significant step forward for other developing countries. Activists called the conclusion of the lawsuit a "moral victory", and South African Minister of Health Manto Tshabalala-Msimang saw the withdrawal of the suit as part of a "broader movement for justice in healthcare—not just for South Africa, but for the whole world."<sup>229</sup> Ellen Hoen of Doctors Without Borders commented that it was unlikely the companies would bring forth a court challenge against a developing country in the future.<sup>230</sup> Interestingly, pharmaceutical companies also issued statements welcoming the end of the lawsuit, showing that they had belatedly come to embrace the new norm.

## VI. Institutionalization of the Emerging Norm in International Laws

The pharmaceutical companies' retreat from the lawsuit demonstrated the companies' *de facto* acceptance of the norm. Bilateral relations between the U.S. and South Africa also institutionalized the norm. After these two critical events—the retreat of the U.S. government and the pharmaceutical companies from their original opposition to the law—the norm also became institutionalized in international statements and rules. For instance, the United Nations Declaration on AIDS, which was issued by the United Nations Special Session

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<sup>229</sup>Singer, *supra* note 219.

<sup>230</sup>Medicins Sans Frontiers Campaign for Access to Essential Medicines, Drug Companies in South Africa Capitulate Under Barrage of Public Pressure, April 19, 2001, *available at* <<http://www.accessmed-msf.org/prod/publications.asp?scentid=218200141159&contenttype=PARA>> (last visited Apr. 29, 2002).



on HIV/AIDS, called for national strategies and international cooperation to disseminate AIDS awareness and prevention.<sup>231</sup> The most critical international statement to fully articulate the norm of improved access to life-saving pharmaceuticals was the Doha Declaration, which was negotiated by the 142 Member States of the World Trade Organization at their annual meeting in Doha, Qatar on November 2001.<sup>232</sup>

#### A. Pre-Doha Events

The World Trade Organization Ministerial Conference ran from November 9 - 14, 2001 in Doha, Qatar. Numerous norm entrepreneurs had representatives in Doha engaged in further lobbying with governments, such as Doctors Without Borders, Oxfam, the Health GAP Coalition, and the Consumer Project on Technology.<sup>233</sup> Many consumer and activist groups within and without the developing countries had also lobbied their governments in concerted campaigns to influence their positions and to win support for developing countries' proposals. For instance, the Canadian HIV/AIDS Legal Network, in conjunction with several other groups conducted the following activities as part of their campaign: distributed letters to key government officials and all Members of Parliament, met with the Prime Minister and other government officials, delivered 12,000 postcards from concerned Canadians to the Prime Minister, and conducted numerous interviews and published opinion pieces in the Press.<sup>234</sup>

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<sup>231</sup>See Karen DeYoung, *U.N. Delegates Agree on AIDS Declaration*, Wash. Post, June 27, 2001, at A17.

<sup>232</sup>See Canadian HIV/AIDS Legal Network, UPDATE: Global Access to Treatment: Outcomes of the Recent WTO Meeting in Doha, November 28, 2001 (visited April 29, 2002) <<http://www.aidslaw.ca/Maincontent/issues/cts/urgentoct01/update-nov2801.htm>>.

<sup>233</sup>See Canadian HIV/AIDS Legal Network, *supra* note 232.

<sup>234</sup>See *id.*

## B. Provisions of the Doha Declaration

The WTO Ministers agreed upon a “Declaration on the TRIPS Agreement and Public Health,” which sets out seven paragraphs clarifying TRIPS.<sup>235</sup>

### Relationship between TRIPS and Public Health Concerns

Developing countries sought a clear statement that “nothing in the TRIPS Agreement shall be used to prevent countries from taking measures to protect public health.”<sup>236</sup> Canada and a handful of wealthy countries, led by the United States and Switzerland, opposed this statement.<sup>237</sup> As a result, the main Declaration stresses the “importance” that the Ministers attach to the interpretation and implementation of the TRIPS Agreement “in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines.”<sup>238</sup> The Declaration contains relatively strong language about the relationship between TRIPS and public health concerns. The WTO Ministers state:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.<sup>239</sup>

This provision stands as a clear political statement that public health concerns *should* override commercial

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<sup>235</sup>Doha WTO Ministerial 2001, Declaration on the TRIPS Agreement and Public Health, Nov. 20, 2001 (visited Apr. 15, 2002) <[http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindec1.trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindec1.trips_e.htm)> [hereinafter Doha Declaration].

<sup>236</sup>Canadian HIV/AIDS Legal Network, *supra* note 232.

<sup>237</sup>See Canadian HIV/AIDS Legal Network, *supra* note —.

<sup>238</sup>Doha Declaration, *supra* note 235.

interests.<sup>240</sup> However, it does not mandate that that nothing in the TRIPS Agreement *shall* prevent countries from taking measures to protect public health

### *Compulsory Licenses*

According to the Declaration, countries can override pharmaceutical patents to gain faster, cheaper access to medicines in situations when poor nations need access to patented drugs.<sup>241</sup> The Declaration gives member countries broad rights to issue a compulsory license that allows the manufacture of generic versions of a patented drug during its patent term, provided that “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”<sup>242</sup> These options are not limited to emergency situations. If countries declare an emergency, however, they can issue compulsory licenses without prior negotiation with the patent owner. It is countries themselves that will determine what constitutes an emergency situation.<sup>243</sup>

However, the Declaration imposes the restriction that this authorization for a compulsory license must be “predominantly” for the supply of that country’s own domestic market.<sup>244</sup> This means that countries that do have drug-making capacity cannot authorize anything more than a limited production of generic drugs for export to countries that need them.<sup>245</sup> The meeting left unresolved the issue of where countries with insufficient or no manufacturing capacity for pharmaceuticals will obtain drugs under a compulsory license.<sup>246</sup>

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<sup>240</sup>Green Light to Put Health First at WTO Ministerial Conference in Doha, Joint NGO Statement, by MSF, OXFAM, Third World Network, Consumer Project on Technology, Consumers International, Health Action International and the Network, Nov. 14, 2001 (visited Apr. 20, 2002) <<http://www.oxfam.org.uk/whatnew/press/doha2.html>> [hereinafter *Green Light to Put Health First*].

<sup>241</sup>See Carlyn Kolker, *Doing the Doha Shuffle—At a WTO Meeting, Nations Agreed to Break Pharmaceutical Patents During Emergencies. Or Did They?*, The American Lawyer, Feb. 2002, available in LEXIS-Nexis, News Library.

<sup>242</sup>Doha Declaration, *supra* note 235.

<sup>243</sup>*Id.*

<sup>244</sup>*Id.*

<sup>245</sup>See Canadian HIV/AIDS Legal Network, *supra* note 232.

<sup>246</sup>See Green Light to Put Health First, *supra* note 240. See also Claire Bissek, *Beware of Counterfeit Medicines, Kenya Warns South Africa*, Fin. Mail (S. Afr.), Oct. 24, 1997, at 40, cited in Nash, *supra* note 58, at 499 (explaining that parallel importation may have less appeal as a strategy to increase access to drugs, partly because of Kenya’s failed experiment with

This was the biggest disappointment for developing countries and activists.<sup>247</sup>

The Africa Group, a coalition of more than eighty developing countries, had lobbied for a provision that would allow generic versions of patented drugs to be exported to poor countries that do not have sufficient industrial capacity to produce the drugs domestically.<sup>248</sup> The Africa Group sought a provision authorizing the export of medicines under Article 30 of TRIPS and sought a clarification of TRIPS that would permit “South-South access” to medicine arrangements, where emerging developing countries, such as India or Brazil, would be allowed to provide those least developed countries, such as those in sub-Saharan Africa, with the medicines they need.<sup>249</sup> Without this clarification, “South-South access” arrangements would most likely be prohibited by Article 31(f) of TRIPS, which limits exports of medicines manufactured under a compulsory license. Article 31(f) requires that a compulsory license be authorized “predominantly for the use of the domestic market of the Member authorizing the compulsory license.”<sup>250</sup> The United States, the European Commission, and Japan opposed this proposed provision, and, as a result, it was not adopted.<sup>251</sup> As a result, the Doha provision on compulsory licenses is of little benefit to countries that do not have the capacity to produce their own generic medicines, which are likely to include some of the countries most in need of cheaper medicines.<sup>252</sup> These countries must import the medicines from countries that have this capacity. But under a compulsory license, countries that do have drug-making capacity cannot authorize anything more than a limited production of generic drugs for export to countries that need them.<sup>253</sup> Rather than moving this barrier, the Doha Declaration instructs the WTO’s subsidiary body, the Council for TRIPS,

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the parallel importation of drugs; Kenyan scientists had warned legislators in South Africa of the possible danger of parallel importation, and this may have influenced South Africa’s approach).

<sup>247</sup> See *id.*

<sup>248</sup> Act-Up, WTO Declaration on TRIPS and Health: People With Aids 1, Drug Industry 0, Press document, November 15, 2001 (visited April 12, 2002) <<http://old.healthnet.org/programs/e-drug-hma/e-drug.200111/msg00029.html>>.

<sup>249</sup> *Id.*

<sup>250</sup> TRIPS Agreement, *supra* note 24, at art. 31(f).

<sup>251</sup> See Act-Up, *supra* note 248.

<sup>252</sup> See Canadian HIV/AIDS Legal Network, *supra* note 232.

<sup>253</sup> See *id.*

“to find an expeditious solution to this problem” and to report back before the end of 2002.<sup>254</sup>

### *Parallel Imports*

The Doha Declaration leaves countries the freedom to decide on their own rules for implementing parallel imports.<sup>255</sup>

### *Transitional Arrangements*

The Declaration also provides the WTO’s least developed member countries an additional ten years until January 1, 2016, to comply with their obligations under the TRIPS agreement.<sup>256</sup>

The legal status of the Declaration is that it is not authoritative, nor does it amend TRIPS. Rather, it has the force of suggestion, similar to a piece of legislative history; it directs countries on how to interpret TRIPS.<sup>257</sup> The final text is likely to guide the interpretation of the TRIPS Agreement in future WTO disputes in a fashion that is more friendly to public health objectives. It will also help developing countries fend off pressure tactics by rich countries who invoke TRIPS and threaten the use of trade sanctions when developing countries limit companies’ exclusive patent rights.<sup>258</sup> The Doha Declaration will be used more as a negotiating tool, under which developing countries will threaten the issuance of compulsory licenses in order to pressure drug companies to lower prices of drugs.

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<sup>254</sup>Doha Declaration, *supra* note 235.

<sup>255</sup>*Id.*

<sup>256</sup>*Id.*; PhRMA, WTO Doha Declaration Reaffirms Value of Intellectual Property Protection, Press release, November 14, 2001.

<sup>257</sup>*See* Kolker, *supra* note 241.

<sup>258</sup>Canadian HIV/AIDS Legal Network, *supra* note 232.

### C. Response to the Doha Declaration

The response to the Doha Declaration by activist groups was celebratory. According to some, this was the first time, since t

Daniel Berman of Doctors Without Borders said of the Declaration:

The threat of punitive action against a country that attempts to address its health needs has been dramatically reduced. With this declaration it is doubtful that a wealthy country would dare file a dispute against a developing country for using one of the safeguards such as compulsory licensing. Now patent holders either offer prices that make their drugs accessible or risk losing their monopoly prices.<sup>260</sup>

Some activist groups heralded the Declaration as a complete victory: “From now on, the dogma of corporate monopoly on life-saving drugs is no longer law. Governments are now free to make or import generic versions of the drugs they need.”<sup>261</sup>

This celebratory mood was partially unwarranted. The Doha Declaration institutionalizes the norm of greater access to pharmaceuticals. It also contains strong language favoring access to drugs and allows developing countries greater flexibility in obtaining much-needed pharmaceuticals. However, while Doha does articulate the new norm favoring greater access to drugs, it is likely to have less determinative impact than the literal text suggests. Developing countries’ fear of unilateral trade sanctions will keep them from issuing compulsory licenses. Instead, however, they will use the Doha Declaration as a rhetorical stick to get pharmaceutical companies to lower prices.

The impact of the Doha Declaration is limited by the U.S. practice of using its leverage in bilateral negotiations to discourag

The U.S. government is likely to continue this practice, and thus, while compulsory licensing and parallel importing are som

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<sup>259</sup> *Gupta*, *supra* note 9.

<sup>261</sup> *See* Act-Up, *supra* note 248.

<sup>262</sup> *See generally* Sweeney, *supra* note 62; Weissman, *supra* note 32.

<sup>263</sup> *See* Kolker, *supra* note 241.

While Executive Order 13155 clearly states that the United States will not use trade sanctions to seek the revocation or rev

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Furthermore, developing countries still face other bilateral pressures outside of the use of Section 301, such as pressure in in

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Although the Declaration has strong symbolic and rhetorical force, developing countries' fear of unilateral trade sanctions will keep them from issuing compulsory licenses. Instead, however, they will use Doha as a rhetorical stick to get pharmaceutical companies to lower prices. But the Declaration does have strong symbolic and rhetorical force; as such, it will have effects and influences beyond what is in the literal text.

## VII. South Africa After the Lawsuit: Has the Norm Been Internalized?

Has the norm had reached the third stage, that of norm internalization, where norms becomes so widely accepted that “the

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### A. Government Does Not Issue Compulsory Licenses and Refuses to Declare a “National Emergency”

Following the conclusion of the pharmaceutical companies' lawsuit, many expected great progress in terms of improving access to drugs. The Minister of Health assured activist organizations that no concessions had been made in the settlement with the pharmaceutical companies and that the South African government would proceed to implement the Medicines and Related Substance Control Amendment Act.<sup>266</sup> In response, activist groups called on the South African government to issue compulsory licenses.<sup>267</sup> Now is the time for the South African government to issue compulsory licenses for HIV/AIDS drugs to generic manufacturers,

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<sup>264</sup>Exec. Order 13155, *supra* note 157.

<sup>265</sup>Finnemore and Sikkink, *supra* note 13, at 904.

<sup>266</sup>Treatment Action Campaign, Victory for Activists, People With HIV/AIDS and Poor People Everywhere!, Press release, April 19, 2001 (visited Apr. 29, 2002)

<[http://www.globaltreatmentaccess.org/content/press\\_releases/01/041701\\_TAC\\_PR\\_lwsuit\\_win.html](http://www.globaltreatmentaccess.org/content/press_releases/01/041701_TAC_PR_lwsuit_win.html)>.

<sup>267</sup>*Id.*

said Robert Weissman, co-director of Essential Action.<sup>268</sup> Compulsory licensing permits generic competition for on-patent products. By authorizing generic competition,” Weissman stated, “South Africa will see prices fall dramatically and steadily and will enable those with HIV/AIDS to gain access to the medicines they need to survive.”<sup>269</sup>

After the settlement of the case, however, some activists were disappointed by the South African government’s response. Activists called on the government of South Africa to issue the compulsory licenses needed to allow for generic production within the country. But the government did not issue compulsory licenses, largely due to the fear of losing the interest of foreign investors.<sup>270</sup>

President Thabo Mbeki also rejected appeals from labor unions, human rights activists, and opposition politicians to declare a state of “national emergency” that would allow the country to issue compulsory licenses without obtaining authorization from the patent holder.<sup>271</sup> Despite pressures on the government to make AIDS drugs immediately available and affordable, Mbeki’s government feared that declaring a state of emergency would worsen the country’s economic situation by scaring away foreign investors just as the government was trying to improve economic conditions.<sup>272</sup> While Mbeki explained his refusal to declare an emergency by saying that South Africa’s own laws were adequate in providing wider access to AIDS medicines, his government has been reluctant to take steps under these laws to dramatically increase access.<sup>273</sup>

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<sup>268</sup>Consumer Project on Technology and Essential Action, US Consumer Groups Respond to Industry Capitulation in South Africa Drug Case, Press release, April 19, 2001 (visited on Apr. 29, 2002) <<http://www.cptech.org/ip/health/sa/CPTEA04192001.html>>.

<sup>269</sup>*Id.*

<sup>270</sup>*See South Africa Resists Call*, *supra* note 202.

<sup>271</sup>TRIPS Agreement, *supra* note 24, at art. 31(b).

<sup>272</sup>*See South Africa Resists Call*, *supra* note 202.

<sup>273</sup>*See id.*



## **B. Government Interprets 15(C) in a Narrow Manner**

Some activists had hoped that the government would set a precedent for the developing world by giving 15(C) its most expansive meaning – that is, to provide an exception under which the South Africa government could acquire cheap generic equivalents of locally patented medicines by any means possible. For instance, James Love, director of Ralph Nader’s Washington-based Consumer Project on Technology, who had a hand in the original drafting of 15(C), was disappointed by the country’s limited interpretation of 15(C).<sup>274</sup> He had hoped that under 15(C), Pretoria would issue compulsory licenses to import generic copies of drugs made in countries like India, which does not recognize drug patents, as well as to manufacture generics in South Africa for both domestic use and for export to other countries.<sup>275</sup>

However, he and others came to realize that the government was construing 15(C) in a more limited sense to include only “classical” parallel importing; that is, buying medicines manufactured and packaged by the patent holder or its designee, but outside its authorized channels.<sup>276</sup> This type of parallel importing is unquestionably permissible under TRIPS. Love was chagrined to find that government itself was construing 15(C) in a much more limited way, and intended to use it only as a legal basis for “classical” parallel importing.<sup>277</sup>

## **C. Government Refuses to Provide Antiretroviral Treatment**

Despite the adoption of the Doha Declaration, the South African government has not used any of the available tools to red

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<sup>274</sup>Barber, *supra* note 222.

<sup>275</sup>*Id.*

<sup>276</sup>*Id.*

<sup>277</sup>*Id.*

<sup>278</sup>Medecins Sans Frontiers, Brazilian Generic Drugs in South Africa – the Background (visited on Apr. 15, 2002) <<http://www.accessmed-msf.org/prod/publications.asp>>.

Antiretroviral medicines stop HIV from reproducing in the human body, allowing people with HIV/AIDS to live longer, healthier lives.<sup>279</sup> One tablet of the antiretroviral nevirapine taken during labor, along with a single dose for the newborn, can reduce the risk of mother-to-child transmission by 80%.<sup>280</sup> Yet, the government has made the drug available at only 18 pilot sites around the country, and not at public hospitals.<sup>281</sup> Boehringer also offered Nevirapine for free only for the use of mother-to-child transmission prevention in the public sector, and not for the private sector.<sup>282</sup> The government has refused to provide nevirapine to the South African population. In December 2001, the AIDS activist organization Treatment Action Campaign (TAC) filed a lawsuit with the South African High Court to force the government to provide nevirapine to the South African population.<sup>283</sup> The South African High Court found that the government was violating its constitutional obligation to improve access to health care.<sup>284</sup> The Court ruled that South Africa must begin a nationwide nevirapine program, making the drug immediately available at all public hospitals.<sup>285</sup>

In early 2002, activist groups also began a campaign to bring generic drugs into South Africa from Brazil. Doctors Without Borders contracted to purchase antiretroviral drugs produced by FarManguinhos, the Brazilian national pharmaceutical producer, which is part of Fiocruz, a Brazilian public research body.<sup>286</sup> The groups purchased and then proceeded to bring several generic drugs produced by the Brazilian company into South Africa: AZT, 3TC, co-formulated AZT/3TC and nevirapine.<sup>287</sup> The generic drugs produced in Brazil were less expensive than the name-brand versions sold in South Africa. Boehringer Ingelheim sells nevirapine to Doctors Without Borders for US\$1.10 per day in South Africa. The generic version sold by the Brazilian company, however, is only US\$0.59 per day. GlaxoSmithKline offered AZT and Lamivudine to the South African government at US\$2 per day, but the Brazilian company sold a generic version to Doctors Without

<sup>279</sup>Treatment Action Campaign, Questions and Answers about TAC and MSF (visited on Apr. 15, 2002) <[http://web.tac.org.za/Q\\_A\\_ImportBrazil.htm](http://web.tac.org.za/Q_A_ImportBrazil.htm)>.

<sup>280</sup>Ayittey, *supra* note 6.

<sup>281</sup>*See id.*

<sup>282</sup>*See* Treatment Action Campaign, *supra* note 280.

<sup>283</sup>*See* Medicins Sans Frontiers, *supra* note 279; Associated Press, *S. Africa Sued for Failing to Distribute AIDS Drug*, Wash. Post, Aug. 22, 2001, at A14.

<sup>284</sup>*Id.*

<sup>285</sup>Ayittey, *supra* note 6.

<sup>286</sup>*See* Generic AIDS Drugs Offer New Lease of Life to South Africans; Importation of Generics Cuts Price in Half, Joint press release of Medicins Sans Frontiers, Treatment Action Campaign, and Oxfam, Jan. 1, 2002 (visited Apr. 12, 2002) <<http://www.accessmed-msf.org/prod/publications.asp?scntid=2912002105937&contenttype=PARA&>>>.

<sup>287</sup>Medecins Sans Frontiers, *supra* note 279.

Borders for US\$0.96 per day.<sup>288</sup> Since the South African government itself did not authorize the importation of the generic drugs into the country under its patent laws, the importing of the Brazilian drugs into the country contravenes South Africa's patent laws. They are, however, succeeding in bringing much-needed drugs to those suffering from HIV/AIDS.

## Conclusion

What began as a sad story had a potential for a happy ending. Over a short span of time, an international consensus emerged favoring wider access to HIV/AIDS drugs for South Africa, and critical actors took historic steps that would allow for increased availability of more affordable HIV/AIDS drugs to the South African people. The pharmaceutical companies withdrew their lawsuit against the South African government, the U.S. government reversed its original position opposing the law, and the 140 member countries of the World Trade Organization passed a declaration that sought to reconcile public health concerns with the provisions in TRIPS. Activist groups on the international scene and within the country of South Africa spent countless hours disseminating information to the media and the public, strategizing their campaigns, and lobbying key policy-making officials.

Yet, the HIV/AIDS crisis in South Africa appears to be relatively undiminished. Although the norm of wider access emerged and was institutionalized, it has failed to become fully internalized within the domestic political community of the country. The activist groups who originally allied themselves *with* the government against the pharmaceutical companies are now assuming an adversarial position *towards* the government, as they sue the government for distributing drugs, illegally smuggle generic HIV/AIDS drugs into the country, and demand that President Mbeki espouse positions that he fears may alarm the foreign investors with the financial resources the country desperately needs.

This is the current "end" to this story, a disappointing anticlimax after the hopeful emergence of a global

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<sup>288</sup>Treatment Action Campaign, *supra* note 280.

consensus favoring the norm of wider access. However, this does not have to be the end of the story. Developing countries with significant HIV/AIDS problems have taken steps to curb the rates of the epidemic in their borders. In neighboring Botswana, where 36 percent of adults are infected with AIDS, the government announced that it hoped to provide antiretroviral medicines by the end of 2001 to all who need it.<sup>289</sup> Brazil's government decided in 1992 to manufacture its own HIV/AIDS drugs, and today, its government labs produce generic AIDS medications for 81,000 AIDS patients at a yearly cost \$400 million per year.<sup>290</sup> South Africa's current government, however, may not have the financial resources nor the political courage to take such drastic actions. The ultimate solution to the HIV/AIDS crisis may lie in greater financial support for the country and its anti-AIDS programs or a dramatic change in the current political climate. Hopefully, progress will come before it is too late for the South African people.

- THE END -

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<sup>289</sup> See *South Africa Resists Call*, *supra* note 6.

<sup>290</sup> Stephen Buckley, *Brazil Becomes Model in Fight Against AIDS*, Wash. Post, Sept. 17, 2000, at A22.