

# ASSESSING THE BARRIERS TO UNIVERSAL ANTIRETROVIRAL TREATMENT ACCESS FOR HIV/AIDS IN SOUTH AFRICA

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## I. INTRODUCTION

An estimated 5.3 to 5.6 million South Africans are living with HIV/AIDS, more than in any other country.<sup>1</sup> The adult infection rate is approximately 21 percent.<sup>2</sup> Of the 5 million people living with HIV/AIDS estimated 230,000 are children under the age of 15.<sup>3</sup> In 2003 alone, approximately 96,228 babies (about 250 per day) were infected with HIV through mother-to-child transmission (MTCT).<sup>4</sup> HIV disease attacks the immune system, and particularly focuses on CD4 (T-cell helpers) cells.<sup>5</sup> CD4 counts in a healthy adult usually fall within the range of 800 to 1200.<sup>6</sup> As HIV attacks the CD4 cells, this count drops. Once a person's CD4 count falls below 200, the HIV-infected person becomes most susceptible to other infections.<sup>7</sup> Eventually, if left untreated, HIV develops into AIDS. Because of its attack on the body's immune system, AIDS leaves a person nearly indefensible against illness. These illnesses will lead to certain death. Antiretroviral (ARV) treatment has proven successful at signifi-

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1. UNAIDS, 2004 REPORT ON THE GLOBAL AIDS EPIDEMIC 190 (2004) [hereinafter 2004 REPORT]; DEP'T OF HEALTH, REPORT, NATIONAL HIV AND SYPHILIS ANTENATAL SERO-PREVALENCE SURVEY IN SOUTH AFRICA 10 (2003) [hereinafter ANTENATAL SURVEY]. UNAIDS estimates the number of South Africans infected with HIV/AIDS at 5.3 million. 2004 REPORT, *supra*, at 190. UNAIDS also provides a range of the number of infections with a low of 4.5 million South Africans infected to a high of 6.2 million South African infected. *Id.* The South African Department of Health estimates that 5.6 million South Africans were infected by the end of 2003. ANTENATAL SURVEY, *supra*, at 10.

2. UNAIDS, 2004 UPDATE: EPIDEMIOLOGY FACT SHEETS ON HIV/AIDS AND SEXUALLY TRANSMITTED INFECTIONS – SOUTH AFRICA 2 (2004).

3. *Id.*

4. ANTENATAL SURVEY, *supra* note 1, at 10.

5. Whitman-Walker Clinic, *HIV/AIDS Basics*, at [http://www.wwc.org/hiv\\_aids\\_services/technical\\_information.html](http://www.wwc.org/hiv_aids_services/technical_information.html) (last visited Jan. 19, 2005).

6. *Id.*

7. *Id.*

cantly slowing the progression of HIV to AIDS.<sup>8</sup> However, as of 2003, less than one percent of the South African HIV-infected population had access to antiretroviral treatment.<sup>9</sup>

This note will examine the recent and continuing struggle to widespread access to ARV treatment in South Africa in the contexts of both internal infrastructure and drug costs due to patent protection. Much has been written about the effects of the world patent system on access to HIV/AIDS medication in developing countries.<sup>10</sup> Particular attention has been paid to South Africa, in large part due to its 1997 Amendment to the Medicines and Related Substances Control Act and the uproar that law caused among major pharmaceutical companies.<sup>11</sup> A patent system that addresses the needs of HIV-infected South Africans in light of the tremendous costs of ARVs is certainly part of any long-term solution for providing ARV treatment on a widespread basis. However, I argue in part that neither the cost of medication nor the current global patent system has been the only, or indeed the most pressing problem facing South Africa's fight for widespread state distribution of ARV medication.<sup>12</sup> Basic domestic infrastructure and the government's delayed response to the crisis have played a larger role in delaying widespread distribution of ARVs. The first part of this note will examine these domestic issues. The second half of the note will then look at avenues for addressing the next step in the access crisis—how to secure affordable, safe ARVs for the treatment of HIV disease.

## II. DOMESTIC FACTORS AFFECTING ACCESS TO ARVS

### A. Income Levels and Medical Costs

At the end of 2003 the World Bank estimated the average per capita gross national income (GNI) in South Africa at US\$2,780.<sup>13</sup> Within South

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8. *Id.*

9. UNAIDS, ACCELERATING ACTION AGAINST AIDS IN AFRICA 60 (2003) (listing South Africa among many African countries whose coverage rate for ARV treatment in 2003 is less than 1 percent).

10. See generally Srividhya Ragavan, *Can't We All Get Along? The Case for a Workable Patent Model*, 35 ARIZ. ST. L.J. 117 (2003).

11. See John Jeter, *Trial Opens in South Africa AIDS Drug Suit*, WASH. POST, March 6, 2001, at A1, for a brief overview of the case. For more in-depth coverage of the case see Mark Heywood, *Debunking 'Conglomo-talk': A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation*, presented at The Health, Law and Human Rights: Exploring the Connections Conference (Sept. 29-Oct. 1, 2001) [hereinafter Heywood, *Debunking 'Conglomo-talk'*].

12. Clearly, cost plays an important role in access to ARVs. It will be discussed further *infra* at Part II.

13. WORLD BANK, *World Development Indicators Database—South Africa* (2004), available at <http://devdata.worldbank.org/dataonline> (last visited Jan. 31, 2005).

Africa this translates to the buying power of INT\$10,270.<sup>14</sup> The cost of ARVs can exceed US\$10,000 per patient, per year.<sup>15</sup> Clearly this cost plays a role in the limited access HIV-infected South Africans have to the medications.

In a 1999 survey published by the Kaiser Family Foundation only 19 percent of South Africans reported full private health coverage.<sup>16</sup> The choice to use private health facilities, where most of the country's health resources are allocated, was largely determined by whether a person had access to private health coverage.<sup>17</sup> This trend was particularly pronounced when comparing public and private hospitals. Patients with private health coverage accounted for 85 percent of those seen at private hospitals while only four percent of patients visiting public hospitals paid via private health coverage.<sup>18</sup> South Africans reported cost as the main reason for not seeking medical attention when needed. In the survey, 66 percent of the respondents cited their inability to afford medical care as the reason they failed to get treatment.<sup>19</sup>

## B. The Fight for Government Support

In recent years South Africans have been fighting an uphill battle with the government on the appropriate response to the AIDS crisis. South African President Thabo Mbeki received world-wide criticism for his public questioning of both the causal link between HIV and AIDS and the effectiveness of ARVs in treating HIV. In October 1999, both Mbeki and "his health minister disputed the safety and effectiveness of AZT, a standard drug used to block transmission of HIV from mother to child."<sup>20</sup> Mbeki

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14. *Id.* This data is based on purchasing power parity of international dollars which are defined as having the same purchasing power over gross national income as the purchasing power of US\$1 within the United States. *Id.*

15. Barton Gellman, *S. African President Escalates AIDS Feud; Mbeki Challenges Western Remedies*, WASH. POST, Apr. 19, 2000, at A1; *see also infra* Part II.

16. HENRY J. KAISER FAMILY FOUND., *The Second Kaiser Family Foundation Survey of Health Care in South Africa* ii (1999), available at <http://www.kff.org/southafrica/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=13242> (last visited Jan. 31, 2005) [hereinafter KAISER FAMILY FOUND.].

17. *See id.* at iii; *see also* Law and Treatment Access Unit of the AIDS Law Project & Treatment Action Campaign, *The Price of Life* 31 (2003).

18. KAISER FAMILY FOUND., *supra* note 16, at iii.

19. *Id.* at 19.

20. Henri E. Cauvin, *South African Retreats from AIDS Debate*, N.Y. TIMES, Oct. 17, 2000, at A14; *see also* Mark Heywood, *Current Developments: Preventing Mother-to-Child HIV Transmission in South Africa: Background, Strategies and Outcomes of the Treatment Action Campaign Against the Minister of Health*, 19 S. AFR. J. OF HUM. RTS. 278, 281-83 (2003) (describing the relationship between

again entered the public debate about AIDS in 2000 by assembling a task force that included experts who denied the causal link between HIV and AIDS.<sup>21</sup> In a letter written to world leaders, including then U.S. President Bill Clinton, Mbeki defended his actions by equating criticism of his inclusion of these scientists in the discourse on the AIDS crisis in South Africa to the “racist apartheid tyranny” previously present in the country.<sup>22</sup> Though Mbeki later retreated from these positions in the wake of public criticism, he went only so far as to say that South Africa’s efforts to fight AIDS would be “based on the ‘thesis’ that HIV causes AIDS.”<sup>23</sup>

It was against the backdrop of this public and prolonged debate that South Africa began to address the prevalence of HIV/AIDS in the country with two distinct but important achievements. The first was the February 2000 release by the Department of Health of a comprehensive Strategic Plan detailing the South African AIDS epidemic and proposals for responding to the crisis.<sup>24</sup> In addition to reporting statistical information about the epidemic and acknowledging the huge scale of the spread of HIV/AIDS in South Africa, the report was “designed to guide the country’s response as a whole to the epidemic” for five years.<sup>25</sup> The Plan detailed issues to be addressed regarding effective implementation of a national program to combat the AIDS epidemic. Included were goals to improve structures of delivery, to address the issue of human resources, and to establish acceptable standards of funding.<sup>26</sup>

Access to ARVs was addressed in Goal 11 of the Plan’s 15 goals.<sup>27</sup> Included in this goal were three objectives:

- (1) “Review and revise policy on anti-retroviral use for reducing mother-to-child HIV transmission.”
- (2) “Conduct research on the cost-effectiveness of other forms of non-retroviral treatment and prophylaxis.”
- (3) “Conduct research on the effectiveness of traditional medicines.”<sup>28</sup>

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“AIDS denial” and the derailment of a national program to prevent MTCT of HIV) [hereinafter Heywood, *Current Developments*].

21. Cauvin, *supra* note 20, at A14.

22. *S. African President Addresses AIDS in Africa*, WASH. POST [Online Edition], April 19, 2000, at <http://www.washingtonpost.com/ac2/wp-dyn/A40387-2000Apr18> (last visited Jan. 31, 2005).

23. Cauvin, *supra* note 20, at A14.

24. *See generally*, MINISTER OF HEALTH, HIV/AIDS/STD STRATEGIC PLAN FOR SOUTH AFRICA 2000-2005 (2000).

25. *Id.* at 5–6.

26. *Id.* at 26–7.

27. *Id.* at 22.

Strikingly, even though it was published in 2000, the report lacked reference to any objective encompassing research on or development of ARV medication outside the context of MTCT.<sup>29</sup>

The second achievement, which was aggressively fought but eventually conceded by the South African government, was the outcome of a Constitutional Court battle in favor of wider distribution of the ARV drug Nevirapine for use in prevention of MTCT.<sup>30</sup> Without any intervention the MTCT rate is 35 percent.<sup>31</sup> Transmission of the virus during pregnancy and during labor and delivery process accounts for 65 percent to 70 percent of infections transmitted from mother to child.<sup>32</sup> The normal course of treatment with Nevirapine—a single dose to the mother during delivery followed by a single dose to the child within 72 hours of birth—can reduce transmissions during pregnancy, labor and delivery by 50 percent.<sup>33</sup>

Results from a study conducted by the National Institutes of Health (NIH) demonstrated the efficacy of Nevirapine as early as 1999.<sup>34</sup> The effectiveness of single-dose Nevirapine was further backed by the release of preliminary results of the South African Intra-partum Nevirapine Trial (SAINT) in 2000.<sup>35</sup> Also in 2000, the manufacturer of Nevirapine, Boehringer Ingelheim, partnered with the United Nations to offer the drug free of charge to developing countries, including South Africa, for five years.<sup>36</sup> Despite this offer, the government “reacted coolly to the preliminary announcement of the SAINT results.”<sup>37</sup> South Africa’s Medicines Control Council (MCC) approved registration of Nevirapine for the ‘prevention of

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28. *Id.*

29. *See id.*

30. *See generally*, Minister of Health v. Treatment Action Campaign (No. 2), 2002 (5) SALR 721 (CC); Heywood, *Current Developments*, *supra* note 20 (documenting litigation challenging the South African government’s policy of limiting provision of Nevirapine for the prevention of MTCT to pilot sites).

31. UNICEF, FACT SHEET, MOTHER-TO-CHILD TRANSMISSION OF AIDS (Feb. 2002), *available at* [http://www.unicef.org/publications/pub\\_factsheet\\_mtct\\_en.pdf](http://www.unicef.org/publications/pub_factsheet_mtct_en.pdf) (last visited Jan. 31, 2005).

32. *Id.* The other mode of transmission from mother to child is breastfeeding which accounts for about 33 percent of all MTCTs. *Id.*

33. *Id.*

34. Heywood, *Current Developments*, *supra* note 20, at 285.

35. *Id.* Prior to the testing of Nevirapine, the drug of choice for preventing MTCT was AZT. While effective in reducing MTCT, AZT required a much more complicated regimen, beginning earlier in a women’s pregnancy. *Id.* at 279–80, 285. The government’s strong opposition to AZT’s use in the prevention of MTCT led to activists focusing on Nevirapine as the drug of choice for the prevention of MTCT in South Africa. *Id.* at 282, 285.

36. UNAIDS, FACT SHEET, UNITED NATIONS SPECIAL SESSION ON HIV/AIDS: GLOBAL CRISIS – GLOBAL ACTION 26 (June 27, 2001), *available at* [http://www.un.org/ga/aids/ungassfactsheets/pdf/allfactsheets\\_en.pdf](http://www.un.org/ga/aids/ungassfactsheets/pdf/allfactsheets_en.pdf) (last visited Jan. 31, 2005).

37. Heywood, *Current Developments*, *supra* note 20, at 285–86.

intra-partum transmission' on April 18, 2001.<sup>38</sup> Even after the registration of Nevirapine, the government refused to release the drug to public hospitals beyond two pilot sites in each province.<sup>39</sup>

The Treatment Action Campaign (TAC)—a group committed to ensuring access to HIV/AIDS medication to South Africans—brought suit against the Minister of Health in the Pretoria High Court in August 2001.<sup>40</sup> The TAC sued to combat the government's refusal to generally distribute Nevirapine, despite its proven effectiveness in reducing MTCT, at public hospitals where testing and counseling was available.<sup>41</sup> Leading up to the court filing in Pretoria, the TAC had repeatedly requested that the government expand its program to prevent MTCT of HIV.<sup>42</sup> In 1999 the government, concerned with the "safety and efficacy of Nevirapine," responded that it could not at the time accelerate its plan to prevent MTCT.<sup>43</sup> Nearly a year later, the Minister of Health announced a plan that failed to provide for general distribution of Nevirapine, instead limiting its distribution to two test sites per province.<sup>44</sup>

The result of this decision was that in public health facilities that were not chosen as pilot sites—which amounted to facilities that oversaw 90 percent of the public sector births—even where counseling and testing was available, mothers were being denied Nevirapine because these facilities were prohibited from distributing it.<sup>45</sup> By contrast any private health facility was allowed to prescribe and dispense Nevirapine.<sup>46</sup> Given that only 19 percent of South Africans carry full private health coverage, and that those without such coverage are far more likely to seek care in public facilities,<sup>47</sup> the government's plan had the effect of excluding a large majority of women and newborns from access to Nevirapine during the birthing process.

The Pretoria High Court issued an order requiring the government to more widely distribute Nevirapine and to implement a nation-wide program

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38. *Id.* at 289. Notably, registration had first been recommended on November 24, 2000. *Id.*

39. *See id.* at 290–291.

40. Though there were other plaintiffs involved in the suit, the main party was the TAC. *Minister of Health v. TAC*, 2002 (5) SALR at 728. More information about the TAC can be found at <http://www.tac.org.za>.

41. *Minister of Health v. TAC*, 2002 (5) SALR at 728.

42. *Id.* at 731.

43. *Id.*

44. *Id.* *See also* Heywood, *Current Developments*, *supra* note 20, at 285–286 (detailing political responses to government plan for limited testing of Nevirapine at pilot sites).

45. *See Minister of Health v. TAC*, 2002 (5) SALR at 734, 746.

46. *Id.* at 734.

47. *See supra* notes 16–19 and accompanying text.

for preventing MTCT.<sup>48</sup> The government appealed this ruling to the Constitutional Court citing a concern that the “judgement could have far-reaching implications in defining our constitutional democracy and in shaping the State’s responsibility for the delivery of social services.”<sup>49</sup> Relying on the South African Constitution’s protection of socio-economic rights, the Constitutional Court found the government’s limitation on the distribution of Nevirapine unreasonable.<sup>50</sup> It additionally charged the government with developing and implementing a “comprehensive and co-ordinated programme to realise progressively the right of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV.”<sup>51</sup>

The most immediate effect of the Constitutional Court’s ruling was to release the restriction on public health facilities’ abilities to prescribe Nevirapine for the prevention of MTCT of HIV. In a statement issued on the same day as the Court’s judgment, the Minister of Health indicated that the “Government welcome[d] the fact that the protracted court case on the provision of Nevirapine to prevent mother-to-child transmission (PMTCT) of HIV ha[d] come to a conclusion.”<sup>52</sup> The government “accept[ed] the ruling of the court on this matter.”<sup>53</sup> Additionally, the Minister announced that

48. Minister of Health v. TAC, 2002 (5) SALR at 730.

49. Press Release, MINISTER OF HEALTH, Response Of Dr Manto Tshabalala-Msimang, Minister Of Health, And MECs To Judgment On Nevirapine (Dec. 19, 2001), *available at* <http://www.info.gov.za/speeches/2001/011220246p1006.htm> (last visited Jan. 30, 2005)

50. Minister of Health v. TAC, 2002 (5) SALR at 764–65. The constitutional provisions relied upon were sections 7(2) and 8(1) which provide:

7(2) The State must respect, protect, promote and fulfill the rights in the Bill of Rights.

....

8(1) The Bill of Rights applies to all law, and binds the Legislature, the Executive, the Judiciary and all organs of State.

*Id.* at 729 (quoting S. Afr. Const. ss 7, 8). The Bill of Rights provisions that provide for the socio-economic rights at question in this case were:

27(1) Everyone has the right to have access to—

(a) health care services, including reproductive health care;

....

(2) The State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

....

28(1) Every child has the right—

....

(c) to basic nutrition, shelter, basic health care services and social services.

*Id.* (quoting S. Afr. Const. ss. 27, 28 (Bill of Rights)).

51. *Id.* at 764.

52. Press Release, MINISTER OF HEALTH, Statement on Constitutional Court Judgment on PMTCT (July 5, 2002), *available at* <http://www.info.gov.za/speeches/2002/02070811461006.htm> (last visited Jan. 30, 2005).

53. *Id.*

the “government will implement the temporary ruling of the Constitutional Court on provision of Nevirapine beyond the designated sites, on the basis of a determination by relevant health authorities regarding the existence of appropriate capacity . . . .”<sup>54</sup> By October 2002, four of South Africa’s nine provinces had expanded the distribution of Nevirapine beyond the test sites.<sup>55</sup> Though by August 2003 four provincial governments had signed on with Boehringer Ingelheim to receive Nevirapine free as part of the company’s donation program, the national government had yet to accept the donations as of August 2003.<sup>56</sup>

Unclear at the close of the case was when the South African government could and would implement a national PMTCT program. In an updated Cabinet Statement in October 2002, the government made a vague statement regarding its plan for a national program.<sup>57</sup> The Statement identified “the most critical challenges” as “training, budget, proper health facilities and community attitudes,” and reported that “training has started in all provinces.”<sup>58</sup> Additionally, the government “continue[d] to upgrade health facilities for testing, counselling and monitoring” and promised that “[f]unds will be made available for the roll-out.”<sup>59</sup> No specific information about how the government planned to combat these challenges was included in the Statement.

An Associated Press series published in December 2004 raised new questions about the demonstrated safety and efficacy of Nevirapine.<sup>60</sup> Two of the stories raised concerns about the protocols followed during a Nevirapine study conducted by the National Institutes of Health (US) in Uganda from 1997 to 1999.<sup>61</sup> These stories alleged that potentially serious side ef-

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54. *Id.*

55. Government Communication and Information System, Update on Cabinet’s Statement of 17 April 2002 on fighting HIV/AIDS (October 9, 2002) [hereinafter Updated Statement], available at <http://www.info.gov.za/speeches/2002/02101011461001.htm> (last visited Jan. 30, 2005).

56. See Press Release, BOEHRINGER INGELHEIM, Forty-four Countries Have Taken Up Boehringer Ingelheim’s Viramune Donation (August 6, 2003), available at <http://www.boehringer-ingelheim.com/corporate/asp/news/ndetail.asp?ID=1054> (last visited Jan. 28, 2005).

57. Updated Statement, *supra* note 55.

58. *Id.*

59. *Id.*

60. Associated Press, *Woman Died During AIDS Drug Study*, Dec. 16, 2004, available at <http://www.msnbc.msn.com/id/6721861> (last visited Jan. 28, 2005); Associated Press, *Gov’n’t MD Doctored AIDS Drug Study*, Dec. 14, 2004, available at <http://www.cbsnews.com/stories/2004/12/13/world/main660803.shtml> (last visited Jan. 28, 2005); Associated Press, *Officials Hid AIDS Drug Dangers*, Dec. 13, 2004, available at [www.cbsnews.com/stories/2004/12/14/world/main661117.shtml](http://www.cbsnews.com/stories/2004/12/14/world/main661117.shtml) (last visited Jan 28, 2005).

61. *Gov’n’t MD Doctored AIDS Drug*, *supra* note 60; *Officials Hid AIDS Drug Dangers*, *supra* note 60.

fects of Nevirapine, including death, were covered up in the Ugandan study to prevent from derailing President Bush's 2002 announcement of a \$500 million aimed at preventing MTCT in Africa.<sup>62</sup> The stories also argued that a closer review of the Ugandan research revealed "that even single doses of Nevirapine can create instant resistance."<sup>63</sup> A third article discussed the August 2003 death of a Tennessee woman who died from a liver disease likely related to long-course Nevirapine.<sup>64</sup>

AIDS activists fear that these articles will unnecessarily derail MTCT programs that rely on single-dose Nevirapine.<sup>65</sup> The African National Congress (ANC), the ruling political party in South Africa and the party to which President Mbeki belongs, has accused the United States government of using Africans as "guinea pigs" and of conspiring "with a pharmaceutical company to tell lies to promote the sales of [N]evirapine in Africa, with absolutely no consideration of the health impact of those lies on the lives of millions of Africans."<sup>66</sup> Such claims are unfounded.<sup>67</sup> There were reporting problems with the Ugandan study but these problems did not undermine the primary conclusion of the study—that single-dose Nevirapine provides an effective and relatively safe option for the prevention of MTCT.<sup>68</sup> These results are supported by at least seven other trials, including one conducted in South Africa.<sup>69</sup> The death of the woman in Tennessee, while tragic, bears little on the issue of safety of single-dose Nevirap-

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62. *Officials Hid AIDS Drug Dangers*, *supra* note 60.

63. *Id.*; *Govn't MD Doctored AIDS Drug*, *supra* note 60.

64. *Woman Died During AIDS Drug Study*, *supra* note 60.

65. John S. James, *Nevirapine Misinformation: Will it Kill?*, AIDS TREATMENT NEWS, Dec. 2004, at <http://www.aidsnews.org/2004/12/nevirapine-ap.html> (last visited Jan. 28, 2004) ("The danger now is that misleading [N]evirapine stories published around the world will cause patients, doctors, or even governments to reject single-dose [N]evirapine to prevent mother-to-child HIV transmission, in cases when no other treatment is possible.").

66. *Nevirapine, drugs & African guinea pigs*, 4 ANC TODAY 50, ¶ 5 (Dec 17, 2004), at <http://www.anc.org.za/ancdocs/ancoday/2004/at50.htm> (last visited Feb. 2, 2005); *See also*, Donald G. McNeil, Jr., *Furor in Africa Over Drug for Women with H.I.V.*, N.Y. TIMES, Dec. 21, 2004, at A6;

67. An excellent critique of the Associated Press stories and the sensationalized response to them can be found at Theo Smart, *Associated Press Story Puts Antiretroviral Programmes at Risk*, HIV & AIDS TREATMENT IN PRACTICE #38, Dec. 22, 2004, *reprinted at* <http://www.essentialdrugs.org/edrug/archive/200501/msg00001.php> (last visited Jan. 28, 2005).

68. *Id.* One story raised concerns about the sloppy reporting techniques of the study claiming that "NIH investigators couldn't be sure from patient records which mothers got the drug. Instead, they had to use blood samples to confirm doses, the documents show." *Officials Hid AIDS Drug Dangers*, *supra* note 60.

69. Treatment Action Campaign, *ANC Today Article is Inaccurate and Contradicts ANC and Government Policy*, Jan. 17, 2005, at <http://www.tac.org.za/ResponseToANCTodayNevirapineArticle.htm> (last visited Jan 28, 2005).

ine.<sup>70</sup> The potential for liver complications for long-course Nevirapine had been well documented as early as 2000.<sup>71</sup> Adequate liver-function monitoring likely could have prevented her death but was not provided to her by the study.<sup>72</sup> Liver-related complications have not arisen from single-dose administration of Nevirapine.<sup>73</sup>

Resistance-related side-effects appear to be the most credible concern raised by the Associated Press stories.<sup>74</sup> At least one other clinical trial has raised some concern about decreased effectiveness of ARVs after the administration of single-dose Nevirapine.<sup>75</sup> However, such resistance has only been observed in a small number of women.<sup>76</sup> Resistance-related concerns are also only most relevant for those women who are in need of immediate ARV treatment after receiving single-dose Nevirapine.<sup>77</sup> Many women who receive single-dose Nevirapine to prevent MTCT of HIV are not immediately in need of continued ARV treatment.<sup>78</sup> Resistance concerns should not be a complete bar to the use of single-dose Nevirapine.<sup>79</sup> Rather, such concerns should be a factor taken into account when deciding whether to administer single-dose Nevirapine to a pregnant woman.<sup>80</sup>

The TAC continues to push for wider distribution of Nevirapine until it reasonably can be replaced by more effective medication. It recently released another statement urging the South African government to comply with the Constitutional Court ruling regarding access to Nevirapine.<sup>81</sup> The statement reminded the South African government that single-dose Nevirapine remains a safe option for the prevention of MTCT.<sup>82</sup>

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70. Smart, *supra* note 67.

71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.* (“Earlier this year, data from a clinical study also showed that some women who took [single-dose Nevirapine] had a less robust virologic response to subsequent antiretroviral therapy.”).

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. *Id.*

81. Statement, Treatment Action Campaign, *Single-Dose Nevirapine Is Safe And Effective, But Government Should Switch To More Effective Regimens Wherever Possible*, Dec. 15, 2004, at [http://www.tac.org.za/newsletter/2004/ns15\\_12\\_2004a.html](http://www.tac.org.za/newsletter/2004/ns15_12_2004a.html) (last visited Jan. 28, 2005).

82. *Id.*

### C. The Operational Plan

After years of struggle with the South African government over the appropriate course of action to address the needs of the millions of HIV-infected South Africans, South African AIDS activists won a potentially huge victory. On November 19, 2003 the South African government announced a comprehensive and aggressive program for combating HIV/AIDS. The Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa addresses issues from the planned course of action in administering ARV treatment to implementation and health care staffing plans to budget and funding priorities.<sup>83</sup> The plan addresses the issue of access to ARV in several ways, including: 1) Setting out a timeframe for distribution; 2) setting out a national health standard for when ARVs will be administered both to adults and children; 3) continuing to include Nevirapine in its plan for the PMTCT of HIV; and 4) considering the funding and research elements necessary to achieving the objectives of the plan.<sup>84</sup> Clearly, the announcement of the Operational Plan marked a significant change in the public attitude the government has displayed toward the existence of and treatment options for the HIV/AIDS epidemic in South Africa. Less clear is how effective the government will be in carrying out the Plan. The failures of the plan in the year since it was first announced will be briefly discussed in the concluding portion of this note.

Under the new plan the government predicted it would provide access to ARVs over a six-year period to 1,470,510 patients.<sup>85</sup> The following table shows the new patients per year to whom the government planned to provide ARVs under the plan:

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83. *See generally* MINISTER OF HEALTH, OPERATIONAL PLAN FOR COMPREHENSIVE HIV AND AIDS CARE, MANAGEMENT AND TREATMENT FOR SOUTH AFRICA (2003) [hereinafter OPERATIONAL PLAN].

84. *Id.* at 68. MINISTER OF HEALTH, EXECUTIVE SUMMARY, OPERATIONAL PLAN FOR COMPREHENSIVE HIV AND AIDS CARE, MANAGEMENT AND TREATMENT FOR SOUTH AFRICA 18, 36, 38–40, 42 (2003) [hereinafter EXECUTIVE SUMMARY].

85. *Id.* at 42.

**New Patients Starting ARVs  
and Total Cumulative Numbers on ARVs<sup>86</sup>**

Year	New Cases Starting ARVs	Total Cases on ARVs
2003/04	53,000	53,000
2004/05	138,315	188,665
2005/06	215,689	381,177
2006/07	299,516	645,740
2007/08	411,889	1,001,534
2008/09	551,089	1,470,510

The national standard adopted by the Operational Plan for the timing of ARV administration is substantially similar to the guidelines suggested by the World Health Organization (WHO) for antiretroviral therapy (ART) in developing countries.<sup>87</sup> The Plan details administration protocol for both adults and children. Following the WHO recommendations for administration of ARVs in developing countries closely,<sup>88</sup> the Operational Plan sets the standard for when ARVs should be administered to adults as:

- CD4 count  $\leq$  200 cells/mm<sup>3</sup> and symptomatic, irrespective of stage,
- or*
- WHO stage IV AIDS defining illness, irrespective of CD4 count,

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86. *Id.*

87. OPERATIONAL PLAN, *supra* note 83, at 63, 69.

88. *See* WORLD HEALTH ORG., EXECUTIVE SUMMARY, SCALING UP ANTIRETROVIRAL TREATMENT IN LIMITED RESOURCE SETTINGS: GUIDELINES FOR A PUBLIC HEALTH APPROACH 11 (2002) [hereinafter ANTIRETROVIRAL THERAPY GUIDE, EXECUTIVE SUMMARY], *available at* [http://www.who.int/hiv/topics/arv/en/scaling\\_exe\\_summary.pdf](http://www.who.int/hiv/topics/arv/en/scaling_exe_summary.pdf) (last visited Feb. 2, 2005). WHO recommends ARV treatment begin after any of three events occur: WHO stage IV of HIV disease (clinical AIDS), regardless of CD4 count; WHO Stages I, II or III of HIV disease, with a CD4 count below 200/mm<sup>3</sup>; or, when CD4 count is unavailable, WHO Stages II or III of HIV disease with TLC (total lymphocyte count) below 1200/mm<sup>3</sup>. *Id.* WHO HIV stages are defined in the full version of the same report. WHO, SCALING UP ANTIRETROVIRAL THERAPY IN RESOURCE-LIMITED SETTINGS: GUIDELINES FOR A PUBLIC HEALTH APPROACH 98–100 (2002) [hereinafter ANTIRETROVIRAL THERAPY GUIDE], *available at* [http://www.who.int/hiv/pub/prev\\_care/en/ScalingUp\\_E.pdf](http://www.who.int/hiv/pub/prev_care/en/ScalingUp_E.pdf) (last visited Feb. 2, 2005). Generally, Stage I is asymptomatic, Stage II and III are characterized by weight loss and certain opportunistic infections, and the final stage, Stage IV, is characterized by HIV wasting syndrome – “weight loss of >10% of body weight, plus either unexplained chronic diarrhea (>1 month) or chronic weakness and unexplained prolonged fever (>1 month)” or other more serious opportunistic infections, such as Kaposi’s sarcoma or Lymphoma, which are often considered AIDS defining. *Id.* at 98–99.

*and*

- Patient prepared and ready to take ARVs adherently.<sup>89</sup>

Again, following pediatric WHO recommendations,<sup>90</sup> for children under six years of age, the Operational Plan calls for treatment when:

- CD4 percentage < 15% and symptomatic,

*or*

- WHO Pediatric Stage III AIDS defining illness, irrespective of CD4 percentage,

*and*

- At least one responsible person capable of administering the child's medication.<sup>91</sup>

The Operational Plan additionally takes into account the need for regular testing to determine when, based on CD4 counts, a patient should begin ARV treatment.<sup>92</sup> The Plan sets up guidelines for when and how frequently testing should occur based on a patient's last CD4 count.<sup>93</sup>

The Operational Plan also addresses the continued goal of PMTCT and treatment guidelines for HIV-infected pregnant women.<sup>94</sup> It not only confirms the continued use of single-dose Nevirapine during labor for HIV-infected women and their babies, but it also sets guidelines for when full course ART should be administered during pregnancy.<sup>95</sup> The guidelines make any pregnant woman after her first trimester eligible for ART if her CD4 count drops below 200.<sup>96</sup> Additionally, the Operational Plan makes strong recommendations that ART eligibility be extended to "pregnant women with CD4 counts between 200 and 350. . . after the first trimester, with therapy to be continued for life."<sup>97</sup>

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89. OPERATIONAL PLAN, *supra* note 83, at 63.

90. WHO recommends that ARVs be administered for children over 18 months if "they have WHO Stage III HIV disease (i.e. clinical AIDS) regardless of CD4 percentage" or, for children with WHO stage I or II HIV disease, ART is recommended if the CD4 percentage is < 15%. ANTIRETROVIRAL THERAPY GUIDE, EXECUTIVE SUMMARY, *supra* note 88, at 11. WHO defines three clinical stages for children. ANTIRETROVIRAL THERAPY GUIDE, *supra* note 88, at 100. Stage I is asymptomatic, Stage II is characterized by symptoms such as persistent fever and recurrent bacterial infections, Stage III is characterized by AIDS defining opportunistic infections or more severe symptoms than those in Stage II such as severe failure to thrive or malignancy. *Id.*

91. OPERATIONAL PLAN, *supra* note 83, at 69.

92. *Id.* at 65–66.

93. *Id.* at 66.

94. *Id.* at 68.

95. *Id.*

96. *Id.*

97. *Id.*

Funding the Operational Plan is a huge challenge that has been addressed as well. Though a large factor in determining cost and success of the program is the future ability of the government to secure ARVs inexpensively, which will be discussed further in Part III, other funding needs are recognized in the Operational Plan and bear mention here. The Plan includes five-year budget estimates for expenses such as ARV drugs, health-care staff, health system upgrades including development and support of new drug distribution methods, testing, and research.<sup>98</sup> It allocates R42 million (Rand, which is approximately US\$6.36 million) to ARVs in the first year and about R1.6 billion (US\$242 million) over five years.<sup>99</sup> The entire program costs are estimated at nearly R12 billion (US\$1.82 billion) for five years.<sup>100</sup>

### III. THE NEXT STEP: SECURING AFFORDABLE ARVS

South Africa now has in place a comprehensive national plan for the prevention and treatment of HIV/AIDS, which includes a plan to distribute ARVs widely over the next five years and which in many respects represents a complete reversal of the position of the South African government less than four years ago. However, a large question remains as to whether the government will be able to procure ARVs to cover all of those it has planned to at a cost it can afford.

As of May 2003 the cheapest price for yearly treatment per person of WHO recommended Highly Active Antiretroviral Therapy (HAART), a treatment that combines three types of ARVs, was US\$675 for a brand name treatment or \$300 for generic treatment.<sup>101</sup> Though these prices represent a significant drop from prices only a few years ago, they still represent a significant cost for the South African government in implementing its Operational Plan.<sup>102</sup> Based on the budget and ARVs coverage information provided in the Operational Plan, the government planned to spend from R792 (US\$119) in the first year of the program to R1956 (US\$296) in

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98. EXECUTIVE SUMMARY, *supra* note 84, at 36–37.

99. *Id.* All conversions from Rand to US dollars are based on the conversion rates applicable on November 19, 2003, the date of the release of the Operational Plan. The conversion rate use is available at <http://www.xe.com/ict/> (select US dollars under “based on this currency. . .” heading and November 19, 2003 under “as of this date. . .” heading) (last visited Jan. 28, 2005).

100. *See id.* at 37.

101. UNAIDS, FACT SHEET, ACCESS TO HIV TREATMENT AND CARE (November 15, 2003).

102. *See id.* (stating that “[e]ven with greatly reduced drug prices, in low-income countries with high AIDS prevalence, significant external financing is needed to provide antiretrovirals to all those in need.”). “In early 2000, the price of [HAART] for one patient for a year was US\$10,000–US\$12,000. By the end of 2000, prices had dropped to US\$500–US\$800 per person per year for first-line antiretroviral treatment in low-income countries.” *Id.*

the second year of the program per person per year on ARVs.<sup>103</sup> For the projections of the Operation Plan to be realized the South African government must develop and implement a strategy that addresses the need to procure affordable ARVs. To do this it will need to rely on both international agreements that allow access to generic substitutions for brand name ARVs and access in certain settings for patented drugs at heavily discounted prices, as well as on its own patent and prescription drug laws.

#### A. International Agreements

The World Trade Organization (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPS)<sup>104</sup> was created in 1994 and took effect on January 1, 1995.<sup>105</sup> The agreement extensively covers intellectual property rights, including patent rights for pharmaceuticals. Patent law protection affords a patent holder the exclusive rights over the patented good or process for a set period of time.<sup>106</sup> The general theory behind patent protection is that such protection allows for a monopoly period during which the patent holder can recover research and development (R&D) costs.<sup>107</sup> This monopoly period, in theory, provides an incentive for future investment into R&D with the promise of potential profit after costs have been recovered.<sup>108</sup>

Developed countries were given one year from the date of effectiveness of TRIPS, until January 1, 1996, to comply with the terms of the agreement.<sup>109</sup> Developing WTO member countries were given until January 2000 to comply generally with patent provisions of the agreement.<sup>110</sup> Developing countries that, unlike South Africa, had no previous patent law covering areas such as pharmaceuticals, were given until 2005 to extend

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103. See EXECUTIVE SUMMARY, *supra* note 84, at 37, 42. The highest amount per person allocated in any given year for ARV spending in is the second year of the program. After the second year, allocated spending per person slowly declines from R1956 (US\$296) to R1647 (US\$249) in the fifth year. See *id.*

104. Agreement on Trade-Related Aspects of Intellectual Property Rights, December 15, 1993, 33 I.L.M 81 [hereinafter TRIPS].

105. See Commission on Intellectual Property Rights, Integrating Intellectual Property Rights & Development Policy, 3 (2002).

106. *Id.* at 14. See also Susan Cleary & Don Ross, *The 1998 Legal Struggle between the South African Government and the International Pharmaceutical Industry: A Game-Theory Analysis*, 27 J. SOC. POL. & ECON. STUD. 445, 448 (2002) (describing the patent protection afforded under the TRIPS Agreement).

107. Commission on Intellectual Property Rights, *supra* note 105, at 14.

108. *Id.*

109. *Id.* at 3.

110. *Id.*

their patent law to the areas protected under TRIPS.<sup>111</sup> South Africa agreed to the provisions of TRIPS and adopted compliance with TRIPS into its own laws in 1997.<sup>112</sup> Patents are covered by the TRIPS agreement in Articles 27–34. TRIPS provides for a minimum term of protection of 20 years,<sup>113</sup> during which time the subject of a patent is protected from use, sale or import without the patent owner's consent.<sup>114</sup>

For South Africa's next step in securing affordable ARVs, the two most important international legal concepts to focus on are parallel importing and compulsory licensing.<sup>115</sup> While both of these concepts are addressed in TRIPS, they rely on domestic laws for definition.<sup>116</sup> The relation of these concepts to South African domestic law will be discussed later in the note.

Parallel importing occurs when goods "are purchased in a foreign market by an independent third party and [then] later resold in the domestic market where their much lower prices compete with those of authorized distributors."<sup>117</sup> It is addressed by Article 6 of TRIPS which states that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."<sup>118</sup> The "issue of exhaustion of rights" in Article 6 refers to the right of resale.<sup>119</sup> Under some domestic patent laws, patent protection only extends to the first sale and not to any subsequent resale of goods by a party other than the patent holder, allowing for

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111. TRIPS, *supra* note 104, art. 65, para. 4 ("To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2 above, it may delay the application of the provisions on product patents of Section 5 of Part II. . .to such areas of technology for an additional period of five years." South Africa, by contrast, had in place an extensive patent protection scheme, which included the protection for pharmaceutical products, at the time of the creation of TRIPS in 1994. *See* Patent Act 57 of 1978, Ch. 5, Art. 25 (S. Afr.) (stating that "a patent may. . .be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture").

112. Intellectual Property Laws Amendment Act 38 of 1997 (S. Afr.).

113. TRIPS, *supra* note 104, art. 33.

114. *Id.* at art. 28; *see also*, Alan O. Sykes, *Public Health and International Law: TRIPS, Pharmaceuticals, Developing Countries and the Doha "Solution,"* 3 *CHI. J. INT'L L.* 47, 50–53 (2002) (discussing pertinent TRIPS provisions).

115. *See* Cleary & Ross, *supra* note 106, at 447–49 (2002) (defining parallel importing and compulsory licensing and their allowed functions under TRIPS).

116. *Id.*

117. Duane Nash, *South Africa's Medicines and Related Substance Control Amendment of 1997*, 15 *BERKELEY TECH. L.J.* 485, 490 (2000).

118. TRIPS, *supra* note 104, art. 6.

119. Cleary & Ross, *supra* note 106, at 448

the possibility of parallel importing.<sup>120</sup> TRIPS leaves the decision about the legality of parallel importing to the discretion of domestic patent laws.<sup>121</sup>

Provisions for compulsory licensing are provided for by Article 31 of the TRIPS agreement. Article 31 sets out an allowed exception to a patent holder's exclusive rights over the patented good, which can be provided for under domestic law.<sup>122</sup> The exception allows for the good to be licensed for use "without the authorization of the right holder," in certain defined situations.<sup>123</sup> Domestic law can allow use of a patented good without authorization when authorization has been sought on "reasonable commercial terms and conditions" and has been refused "within a reasonable period of time."<sup>124</sup> The requirement for authorization can be waived altogether in light of a "national emergency. . . or in cases of public non-commercial use."<sup>125</sup> The conditions on use set forth in Article 31 are not applicable if "such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive."<sup>126</sup>

Article 31 originally required that all use, except in cases to correct anti-competitive behavior, be "authorized predominantly for the supply of the domestic market of the Member authorizing such use."<sup>127</sup> In countries with little or no manufacturing ability, TRIPS' allowance for compulsory licensing therefore had little value.<sup>128</sup> A recent amendment to the agreement, however, recognized this problem and instructed the Council for TRIPS to find and report on an "expeditious solution to this problem" before the end of 2002.<sup>129</sup> One proposal put forth in response to Paragraph 6 of the Doha Declaration would make it possible under TRIPS for a country

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120. *Id.*

121. *See* Nash, *supra* note 117, at 490 ("TRIPS avoids mandating worldwide norms on the legality of parallel importation").

122. TRIPS, *supra* note 104, art. 31.

123. *Id.* It is an important clarification that Article 31, and compulsory licensing in general, only refers to an allowance of another to make the good in question. There are no provisions included in TRIPS that require the patent holder to forcibly produce or provide the good in question under the compulsory license. *See* Commission on Intellectual Property Rights, *supra* note 105, at 44–45.

124. TRIPS, *supra* note 104, art. 31(b).

125. *Id.* *See also* World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (Nov. 14, 2001) at Para. 5(c) [hereinafter "Doha Declaration"] (stating that it is "understood that public health crises, including those relating to HIV/AIDS. . . can represent a national emergency" for the purposes of Article 31 of TRIPS).

126. *Id.* art. 31(k).

127. *See id.* art. 31(f), 31(k).

128. *See* Commission on Intellectual Property Rights, *supra* note 105, at 44–46 ("The practical effect of this provision is to render the compulsory licensing provisions practically worthless for the very countries which are likely to need it most").

129. Doha Declaration, *supra* note 125, para. 6.

who qualifies for compulsory licensing to export a portion of pharmaceuticals produced under a compulsory license to another country in need of the medicines.<sup>130</sup> This proposal presumes that the importing country does not have the manufacturing ability to produce the drugs.<sup>131</sup> It also appears to rely on the exportation of only a portion of the compulsory-licensed pharmaceuticals so as not to violate Art. 31(f) of TRIPS.<sup>132</sup>

## B. Domestic Law

1997 Medicines and Related Substances Control Amendment Act, which took effect in May 2003, added this contentious portion to the 1965 Medicines and Related Substances Control Act:

15C. Measures to ensure supply of more affordable medicines.

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may—

(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;

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

(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).<sup>133</sup>

The introduction of the Medicines Amendment Act invited international criticism and action against the South African government from such players as the United States government and large pharmaceutical companies, as well as domestically from the Pharmaceutical Manufacturers' As-

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130. See, Commission on Intellectual Property Rights, *supra* note 105, at 48.

131. *Id.*

132. *Id.* (arguing that “a proportion of the supplies manufactured could be offered for export to countries in need. . .”); see also, TRIPS, *supra* note 104, Art. 31(f).

133. Section 10 of Medicines and Related Substances Control Amendment Act 90 of 1997 (S. Afr.) [hereinafter Medicines Amendment Act] (referring back to §15C of Medicines and Related Substances Control Act 101 of 1965 [hereinafter Medicines Act]).

sociation of South Africa (PMA).<sup>134</sup> The debate centered around whether the South African government would use its powers under this amendment to circumvent patent protections provided both under TRIPS and domestic patent laws.<sup>135</sup> The United States responded to the amendment by threatening the South African government with economic sanctions if it insisted on allowing the amendment to enter into force.<sup>136</sup> The U.S. government agreed to remove this threat in 1999 however when South Africa “affirmed the Act’s validity under international law and alleged that the United States was pressuring South Africa simply to protect American pharmaceutical interests.”<sup>137</sup> In a press statement announcing the agreement between the United States and South Africa, the South African government asserted its ability to use compulsory licensing and parallel importing under provision 15C provided for by the Medicines Amendment Act, while at the same time promising to “hon[or] its obligations under the TRIPS Agreement.”<sup>138</sup> Indeed, as previously mentioned, TRIPS allows for parallel importing and, with certain restrictions, for compulsory licensing as well.

What concerned the major international pharmaceutical companies and the PMA was the lack of constraints placed on the Minister of Health to protect patent interests in the process of procuring affordable medicines.<sup>139</sup> PMA argued that section 15C “could be used to justify and sanction both parallel importation and compulsory licensing of certain medicines” without also providing the TRIPS safeguards for the protection of the patent holder.<sup>140</sup> In February 1998, the PMA and 42 pharmaceutical companies (this number later dropped to 39) filed a suit against the South African government in the Pretoria High Court, claiming that section 15C violated the South African Patents Act and South Africa’s TRIPS obligations.<sup>141</sup> As the case became associated with the struggle for access to HIV/AIDS medications in the popular press, the PMA and the pharmaceu-

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134. See Cleary & Ross, *supra* note 106, at 450–57 (providing overview of the international legal dispute that arose as a result of the introduction of the Medicines Amendment Act). See generally, Heywood, *Debunking ‘Conglomo-talk’*, *supra* note 11 (detailing the international lobbying against the Act by the PMA and the resulting legal action).

135. See Cleary & Ross, *supra* note 106, at 451–52.

136. Nash, *supra* note 117, at 486–87.

137. *Id.* at 487; Cleary & Ross, *supra* note 106, at 454.

138. Department of Trade and Industry, A Joint Understanding between the Governments of South Africa and the United States of America (September 17, 1999), available at <http://www.polity.org.za/html/govdocs/pr/1999/pr0917b.html?rebookmark=1> (last visited Jan. 28, 2005).

139. Cleary & Ross, *supra* note 106, at 451.

140. *Id.* at 451–52.

141. *Id.* (quoting PMA’s Notice of Motion in the court case).

tical companies drew world-wide criticism for their position in the lawsuit.<sup>142</sup> After the announcement of an agreement between the United States and South Africa, the PMA announced it would settle its case out of court.<sup>143</sup> But, about a year later, the PMA withdrew from settlement talks and prepared to return to court.<sup>144</sup> Then, in April 2001, one month after the TAC had entered the case on the side of the government, the PMA again dropped the suit.<sup>145</sup>

When the South African government announced draft regulations to amend the Medicines Act after the settlement with PMA and removed any suggestion of the right to compulsory licensing in that draft, there was some question as to whether the South African government had privately conceded the issue of compulsory licensing to the PMA.<sup>146</sup> However, these regulations seem not to have taken effect and currently the Medicines Amendment Act of 1997 remains in force.<sup>147</sup> Given the current state of the law, and the end of international opposition to it, the South African government, at least for now, is in a position to implement parallel importing and/or compulsory licensing in its quest to find affordable ARVs to fulfill its promises under the Operational Plan.

Because the 1997 Medicines Amendment Act allows the Minister of Health great discretion in determining the appropriate rights of a patent holder in light of a need to supply affordable medications,<sup>148</sup> the Act may also allow for generic substitution of name brand ARVs. Generally, generic substitution “entails prescribing a generic drug once the patent has expired on the brand name drug as long as the generic is cheaper.”<sup>149</sup> This definition then would seem to rule out generic substitutions for any drugs that are currently patented in South Africa. At least 13 of 15 common ARVs are patented in South Africa—more than any other country on the continent.<sup>150</sup> Given this fact, the government will likely have to rely largely on compulsory licensing, rather than generic substitution, unless it can find generic substitutions for enough ARVs that are yet to be patented in South Africa. A recent deal struck by the Clinton Foundation with four

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142. Cleary & Ross, *supra* note 106, at 453.

143. *Id.* at 454.

144. *Id.*

145. *See id.* at 455; Robert Block & Gardiner Harris, *Drug Makers Agree to Drop South African Suit—Bad PR Over AIDS Quells Efforts to Defend Patents; Pretoria Concedes Little*, WALL ST. J., April 19, 2001, at A12.

146. *See* Cleary & Ross, *supra* note 106, at 455–56.

147. *See* Medicines Act, *supra* note 133, at §15C.

148. Cleary & Ross, *supra* note 106, at 450.

149. *Id.*

150. Commission on Intellectual Property Rights, *supra* note 105, at 35.

generic drug companies, including the South African company Aspen Pharmacare Holdings Ltd, to distribute ARVs for as little as 38 cents per day, may be able to provide these generics.<sup>151</sup> Before Aspen will be able to effectively supply the drugs to South Africa, the government will have to find more of the company's drugs to be safe and approve them for use in treating HIV disease.<sup>152</sup>

#### IV. CONCLUSION: THE ON-GOING STRUGGLE

In early 2002, then National Secretary of the TAC, Mark Heywood commented that South Africa "need[ed] a comprehensive national treatment plan, and that [was] not yet something that [was] being seriously entertained."<sup>153</sup> In late 2003 the Operational Plan represented a promising and dramatically quick turn-about in the South African government's position on the AIDS crisis, particularly on the issue of access to and supply of ARVs. After a prolonged battle with the government, AIDS activists had won a crucial battle in securing ARVs for South Africans.

The next step is to ensure that safe and affordable ARVs are available under the new plan. Unfortunately the results in achieving this goal have been mixed at best. The government did not begin the formal drug procurement process until February 2004, three months after it initiated the Operational Plan.<sup>154</sup> As of January 2005, drug procurement contracts for the desperately needed ARVs still had not been awarded.<sup>155</sup> Also notable is the government's significant reduction in the planned budget for the first year of the Plan's implementation. An announcement by the government that it reduced the first-year budget from R296 million to R90 million coincided with the beginning of the formal drug procurement process.<sup>156</sup> Although the Operational Plan set the goal of 53,000 new patients on ARVs in its first year, to date only 13,000 to 15,000 patients have received ARV treatment under the Plan.<sup>157</sup>

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151. Mark Schoofs, *South Africa Reverses Course on AIDS Drugs*, WALL ST. J., Nov. 20, 2003, at B1.

152. *Id.*

153. Ann M. Simmons, *Dissent Is Growing Over AIDS Policies; Health: Doctors, clergy and most provinces defy the South African government's limited use of drugs to fight the growing epidemic*, L.A. TIMES, Feb. 22, 2002, at A5.

154. TAC, Updated First Report on the Implementation of the Operational Plan for Comprehensive HIV/AIDS Case, Management and Treatment for South Africa (Operational Plan), 8 (July 2004).

155. E-mail from Fatima Hassan, Attorney, Law & Treatment Access Unit, AIDS Law Project, to Mary Beth Walker (Feb. 3, 2005 04:39:56 EST) (on file with journal).

156. Nicol Degli Innocenti and James Lamont, *South Africa slashes Aids Budget by two-thirds*, FIN. TIMES, Feb. 3, 2004, at 11.

157. *Id.*

In order to successfully address the ever increasing AIDS epidemic in South Africa, the government must move toward reaching the goals set out in the Operational Plan. Recently, the TAC returned to the South African courts to demand answers to the government's slow implementation of the Operational Plan.<sup>158</sup> It demanded that the government explain its implementation timetable, increase the availability of ARVs, and expand the public health system over the next five years.<sup>159</sup> When the Operational Plan was originally released it referenced two annexes that apparently were to have set out a timetable for implementation of the plan.<sup>160</sup> When the TAC's requests for production of those annexes were repeatedly ignored, the TAC returned to court to force the government to produce the implementation timetables.<sup>161</sup> Unfortunately, the litigation revealed that no such timetables existed. Reference to them in the Operational plan was included by mistake.<sup>162</sup> So, while the Operational Plan seemed a promising shift in the government's position on the treatment of HIV/AIDS when it was first released, the year since its release has demonstrated the ongoing battle for HIV-infected South Africans to receive adequate access to ARV treatment. The TAC and millions of HIV-infected South Africans continue to wait for the government to implement a comprehensive plan to combat the AIDS crisis in South Africa.

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158. Treatment Action Campaign v. Minister of Health, 2004 Case No. 15991/04 (SA) *available at* <http://www.tac.org.za/Documents/judgement.doc> (last visited Jan. 31, 2005); TAC Pamphlet Explaining 4 November Court Case *available at* <http://www.tac.org.za/Documents/AccessToInfoCourtCase/TACPamphletExplaining4NovemberAction.htm> (last visited Jan. 31, 2005).

159. TAC Pamphlet Explaining 4 November Court Case, *supra* note 158.

160. Treatment Action Campaign v. Minister of Health, 2004 Case No. 15991/04 at 2–3.

161. *Id.* at 3.

162. *Id.* at 4.