The South Africa AIDS Controversy: A Case Study in Patent Law and Policy

The South Africa AIDS Controversy
A Case Study in Patent Law and Policy

Prof. William W. Fisher III
Dr. Cyrill P. Rigamonti

A Brief History of AIDS

The world first became aware of what is now called AIDS in 1981, when an increased number of relatively rare diseases was detected in gay men without any identifiable cause.[1] The Center for Disease Control (CDC) formed a task force to study these opportunistic infections, and over time it was discovered that they all stemmed from what seemed to be a new disease, termed "Acquired Immune Deficiency Syndrome" (AIDS) in August 1982. In May 1983, researchers at the Pasteur Institute in France isolated a new virus which they believed caused AIDS. The virus was named "lymphadenopathy-associated virus" (LAV), and samples were sent to the CDC and the National Cancer Institute (NCI), with which the Pasteur Institute collaborated to find the cause of AIDS. In April 1984, the NCI announced that their Dr. Robert Gallo had identified the virus and had named it "human T-cell lymphotropic virus, type III" (HTLV-III). Patent applications were filed both for the Pasteur Institute's and Dr. Gallo's work. Private companies began developing commercial blood tests for AIDS, and the Food and Drug Administration (FDA) approved the first HIV antibody test in January 1985. When the U.S. Patent Office refused to grant a patent on a test based on the research by the Pasteur Institute, the French scientists sued the NCI over who had first isolated the virus. The case was ultimately settled, and the Pasteur Institute and the NCI agreed to share the credit for their discovery. The name of the virus was subsequently changed to "Human Immunodeficiency Virus" (HIV).

In September 1986, early clinical tests showed that Azidothymidine (AZT), a drug first synthesized in 1964 to be used as chemotherapy for leukemia, slowed down the progress of the disease. In 1987, AZT (Zivoduvine, Retrovir®) became the first anti-HIV drug to be approved by the FDA. By then, AIDS had become sufficiently important to be discussed by the U.N. General Assembly, and on De-

[1] The following account is based on "The History of AIDS", available at http://www.avert.org.

cember 1, 1988, the first World AIDS Day took place. In 1990, the number of people living with HIV/AIDS was estimated to be ten million worldwide. In 1991, the second AIDS drug was approved by the FDA, and new drugs followed year after year. These drugs are antiretroviral drugs, which are not a cure, but do slow down the reproduction of HIV in the body, thereby delaying the progression of the disease for many years. They have proven to be quite effective, and by 1997, the number of AIDS deaths had declined significantly in the U.S. The drugs are patented in the U.S. and marketed by pharmaceutical companies, in some instances as exclusive licensees of the U.S. government. Patents relating to AIDS drugs were granted across the globe, including in South Africa (see **Exhibit 1**).

As of December 2003, more than twenty million people worldwide had died from AIDS, and another forty million people were living with HIV/AIDS. There was an almost exponential growth of the epidemic in the early 1990s, particularly in Africa, which accounts for two-thirds of the people living with HIV/AIDS, while comprising only about eleven percent of the world's population (see **Exhibit 2**).[2] The uneven spread of the pandemic is aggravated by the fact that in those regions of the world where the burden is highest, the coverage of antiretroviral treatment is lowest. By the end of 2003, fewer than seven percent of people in developing countries in urgent need of antiretroviral treatment had access to these medicines (see **Exhibit 3**).[3] The case of South Africa, economically the strongest African country, is particularly illustrative of this public health crisis and showcases the role domestic and international patent law and policy may play in this context.

Health Care Reform in South Africa

South Africa, a country about twice the geographical size of Texas, has approximately forty-two million inhabitants, 75.2% of whom are black, 13.6% are white, 8.6% are of mixed race, and 2.6% are Indian. Fifty percent of the population live in poverty, and the unemployment rate is 31%.[4] The GDP was about 160 billion U.S. dollars in 2003 (10,880 billion U.S. dollars in the U.S.), while the GNI per capita was $2,780 ($37,610 in the U.S.) (see **Exhibit 4**). When Nelson Mandela, whose eldest son died of AIDS in January 2005, became President of South Africa after the first democratic elections in 1994, the country's health care system was based on a two-tiered approach. Approximately 20% of the population, mostly white, was covered by private health care, while the black majority relied on public sector care characterized by "irrational use of resources, poor working conditions and inadequate infrastructure."[5] Many South Africans did not have access to

---

2 *See* WHO, World Health Report 1 (2004); UNAIDS, 2004 Report on the global AIDS epidemic 13, 23, 30 (2004).

3 *See* WHO, World Health Report 21 (2004); UNAIDS, 2004 Report on the global AIDS epidemic 101-102 (2004).

4 Source: CIA, The World Factbook, available at http://www.cia.gov/cia/publications/factbook.

5 South African Department of Health, National Drug Policy for South Africa 3 (1996).

health care at all, making health care reform one of the most important items on the agenda of the newly elected post-apartheid government, in line with the mandate in their new Constitution to take reasonable measures to provide access to health care services for everyone.[6] The new Minister of Health, Dr. Nkosazana Zuma, a native of Natal who had worked underground for the African National Congress (ANC) before spending years in exile, quickly appointed a National Drug Policy Committee to revamp South Africa's health care system. After a series of investigations and consultations with stakeholders, including representatives of the pharmaceutical industry and the World Health Organization (WHO), the Committee found that among the most notable deficiencies were the lack of equity in access to essential drugs, the comparatively high prices for pharmaceuticals in the private sector, and the losses of drugs through poor security in the public sector.[7] The price differential between the private and public sector was such that the private sector accounted for 80% of the country's total expenditures on drugs, despite the fact that 60-70% of the total volume of pharmaceuticals were sold to the public sector.[8] Furthermore, while a large amount of the public health budget was spent on prescription drugs, approximately 50% of the drugs in public hospitals were stolen and sold to the private sector, thus increasing the shortage of prescription drugs in the public sector.[9] The Committee finally released the revised National Drug Policy in January 1996, setting forth a number of different objectives designed to address these issues, including lowering drug prices, supporting the development of a local pharmaceutical industry for the local production of essential drugs, and promoting the prescription of generic drugs in both the public and private sectors (see **Exhibit 5**).[10]

South Africa's Approach to the AIDS Crisis

At the same time, South Africa was facing a tremendous increase in HIV infection rates (see **Exhibit 6**), which further contributed to the magnitude of the public health problem. South Africa rapidly became the country with the highest absolute number of people living with HIV/AIDS. The overall adult prevalence rate approached the twenty percent mark, and approximately forty-five percent of military personnel were infected with HIV.[11] However, with an average annual income of $2,600, most South Africans suffering from HIV/AIDS could not afford to pay for treatment with antiretroviral drugs, which at that time cost about $1,000 a month.[12] Life expectancy at birth dropped significantly (see **Exhibit 7**), and the number of orphans was increasing steadily (see **Exhibit 8**). The impact of these

---

6 *See* Articles 27(1)(a) and 27(2) of the Constitution of the Republic of South Africa, Act. 108 of 1996.

7 *See* South African Department of Health, National Drug Policy for South Africa 3 (1996).

8 *Id.*(figures are for 1990).

9 *See, e.g.*, Donald G. McNeil Jr., South Africa's Bitter Pill for World's Drug Makers, New York Times, March 29, 1998, Section 3, p. 1.

10 *See* South African Department of Health, National Drug Policy for South Africa 4, 10-11 (1996).

11 *See, e.g.*, Sabin Russell, New Crusade to Lower AIDS Drug Costs, The San Francisco Chronicle (May 24, 1999), p. A1.

12 *See id.*

demographic developments (see **Exhibit 9**) on South Africa's productivity could hardly be underestimated. Nevertheless, while reforming the health care system was a top priority, the South African government initially remained rather passive in combating AIDS, and when it took action, it was widely criticized as ineffective. For example, the Ministry of Health authorized the spending of a large portion of the AIDS budget on the production of an AIDS awareness musical called "Sarafina II" and awarded the contract to one of Dr. Zuma's friends. It later turned out that over one million dollars remained unaccounted for, and Dr. Zuma was accused of mismanagement. Moreover, she promoted the use of Virodene, a locally produced AIDS treatment that contained an industrial solvent harmful to humans and that had not been approved by the Medicines Control Council (MCC) – the South African equivalent of the FDA.[13] Dr. Zuma also discontinued a program that provided pregnant women with AZT, because it was unaffordable. It was not until AIDS activists close to the ANC met with Dr. Zuma and told her of their support for her battle against unreasonably high drug prices that she reversed her policy on AZT for pregnant women.[14]

The Media Battle Over Drug Prices

It was precisely the South African government's emphasis on the reduction of drug prices that drew significant criticism from the pharmaceutical industry, and a media battle between the Pharmaceutical Manufacturers Association of South Africa (PMA) and the Minister of Health ensued. The Minister of Health took the position that both the shortage of prescription drugs in the public sector and the exceptionally high prices in the private sector were the result of the pricing strategies adopted by multinational pharmaceutical companies who held patents in South Africa on most antiretroviral drugs.[15] The PMA opposed this position and claimed that their rates for the South African government were lower than those offered by international aid organizations and that any shortages in the public sector were due to the rampant theft of pharmaceuticals.[16] Furthermore, the pharmaceutical companies denied that lowering drug prices would solve the access problem due to the fact that South Africa did not have an adequate infrastructure for the distribution of drugs, pointing to India as an example of a country where access was and is an issue despite the availability of generic versions of AIDS drugs.[17] In June 1997, the PMA filed a complaint with the Public Protector of South Africa (a neutral ombudsman with limited investigative and no sanctioning powers), alleging that certain officials from the Department of Health had made

---

13 *See,* Donald G. McNeil Jr., South Africa's Bitter Pill for World's Drug Makers, New York Times, March 29, 1998, Section 3, p. 1.

14 *See* Mark Schoofs, AIDS – The Agony of Africa, Part 7, Village Voice (Dec. 28, 1999), p. 67.

15 *See* Amir Attaran & Lee Gillespie-White, Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?, 286 No. 15 J. Am. Med. Ass'n 1886, 1888 (Oct. 17, 2001).

16 *See* Transcript No. 98011205-212 of NPR Broadcast Show "All Things Considered" (January 12, 1998), available as audio stream at http://www.npr.org/templates/story/story.php?storyId=1036870.

17 *See, e.g.*, Sabin Russell, New Crusade to Lower AIDS Drug Costs, The San Francisco Chronicle (May 24, 1999), p. A1.

offensive statements in the news media to create "a perception in the minds of the general public that medicines in South Africa are unreasonably expensive and moreover that the blame for such expensive medicines lies with the manufacturing and primary importing companies."[18] The PMA feared that this perception would lend support to legislation proposed by the Minister of Health on the express basis that drug prices in South Africa were unreasonably high compared to prices charged abroad. The controversial legislative proposal contained the explicit authorization of parallel imports of patented pharmaceuticals. It was drafted by Dr. Ian Roberts, a consultant to Dr. Zuma, and the language used was largely taken from a draft WIPO patent treaty.[19] The proposal quickly passed a parliamentary subcommittee dominated by members of the ANC, the majority party to which Dr. Zuma belongs. She also enjoyed strong support from President Mandela. Ultimately, a new Section 15C was inserted into the South African Medicines and Related Substances Control Act (MRSCA) (see **Exhibit 10**). The primary purpose of this amendment was to enable South Africa to benefit from lower prices abroad for the same drugs.

South Africa's Legislative Measures

Fearing a domino effect in the developing world, the U.S. pharmaceutical industry[20], backed by the U.S. government, vigorously opposed the enactment of Section 15C, arguing that it was tantamount to a complete abrogation of patent rights and that it violated the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). As a representative of Bristol-Myers Squibb put it, "Patents are the lifeblood of our industry. Compulsory licensing and parallel imports expropriate our patent rights," adding that the only beneficiary of the erosion of patents would be the generic drug industry.[21] Nevertheless, the planned modifications, including Section 15C, were signed into law by President Nelson Mandela on December 12, 1997.[22] In an attempt to block the implementation of the amendments, the pharmaceutical companies took the matter to court and challenged the constitutionality of the amended MRSCA before the High Court of South Africa in February 1998.[23] With respect to Section 15C, the plaintiffs argued (i) that it en-

---

18 *See* Public Protector of the Republic of South Africa, Report on the Propriety of the Conduct of Members of the Ministry and Department of Health Relating to Statements in Connection with the Prices of Medicines and Utilisation of Generic Medicines in South Africa, Special Report No. 6 (1997).

19 *See* Frederick M. Abbott, WTO TRIPS Agreement and Ist Implications for Access to Medicines in Developing Countries, Study Paper 2a, Commission on Intellectual Property Rights 53-54 (2002).

20 Note that American subsidiaries accounted for 27% of the pharmaceutical market in South Africa, which was more than South African firms had; *see* Lynne Duke, Nkosazana Zuma – Activist Health Minister Draws Foes in S. Africa, Washington Post (December 11, 1998), p. A41.

21 *See, e.g.*, Sabin Russell, New Crusade to Lower AIDS Drug Costs, The San Francisco Chronicle (May 24, 1999), p. A1.

22 *See* Medicines and Related Substances Control Amendment Act No. 90 of 1997, South African Government Gazette No. 18,505 of December 12, 1997 (amending the Medicines and Related Substances Control Act No. 101 of 1965, as amended by Acts Nos. 65/1974, 17/1979, 20/1981 and 94/1991).

23 *See* Notice of Motion in the High Court of South Africa (Transvaal Provincial Division), Case No. 4183/98.

tailed an impermissible delegation of powers from the legislative to the executive branch of government, because the Minister of Health was authorized to determine the application of patent rights irrespective of the South African Patents Act, and because she was authorized to determine the conditions for the supply of more affordable medicines without any limiting guidelines, (ii) that it would enable the Minister of Health to deprive intellectual property owners of their property without compensation in violation of Article 25 of the South African Constitution, and (iii) that it was a violation of Art. 27 TRIPS and, because TRIPS binds South Africa, also a violation of Articles 44(4) and 231(2)-(3) of the South African Constitution. The South African government defended its new legislation on two grounds. First, it claimed that Section 15C was constitutional, because it did not grant the Minister of Health broad powers to abrogate patent rights. Second, it maintained that Section 15C complied with TRIPS, arguing that TRIPS would not prohibit parallel imports and that Section 15C did not address the controversial issue of compulsory licensing.[24] Indeed, South Africa believed that it was being held to a "TRIPS plus" standard (a higher level of patent protection than required by TRIPS) both by the U.S. government and by the private plaintiffs in the lawsuit against Section 15C.[25] Procedurally, the constitutional challenge had the effect of a temporary stay of the implementation of the amended MRSCA.

While AIDS activists such as the South African Treatment Access Campaign (TAC) called for international protests against "drug profiteering" and claimed that delaying the implementation of the amended MRSCA would only cost additional lives, the pharmaceutical companies defended the court action on the grounds that "parallel importation of drugs would undermine the ability of pharmaceutical companies to charge different prices in different parts of the world" and that a "tiered pricing strategy allows wealthier countries to subsidize poorer ones, and the drug companies still get profits they need for research."[26] Furthermore, a spokesman for the pharmaceutical companies was quoted as saying, "A lot of parallel imports come from places like India, and half the time there are no active ingredients. It's killing patients, causing drug resistance and giving false hope."[27] The South African Minister of Health conceded to the pharmaceutical companies the ability to segment the market by charging different prices in different countries, but reserved the right to "purchase from a segment that suits our purse."[28] She also clarified that South Africa was not going after the profits of the drug companies and suggested that what is lost in price could be made up in volume.[29] She also rejected the charge that she wanted to abrogate patents and further stated, "I

---

24 *See* WHO & WTO, WTO Agreements & Public Health 106 (2002).

25 *See* Statement by the South African Delegation, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines, IP/C/M/31 (July 10, 2001), p. 27.

26 357 The Lancet 775 (March 10, 2001).

27 *See* Sabin Russell, World Trade Showdown, The San Francisco Chronicle (Nov. 24, 1999), p. A1.

28 Lynne Duke, Nkosazana Zuma – Activist Health Minister Draws Foes in S. Africa, Washington Post (December 11, 1998), p. A41.

29 *See* Steve Sternberg, Victims lost in battle over drug patents, USA Today (May 24, 1999), p. 2D.

think the lives of our people overrides everything else. We are not intending to bust any patents. We're not intending breaking any treaties. All we want to do is to give health services to the people who are poor in this country, and to the people who have been denied those health services for centuries."[30] Nevertheless, the pharmaceutical companies viewed Section 15C as a threat to their business that went beyond its potential impact on the comparatively small South African market. They feared that the explicit authorization of parallel imports could set an example for other countries.

U.S. Reaction to South Africa's Legislative Measures

The Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group representing the U.S. pharmaceutical industry, managed to convince the U.S. government that the issue was sufficiently important to warrant putting pressure on South Africa to repeal the contested legislative measures. As a result, Section 15C was put on the agenda for high-level bilateral trade talks between the United States and South Africa (see **Exhibit 11**). James Joseph, at that time U.S. Ambassador to South Africa, wrote a letter to representatives of the South African government, strongly urging South Africa to alter Section 15C and stating that "my Government opposes the notion of parallel imports of patented products anywhere in the world."[31] South Africa was also put on the Special 301 "watch list"[32] both in 1998[33] and 1999[34] upon a determination by the U.S. Trade Representative (USTR) that South Africa lacked adequate intellectual property protection to an extent that merited bilateral attention. Being on the watch list also meant that South Africa was one step closer to the imposition of unilateral trade sanctions by the United States. In February 1998, forty-seven members of Congress sent a letter to the USTR calling for a response to the MRSCA, stating that Section 15C permitted parallel importation and allowed for the "administrative expropriation of patented technology," both of which would violate the TRIPS Agreement (see **Exhibit 12**). In July 1998, pending adequate progress on intellectual property rights protection in South Africa, the USTR used its discretion to withhold trade benefits for a range of South African products that had previously been approved under the Generalized System of Preferences (GSP) program.[35] Furthermore, a provision was inserted into an omnibus appropriations act in October 1998 that conditioned U.S. development assistance to South Africa on the Secretary of State's written report on the steps being taken by the U.S. government to work with South Africa "to negoti-

---

30 *See* Transcript No. 98011205-212 of NPR Broadcast Show "All Things Considered" (January 12, 1998), available as audio stream at http://www.npr.org/templates/story/story.php?storyId=1036870.

31 *See* South Africa's Health Committee Rejects MRSCA Bill Change, Pharma Marketletter (October 21, 1997).

32 *See* 19 U.S.C. § 2411.

33 *See* 10 No. 6 J. Proprietary Rts. 19 (June 1998).

34 *See* 1999 USTR Special 301 Report (also stating that "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").

35 *See* Simon Barber, U.S. Withholds Benefits Over Zuma's Bill, Africa News (July 15, 1998).

ate the repeal, suspension, or termination" of Section 15C.[36] The Department of State submitted this report in February 1999, stating that all relevant agencies of the U.S. government "have been engaged in an assiduous, concerted campaign" to persuade South Africa to withdraw or modify Section 15C which the State Department believed was "inconsistent" with South Africa's obligations and commitments under TRIPS.[37] Despite this assessment, which mirrored statements made by PhRMA[38], the U.S. did not bring a WTO case against South Africa.

Shift in U.S. Foreign Trade Policy

During 1999, the high stakes of the controversy between the United States and South Africa attracted a great deal of attention in the media, which ultimately led to a shift in the U.S. Administration's policy towards South Africa. The fact that Vice President Al Gore, as co-chairman of the United States/South Africa Binational Commission (established to improve communication and cooperation between the two countries), had been actively involved in pressuring South Africa to give in to the demands of the pharmaceutical industry, seems to have been particularly important, as he became one of the main targets of AIDS activists who had long urged the U.S. government to change its policy towards South Africa. AIDS activists – realizing that the 2000 Presidential campaign made Gore particularly vulnerable to negative publicity – disrupted a number of his campaign events shouting "Gore's greed kills", including the event where he announced that he would be running for President. Ralph Nader openly attacked him for engaging in "an astonishing array of bullying tactics to prevent South Africa from implementing policies, legal under international trade rules, that are designed to expand access to HIV/AIDS drugs."[39] These actions further increased public awareness of the conflict between the pharmaceutical industry and developing countries.

Meanwhile, Rep. Jesse Jackson, Jr., (D-Ill.) had introduced the HOPE for Africa Bill that contained a provision drafted by AIDS activists that called upon the U.S. government not to "seek, through negotiation or otherwise, the revocation or revisions of any sub-Saharan African intellectual property or competition law or policy that is designed to promote access to pharmaceuticals or other medical technologies" and that complies with TRIPS.[40] In June 1999, Gore replied to a letter sent to him by the Chairman of the Congressional Black Caucus, James E. Clyburn, inquiring into the issue of affordable medicines for South Africa. In his letter, Gore indicated that U.S. policy may change by saying that he supported South Africa in

---

36 *See* Pub. L. 105-277, 112 Stat. 2681-155 (1998).

37 *See* United States Department of State Report on U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(C) of the South African Medicines and Related Substances Act of 1965 (February 5, 1999).

38 *See, e.g.*, South African/US Patent War Continues, Pharma Marketletter (April 1, 1998).

39 Ralph Nader, Al Gore bullies South Africa on U.S.-made AIDS drugs, Knight Ridder/Tribune (April 26, 1999).

40 *See* HOPE for Africa Bill, H.R. 772, 106th Cong., 1st Sess., § 601 (1999).

its efforts to provide AIDS drugs at reduced prices through compulsory licensing and parallel importing, as long as they were carried out in a manner consistent with international agreements (see **Exhibit 13**). In July 1999, the House Committee on Government Reform, Subcommittee on Criminal Justice, Human Resources and Drug Policy, took up the issue and held hearings on the role of the United States in combating the global HIV/AIDS epidemic, for the first time inviting consumer advocates to express their views on U.S. foreign trade policy regarding patent protection and public health.

In September 1999, the USTR and the South African government announced that the controversy was resolved and that the U.S. government would no longer pressure South Africa, and in return, South Africa promised to adhere to its obligations under TRIPS.[41] Consequently, South Africa was taken off the Special 301 watch list. At about the same time, the plaintiffs in the MRSCA case announced the suspension of their lawsuit against the South African government.[42] In a speech given at the 1999 WTO Ministerial Conference in Seattle, President Clinton made it clear that the United States would adjust its trade policies to enable poor countries, such as South Africa, to gain access to essential medicines. On May 10, 2000, he formally ordered that "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 […] that regulates HIV/AIDS pharmaceuticals or medical technologies" and prohibited the U.S. Government from taking action pursuant to Section 301 with respect to laws or policies that promote access to HIV/AIDS pharmaceuticals or medical technologies and that provide adequate and effective intellectual property protection consistent with TRIPS.[43] In February 2001, the Bush Administration reaffirmed that the United States would not raise any objection if WTO Members taking steps to address major health crises "availed themselves of the flexibility" afforded by TRIPS.[44] Moreover, in April 2001, the pharmaceutical companies dropped their court challenge of Section 15C and agreed to cover the South African government's legal expenses in the face of what has been described as a public relations nightmare.[45] The talks behind the scenes leading to the withdrawal involved Kofi Annan, the Secretary General of the United Nations, who was contacted by Jean-Pierre Garnier, the CEO of GlaxoSmithKline, on behalf of the largest pharmaceutical companies to broker a deal with Thabo Mbeki, the President of South Africa. Both the

---

41 *See* Robert Weissman, AIDS Drugs for Africa, 20 No. 9 Multinational Monitor 9 (1999).

42 *See* Neil A. Lewis, U.S. Industry to Drop AIDS Drug Lawsuit Against South Africa, New York Times (Sept. 10, 1999), p. A3.

43 *See* Exec. Order No. 13,155, 65 Fed. Reg. 30,521 (May 12, 2000), §§ 1(a) and 3(a).

44 *See* Statement by the U.S. Delegation, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines, IP/C/M/31 (July 10, 2001), pp. 33-34.

45 As some journalists put it, "Can the pharmaceuticals industry inflict any more damage upon its ailing public image? Well, how about suing Nelson Mandela?"; Helene Cooper et al., AIDS Epidemic Puts Drug Firms In a Vise: Treatment vs. Profits, Wall Street Journal (March 2, 2001).

European Union and the WHO supported South Africa's position.[46] As part of the deal, South Africa reiterated its pledge to comply with TRIPS when implementing the amendments to the MRSCA and invited the pharmaceutical industry to help draft future regulations.[47]

The withdrawal of the lawsuit was welcomed by most commentators, including Mike Moore, the Director General of the WTO, who said that the "settlement" was a "win-win situation" for all stakeholders. While pharmaceutical companies stressed South Africa's commitment to protect patents, AIDS activists celebrated the withdrawal as a direct result of their efforts to create negative publicity for the pharmaceutical companies by pitching the conflict as one of putting profits before people. Indeed, as Garnier put it, "We're a very major corporation. We're not insensitive to public opinion. That is a factor in our decision-making. We don't want the public to misunderstand the issues. We have never been opposed to wider access. We have discounted our drugs. We've done everything we could. Frankly, the legislation was the worst distraction. It did not allow us to communicate our message effectively."[48] The question of profits for pharmaceutical companies was also raised during Merck's Q1 Earnings Release Conference Call, when Laura Jordan, Senior Director of Investor Relations at Merck, was asked about the potential impact of the withdrawal and of Merck's price reductions for its AIDS drugs, Crixivan and Stocrin, on Merck's profits. She answered that Merck had indeed announced that it would not profit in the sale of those medicines in the developing world, but that Merck's new prices - $600 per patient per year for Crixivan, and $500 for Stocrin – would not lead to lost sales, because "the sales of these medicines in the developing world were virtually nonexistent" and that the new sales would be "incremental sales."[49] With respect to price reductions, however, the new South African Minister of Health, Manto Tshabalala-Msimang, cautioned that the withdrawal of the lawsuit would not mean that South Africa would provide low-cost drugs immediately, because "the country's medical infrastructure is insufficient."[50] In any event, the controversial provisions of the amended MRSCA could finally take effect. When the MRSCA was modified again in 2002[51], Section 15C was left untouched.

The Doctrinal Issues – Parallel Importation and Compulsory Licensing

---

46 *See* Rachel L. Swarns, Drug Makers Drop South Africa Suit Over AIDS Medicine, The New York Times (April 20, 2001), p. A1.

47 *See* Ann M. Simmons, Firms Clear Way for Cheaper AIDS Drugs, Chicago Tribune (April 20, 2001), p. 4.

48 *See* Rachel L. Swarns, Drug Makers Drop South Africa Suit Over AIDS Medicine, The New York Times (April 20, 2001), p. A1.

49 *See* Q1 2001 Merck Earnings Conference Call, Transcript 042001ap.732, FD (Fair Disclosure) Wire (April 20, 2001).

50 *See* Susan Warner, AIDS drug lawsuit dropped in S. Africa, The Dallas Morning Star (April 20, 2001), p. 1A.

51 *See* Medicines and Related Substances Amendment Act No. 59 of 2002, South African Government Gazette No. 24,279 of January 17, 2003.

From the standpoint of international patent law, the key legal issue underlying the South African controversy was whether the explicit authorization of parallel imports of patented pharmaceuticals in Section 15C complied with TRIPS. Note that the South African Patents Act, which had just been brought into compliance with TRIPS in 1997,[52] granted the patentee the exclusive right to import patented products,[53] but was (and still is) silent on the issue of whether this right is subject to national or international exhaustion. During the conflict between the U.S. and South Africa, three different views were expressed on the legality of parallel imports:

(1) Representatives of the U.S. pharmaceutical industry claimed that authorizing parallel imports of patented drugs plainly violates the patent holder's exclusive right of importation prescribed by Article 28 TRIPS and is not covered by the exceptions set forth in Articles 30 and 31 TRIPS.[54] The U.S. government shared this view but provided a more subtle legal explanation of its position by saying that while there is no question that Article 6 TRIPS denies WTO Members the ability to avail themselves of dispute settlement in relation to most questions involving parallel imports, Article 6 TRIPS does not authorize parallel imports, because it "does not alter the substantive obligations of the TRIPS Agreement, particularly those contained in Part II of the Agreement."[55] The U.S. did not explain whether the footnote in Article 28 TRIPS (explicitly stating that the rights under Article 28 TRIPS are "subject to the provisions of Article 6") had an impact on its analysis.

(2) South Africa took the position that the issue of parallel imports is a matter left to the individual WTO Member State to decide. Most countries and commentators agree with South Africa that Article 6 TRIPS is based on a country-by-country approach to the exhaustion of intellectual property rights and parallel imports. This view is based on a plain reading of the TRIPS Agreement as well as on its drafting history. Although the issue of parallel imports was discussed by the TRIPS negotiators, they failed to reach a consensus on the subject, precisely because developing countries favored international exhaustion while the U.S. advocated national exhaustion (and the European Union tried to preserve the principle of EU-wide exhaustion).

---

52 *See* Intellectual Property Laws Amendment Act No. 38 of 1997, South African Government Gazette No. 18,325 of October 1, 1997 (amending, *inter alia*, the South African Patents Act No. 57 of 1978).

53 § 45(1) South African Patents Act No. 57/1978, as amended, reads: "The effect of a patent shall be to grant to the patentee in the Republic, subject to the provisions of this Act, for the duration of the patent, the right to exclude other persons from making, using, exercising, disposing or offering to dispose of, or importing the invention, so that he or she shall have and enjoy the whole profit and advantage accruing by reason of the invention."

54 *See, e.g.*, the Submission of the Pharmaceutical Research and Manufacturers of America (PhRMA) for the National Trade Estimate Report on Foreign Trade Barriers (NTE) 1999 (December 4, 1998).

55 *See* Statement by the U.S. Delegation, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines, IP/C/M/31 (July 10, 2001), p. 40.

(3) Some international trade scholars suggest a third position.[56] While acknowledging that Article 6 TRIPS does not settle the issue one way or another, they argue that Article 6 is limited to TRIPS ("nothing in *this* Agreement") and that some rules in the General Agreement on Tariffs and Trade (GATT) of 1994 may be read as mandating the adoption of an international exhaustion regime. More specifically, outlawing parallel imports may be viewed as a non-tariff trade barrier in violation of Article XI:1 of GATT 1994 and as a form of discrimination in favor of domestically produced goods that violates the principle of national treatment contained in Article III of GATT 1994. It is controversial whether parallel imports would qualify under a general exception contained in Article XX(d) of GATT 1994.

The second important issue that was raised in the context of the dispute over South Africa's amendment to the MRSCA relates to compulsory licensing. It appears that, at the time the MRSCA was enacted, the South African government did not intend to expand the government's ability to grant compulsory licenses beyond what was already provided in South Africa's patent law.[57] However, compulsory licensing was brought to the forefront of the international debate about intellectual property and public health policy in January 1998, after the Executive Board of the World Health Assembly adopted a resolution urging the member states to put public health above commercial interests and to review their options under TRIPS to safeguard access to essential drugs.[58] This resolution triggered a series of heated discussions on the subject over the course of various meetings held at the WHO, during which representatives of the South African government made statements that included compulsory licensing as an option for increasing access to essential drugs.[59] The possibility that South Africa could resort to compulsory licensing was of major concern to pharmaceutical companies holding patents covering AIDS drugs and was rapidly becoming the most important issue in international negotiations, particularly in view of the fact that Brazil had already set a precedent for compulsory licensing.

In 1996, in order to alleviate the AIDS crisis, Brazil had amended its Industrial Property Law to establish a "local working" requirement enabling the Brazilian government to grant compulsory licenses if a patent is not "worked" in Brazil.[60] In June 2000, the U.S. initiated WTO dispute settlement proceedings against Brazil, alleging that the recent amendment was inconsistent with the principle of non-discrimination set forth in Articles 27 and 28 TRIPS.[61] Brazil, in return, requested

---

56 *See, e.g.*, Frederick M. Abbott, *First Report (Final) To The Committee On International Trade Law Of The International Law Association on the Subject of Parallel Importation*, 1 J. INT'L ECON. L. 607, 632-33 (1998).

57 *See, e.g.*, §§ 55, 56, 78, 79 South African Patents Act No.57 of 1978.

58 World Health Assembly, Executive Board, 101st Sess., Resolution No. EB101/R.24, Revised Drug Strategy (January 27, 1998).

59 *See* e-mail dated November 27, 2004, from James Love, Director, Consumer Project on Technology, to William W. Fisher (on file with authors).

60 *See* Article 68 of Law No. 9,279 of May 14, 1996, effective May 1997.

61 *See* U.S. Request for Consultations, WT/DS199/1 (June 8, 2000).

consultations under the WTO Dispute Settlement Understanding (DSU)[62], claiming that certain provisions in the U.S. Patent Act governing "Patent Rights in Inventions Made with Federal Assistance" violated the TRIPS Agreement, because they required products embodying specific inventions to be "manufactured substantially in the United States."[63] Facing growing international criticism, the U.S. withdrew its complaint in July 2001, just a few months after the U.N. Human Rights Commission had declared that the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health is a human right" based on a draft resolution provided by Brazil.[64] The U.S. and Brazil jointly notified the WTO of a Mutually Agreed Solution, in which Brazil agreed to hold prior talks with the U.S. government should Brazil deem it necessary to apply the provisions in question to grant compulsory licenses on patents held by U.S. companies.[65]

While the dispute between Brazil and the U.S. focused on the application of the principle of non-discrimination, the South African controversy centered around the question of whether it would be compatible with Articles 30 and 31 TRIPS for a WTO member state to grant compulsory licenses to lower drug prices to combat AIDS. Articles 30 and 31 TRIPS set forth the conditions for the validity of a domestic compulsory licensing scheme. To the extent that such scheme does not "unreasonably conflict with the normal exploitation of the patent" and does not "unreasonably prejudice the legitimate interests of the patent owner," it is legal under Article 30 TRIPS.[66] If these general requirements are not met, however, the compulsory licensing mechanism is only permissible if it complies with the detailed prerequisites listed in Article 31 TRIPS. In the South African context, the pharmaceutical companies feared that the Minister of Health could use the amended MRSCA to bypass these provisions to their detriment and to the benefit of South African manufacturers of generic drugs.

The Policy Issue –Legislative Flexibility under TRIPS

The significance of the South African controversy goes beyond doctrinal issues. It touches upon the more fundamental question of to what extent WTO Member States – in this context, primarily developing countries – should be free to take legislative measures to deal with public health crises and to what extent the patent protection of pharmaceuticals required under TRIPS should limit the range of options available. Developing countries consider both parallel imports and compulsory licensing as tools to bring down drug prices, which they view as the

62 *See* Brazilian Request for Consultations, WT/DS224/1 (February 7, 2001).

63 *See* 35 U.S.C. §§ 204, 209 (2004).

64 U.N. Commission on Human Rights, Access to Medication in the Context of Pandemics such as HIV/AIDS, Resolution No. 2001/33, Doc. No. E/CN.4/RES/2001/33 (April 23, 2001).

65 *See* Joint Notification of Mutually Agreed Solution, WT/DS199/4 (July 19, 2001).

66 For instance, in a case brought by the European Union against Canada, a WTO Panel decided that Canada's "pre-expiration testing" exemption was consistent with Article 30 TRIPS, while its "stockpiling" exemption was not; *see* WTO Panel Report, Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R (March 17, 2000).

most important obstacle to enhancing access to essential medicines.[67] Pharmaceutical companies in the developed world, with the aid of their governments, resist legislation that threatens the strength of their patents, fearing that they will not be able to recoup the investments they have made to develop AIDS drugs and that they will lose business to manufacturers of generics located in the developing world. The South African experience brought the potential tension between patent protection for pharmaceuticals and public health concerns to the forefront of public awareness and triggered a global debate about what should be allowed and what should be prohibited under TRIPS in order to preserve the incentives for investments in research and development of pharmaceuticals, while still allowing countries the flexibility to respond to public health crises as they deem fit. In this context, one provision at the intersection between parallel imports and compulsory licensing garnered a great deal of attention. Article 31(f) TRIPS requires that the use of a patent for which a compulsory license has been granted be "predominantly for the supply of the domestic market." In practice, this means that if a country grants a compulsory license to make a patented pharmaceutical without authorization from the patent holder, the drugs manufactured under this compulsory license cannot be exported to another country. The result is that developing countries without manufacturing capabilities cannot benefit from the compulsory licenses allowed under TRIPS, because they cannot manufacture the pharmaceuticals themselves and because they cannot import pharmaceuticals manufactured abroad under a compulsory license. This rule is likely to become more important as more developing countries with manufacturing capacity will provide patent protection for pharmaceuticals pursuant to the transitional rules imposed by TRIPS.

At the initiative of the African Group of WTO Members, of which South Africa was a part, the concerns outlined above were discussed within the framework of the WTO and put on the agenda of the Fourth Ministerial Conference, held in Doha, Qatar, in November 2001. At the end of the conference, the WTO Member States adopted the Declaration on the TRIPS Agreement and Public Health ("Doha Declaration")[68] (see **Exhibit 14**), acknowledging the gravity of the public health problems afflicting many developing countries and recognizing both the importance of intellectual property protection for new medicines and the concerns about its effects on drug prices. Many factors may have made it possible for the Doha Declaration to pass, but commentators usually point to three factors.[69] First, the developing countries were united and acted as one group. Second, the previously firm traditional views adopted by the United States and other Western countries

---

67 *See* Statement by the Delegation of Tanzania, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines, IP/C/M/31 (July 10, 2001), p. 30.

68 WT/MIN(01)/DEC/2 (November 20, 2001). *See also* Section 6 of the Ministerial Declaration adopted on November 14, 2001, WT/MIN(01)/DEC/1 (November 20, 2001). In terms of its legal status, the Doha Declaration has interpretive force as "subsequent practice" in the application of TRIPS in the sense of Article 31(3)(b) of the Vienna Convention on the Law of Treaties.

69 *See, e.g.*, Ellen 't Hoen, TRIPS, Pharmaceutical Patents, and Access to Essential Medicines – A Long Way From Seattle to Doha, 3 Chi. J. Int. L. 27, 42-43 (2002).

were not easy to maintain given the reaction by both Canada and the United States to the potential shortage of Ciprofloxacine (Cipro) during the anthrax scare. Both countries were quick to express their readiness to override patents on Cipro held by Bayer, a German pharmaceutical company, if the situation could not be solved to their satisfaction – a move opposed by PhRMA. Third, a large number of AIDS activists and non-governmental organizations made sure that the issue received a great deal of publicity. The final version of the Doha Declaration was ultimately negotiated between Brazil and the United States.

In terms of its content, the Doha Declaration strives to reconcile the TRIPS Agreement with efforts of WTO Member States to protect public health by reaffirming their right to use "the provisions in the TRIPS Agreement, which provide flexibility for this purpose" (Article 4). In Article 5, the Doha Declaration addresses the issues mentioned above and clarifies that each WTO Member (i) has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted, (ii) has the right to determine what constitutes a national emergency or other circumstances of extreme urgency (the HIV/AIDS crisis is explicitly recognized as a case of emergency or urgency), and (iii) is free to establish its own patent exhaustion regime without challenge (and thus free to allow parallel imports). In Article 7, the deadline for providing patent protection for pharmaceuticals was extended for least-developed countries until 2016,[70] while the deadline for developing countries pursuant to Article 65(4) TRIPS was not extended, remaining at 2005.

The Doha Declaration also recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under TRIPS. As a result, the Council for TRIPS was instructed to find an "expeditious solution" to this problem (Article 6 of the Doha Declaration). A series of negotiations ensued, and a number of solutions were proposed. The developing countries – initially supported by the European Union – favored a solution based on a general exception under domestic patent law in line with Article 30 TRIPS. The United States opposed this approach from the very beginning and proposed either a waiver solution or – preferably – a simple moratorium on dispute settlement. A formal amendment to Article 31(f) TRIPS could have also been an option, but it would probably have proven to be too cumbersome and time-consuming to come to an agreement as to the precise wording of an amendment. In addition, the United States clearly preferred a transitory or provisional solution that would not touch the TRIPS Agreement. The WTO Member States managed to agree on a waiver solution, but the negotiations nevertheless stalled in December 2002, as the WTO Member States failed to agree on the precise wording of a waiver provision. In particular, the United States feared that the disease scope was too broadly defined (expanding beyond those to treat infec-

[70] This article was implemented through a Council for TRIPS decision. *See* Council for TRIPS, Decision of June 27, 2002, IP/C/25 (July 1, 2002).

tious diseases into the area of "lifestyle drugs" such as Viagra®) and that drugs sold cheaply to meet the needs of developing countries could be diverted and re-exported to high price countries in the developed world.[71] Further negotiations – sometimes directly between representatives of U.S. pharmaceutical companies and developing countries – ultimately led to the WTO Decision of August 30, 2003 (see **Exhibit 15**)[72].

The approach chosen was to waive the obligations set forth in Article 31(f) TRIPS (supply for domestic market) for countries exporting pharmaceuticals to certain eligible countries, and to waive the obligations under Article 31(h) TRIPS (adequate remuneration) for eligible importing countries, which in turn must take appropriate measures to prevent trade diversion.[73] Assuming that the relevant pharmaceuticals are patented in the countries in question, this system requires two compulsory licenses, one in the importing country and another in the exporting country. The mechanism applies to all pharmaceutical products, but is intentionally ambiguous as to the disease scope. Any WTO Member State qualifies as an exporting country, and any WTO Member State may qualify as an importing country, as long as it can show that it has insufficient manufacturing capacities, which are assessed on a product-by-product basis. As of October 2004, no notifications had been made to the Council for TRIPS[74], but some reports indicate that the Malaysian government has granted compulsory licenses to Cipla, an Indian generic manufacturer, for AIDS drug patents held by Bristol-Myers Squibb and GlaxoSmithKline,[75] and that Zambia has granted a compulsory license to Pharco Ltd., an Italian company incorporated in Zambia, to manufacture a combination of three AIDS drugs covered by patents held by Boehringer Ingelheim and Bristol-Myers Squibb. Under the terms of the license, the royalties due to the patent holders are limited to 2.5% of the total turnover generated by Pharco Ltd.[76]

Developments Outside WTO and TRIPS

Since South Africa introduced Section 15C in 1997 to reduce the cost of prescription drugs, a number of efforts have been made by a variety of actors to make access to antiretroviral treatment more affordable for people in developing countries. In May 2000, five U.N. organizations – UNFPA, UNICEF, WHO, UNAIDS,

---

71 *See* Paul Vandoren & Jean Charles Van Eeckhaute, The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Making it Work, 6 J. World Intell. Prop. 780-781 (2003).

72 WT/L/540 (September 2, 2003).

73 In legal terms, the WTO Decision rests on Articles IV:1 and IV:2 of the Agreement establishing the WTO, and the waivers contained in Articles 2, 3, and 6 are based on Article IX:3 of the WTO Agreement.

74 The WTO maintains a Web site dedicated to notifications under the WTO Decision; *see* http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm.

75 *See* Latha Jishnu & Gina S. Krishnan, The Cipla Test of Para 6, Businessworld (India) (March 8, 2004).

76 *See* Republic of Zambia, Ministry of Commerce, Trade, and Industry, Compulsory License No. DC 01/2004, Doc. No. MCT1/104/1/1c (Sept. 21, 2004); *see also* The Times of Zambia (Sept. 23, 2004).

and the World Bank – initiated the Accelerating Access Initiative (AAI), a partnership with five major pharmaceutical companies (Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck, F. Hoffmann-La-Roche, and Abbott Laboratories) to further reduce the cost of HIV/AIDS drugs. Within the framework of this Initiative, the drug companies provide antiretroviral drugs to countries in the developing world at a significant discount, in some instances at 10-20% of the price charged in developed countries. Some companies have also made their drugs available to recipients outside the AAI, such as nongovernmental organizations, private sector employers and health care organizations.[77] As a result, prices for antiretroviral treatment in developing countries have decreased sharply (see **Exhibit 16**). At the same time, funding to fight HIV/AIDS has been increased. In 2000, at a meeting of the G8 countries, Japan suggested the creation of a global fund to fight HIV/AIDS, tuberculosis, and malaria. The idea was promoted by U.N. Secretary General Kofi Annan and approved by the U.N. General Assembly in June 2001. The Global Fund was established in January 2002 and is funded by governments, private organizations, and individuals worldwide (see **Exhibit 17**). As of October 2004, more than $3 billion has been donated to the Global Fund, and about $650 million has been disbursed worldwide. Yet, when Senator Norm Coleman (R-MN), member of the Senate Foreign Relations Committee, visited South Africa in August 2003, the situation in terms of access to essential medicines did not seem to be much better, "It is a country in which there are 11 million orphans from AIDS, over 5 million people are HIV positive. And yet with 5 million people being HIV positive only 20,000 are receiving the anti-retro viral drug that is needed to treat AIDS and descend its tide."[78]

Since this statement was released, further efforts have been made to cut prices on both diagnostics and drugs to combat HIV/AIDS. The most notable of these efforts is South Africa's cooperation with the William J. Clinton Presidential Foundation, which provides technical and financial assistance to implement South Africa's first comprehensive treatment plan approved in November 2003. The goal is to provide treatment to more than three million people within a few years, with more than a million of those receiving antiretroviral treatment.[79] To this end, the Clinton Foundation managed to reach agreements with five suppliers of generic antiretroviral drugs to reduce the price of the most commonly used drug therapy combinations to less than $140 per person per year.[80] One of these suppliers is the South African generic manufacturer Aspen Pharmacare, whose stock price jumped to new heights when the deal was announced, despite the fact that it agreed to keep its profit margins low (see **Exhibit 18**). In January 2004, the Clinton Foundation struck deals with the market leaders for diagnostics to reduce prices by up to 80% as compared to the then current market prices. As of April 2004, the Clinton

77 *See* WHO & UNAIDS, Accelerating Access Initiative – Progress Report (June 2002).
78 Norm Coleman, Audio Update (August 22, 2003), available at http://coleman.senate.gov.
79 *See* http://www.clintonpresidentialcenter.org/country.php?c=SouthAfrica.
80 *See* http://www.clintonpresidentialcenter.org/aids-initiative4a.htm.

Foundation also works with the Global Fund, the World Bank, and UNICEF to extend access to its pricing for drugs and diagnostics to countries in which these organizations are active.[81]

Latest Developments in South Africa

The latest news from South Africa relates to the conclusion of investigations of pricing practices by pharmaceutical companies conducted by the South African Competition Commission. The investigations were triggered by complaints and private lawsuits filed independently by manufacturers of generics and by public interest groups dissatisfied with the price reductions that occurred during 2001 and worried that the public pressure on pharmaceutical companies would decline if the issue were left to private negotiations between the drug industry, generic manufacturers, and the government. The ultimate goal of these complaints and lawsuits was and still is to enable or increase generic competition for name-brand antiretroviral drugs, either by imposing compulsory licenses or by encouraging voluntary licenses. The first case was settled in December 2003 after the South African Competition Commission found GlaxoSmithKline (Glaxo) and Boehringer Ingelheim in violation of antitrust laws by reason of excessive pricing and refusal to license their patents to certain generic manufacturers (see **Exhibit 19**). More precisely, they had refused to license their patents to generic manufacturers other than Aspen Pharmacare. Under the settlements, reached prior to the beginning of hearings before the Competition Tribunal, the two companies allow select generic companies to manufacture and sell some of their antiretroviral drugs in sub-Saharan Africa in return for a royalty that does not exceed 5% of net sales of the relevant antiretroviral drugs (as opposed to the 30% and 15% royalties Glaxo and Boehringer charged Aspen Pharmacare prior to the settlement). [82] The public interest organizations hope that the combined annual prices for AZT, 3TC, and Nevirapine will drop from $3,000 at the time the complaint was filed to $300 after the implementation of the settlements.[83] A similar case brought against Glaxo by the U.S.-based AIDS Healthcare Foundation was not settled, however, despite the fact that Glaxo, in June 2003, had agreed to provide the AIDS clinic run by AIDS Healthcare with antiretroviral drugs at not-for-profit prices. The case was referred to the Competition Tribunal in August 2004, but, as of January 2005, no decision had been reached.[84] The proceedings before the Competition Tribunal are just a new chapter in an ongoing battle between Glaxo and the AIDS Healthcare Foundation that includes challenges of Glaxo's U.S. patents, petitions to revoke FDA approval for one of Glaxo's drugs, and a class action lawsuit against Glaxo on behalf

---

81 *See* http://www.clintonpresidentialcenter.org/aids-initiative5.htm.

82 *See* The Guardian (London), October 17, 2003, p. 23.

83 *See, e.g.*, John Donnelly, Deal Paves Way for Generic HIV Drug Companies to Allow Sales in Sub-Saharan Africa, The Boston Globe (December 11, 2003), p. A8.

84 *See* In the Matter of Mpho Mkhathnini et al. and GlaxoSmithKline (Pty) Ltd. et al., Case No. 34/CR/Apr04; *see also* John Carvel, New Aids Drug Battle for Glaxo, The Guardian (London) (August 21, 2004), p. 5.

of AIDS patients who allege that Glaxo's illegal pricing strategy is responsible for their not having access to life-saving medicines (see **Exhibit 20**).

Reflections on the South Africa Controversy by the CEO of Novartis

In October 2004, the CEO of Novartis, Dr. Daniel Vasella, became the new president of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), replacing the CEO of Merck, Ray Gilmartin. On this occasion, Dr. Vasella gave an interview to a Swiss newspaper, discussing the question of how the pharmaceutical industry could improve its declining reputation.[85] When asked what went wrong in the industry over the past twenty-five years, Vasella responded[86], "This is in part the consequence of the continuously increasing costs of health care, which are attributed to drug prices, even though they only make up about 15% of health care costs. Much more important than drug prices is the fact that the number of elderly people, who are sick more often, increases constantly. Another incisive change followed from the AIDS epidemic. This was the first time – at least in my recollection – when the pharmaceutical companies were confronted with self-organized AIDS patients. The conflict was about who would get access to the first effective anti-AIDS-drug and how much the company would be allowed to charge for life-saving treatment. In this discussion, the pharmaceutical companies took a very traditional position. This was a mistake." However, Vasella rejected the idea that it was patent protection that was at the core of the issue by saying, "The debate about patents emerged under the impression that patents would prevent access to life-saving medicines for poor patients. People forgot that patents are a fundamental condition for obtaining the financial means to pay for research and development. But again – instead of developing timely alternatives with partners, the industry behaved defensively."

85 *See* NZZ am Sonntag (Zurich), pp. 47-48 (October 31, 2004).

86 The following statements were translated from German by Cyrill Rigamonti.

Exhibit 1

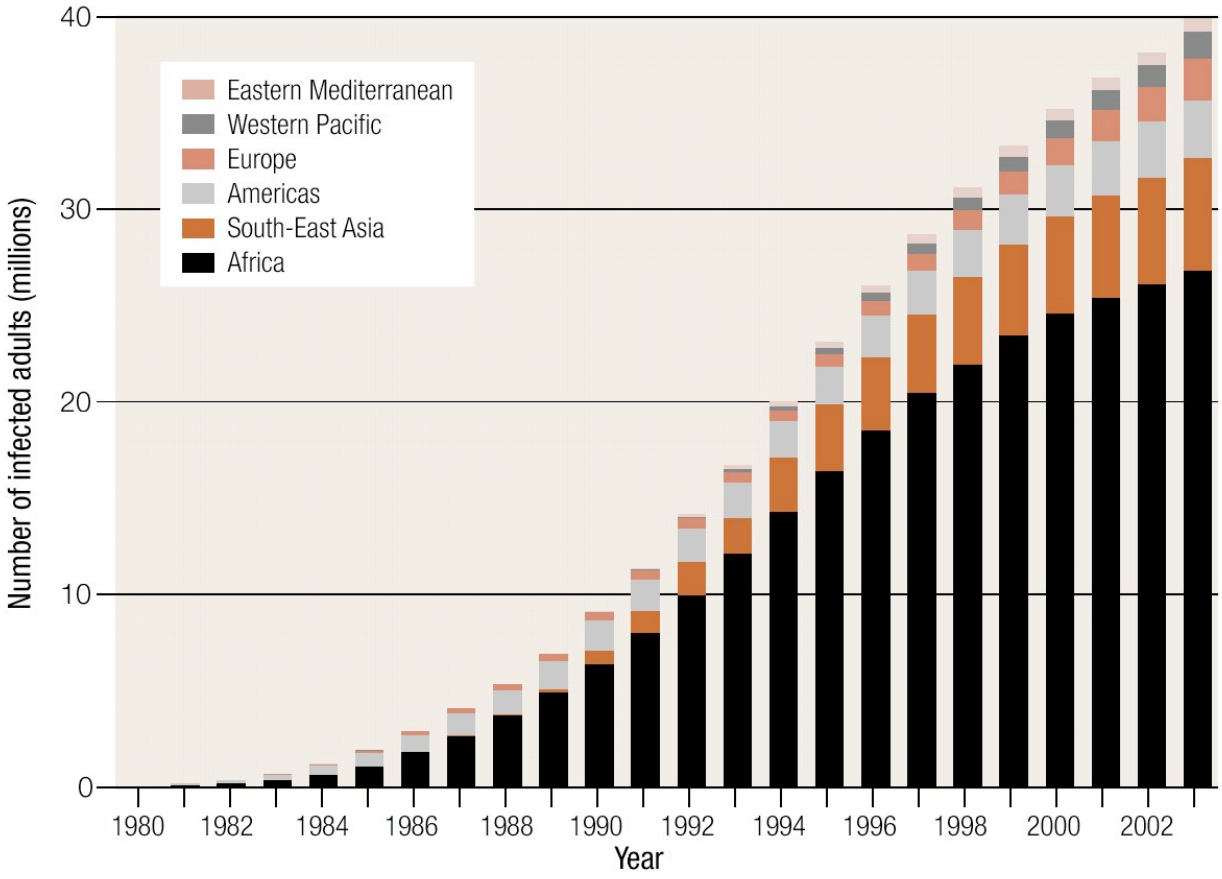
OVERVIEW OF AIDS DRUGS

Generic Name	Brand Name	FDA	Marketing Firm	U.S. Patent Holder	SA Pat.
Zidovudine (AZT)	Retrovir	1987	GlaxoSmithKline	Burroughs Wellcome	Yes
Didanosine (ddI)	Videx	1991	Bristol-Myers Squibb	United States	Yes
Zalcitabine (ddC)	Hivid	1992	Roche	United States	No
Stavudine (d4T)	Zerit	1994	Bristol-Myers Squibb	Yale University	Yes
Lamivudine (3TC)	Epivir	1995	GlaxoSmithKline	IAF Biochem Int'l	Yes
Abacavir Sulfate	Ziagen	1998	GlaxoSmithKline	Burroughs Wellcome	Yes
Sequinavir Mesylate	Invirase	1995	Roche	Roche	Yes
Saquinavir	Fortovase	1997	Roche	Roche	Yes
Ritonavir	Norvir	1996	Abbott Laboratories	Abbott Laboratories	No
Indinavir Sulfate	Crixivan	1996	Merck & Co.	Merck & Co.	Yes
Nelfinavir Mesylate	Viracept	1997	Pfizer	Pfizer	Yes
Amprenavir	Agenerase	1999	GlaxoSmithKline	Vertex	Yes
Nevirapine	Viramune	1996	Boehringer Ingelheim	Boehringer Ingelheim	Yes
Delavirdine Mesylate	Rescriptor	1997	Pfizer	Pfizer	Yes
Efavirenz	Sustiva	1998	Bristol-Myers Squibb	Merck & Co.	Yes

Sources: Consumer Project on Technology (http://www.cptech.org); Amir Attaran & Lee Gillespie-White, Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?, 286 No. 15 J. Am. Med. Ass'n 1886, 1888 (2001); U.S. Food and Drug Administration, Orange Book (http://www.fda.gov/cder/ob/default.htm)

Exhibit 2

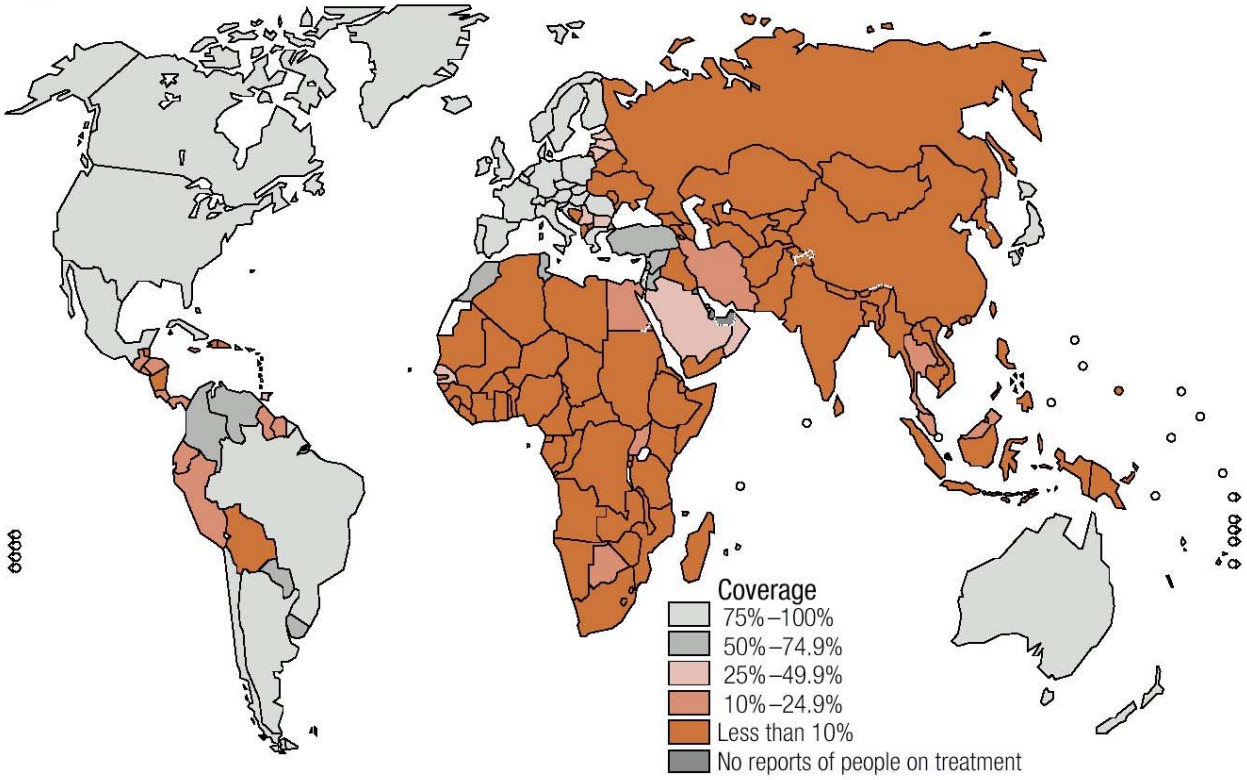
Figure 1.1 Estimated number of adults infected with HIV, by WHO region, 1980–2003



Source: WHO, World Health Report 2 (2004)

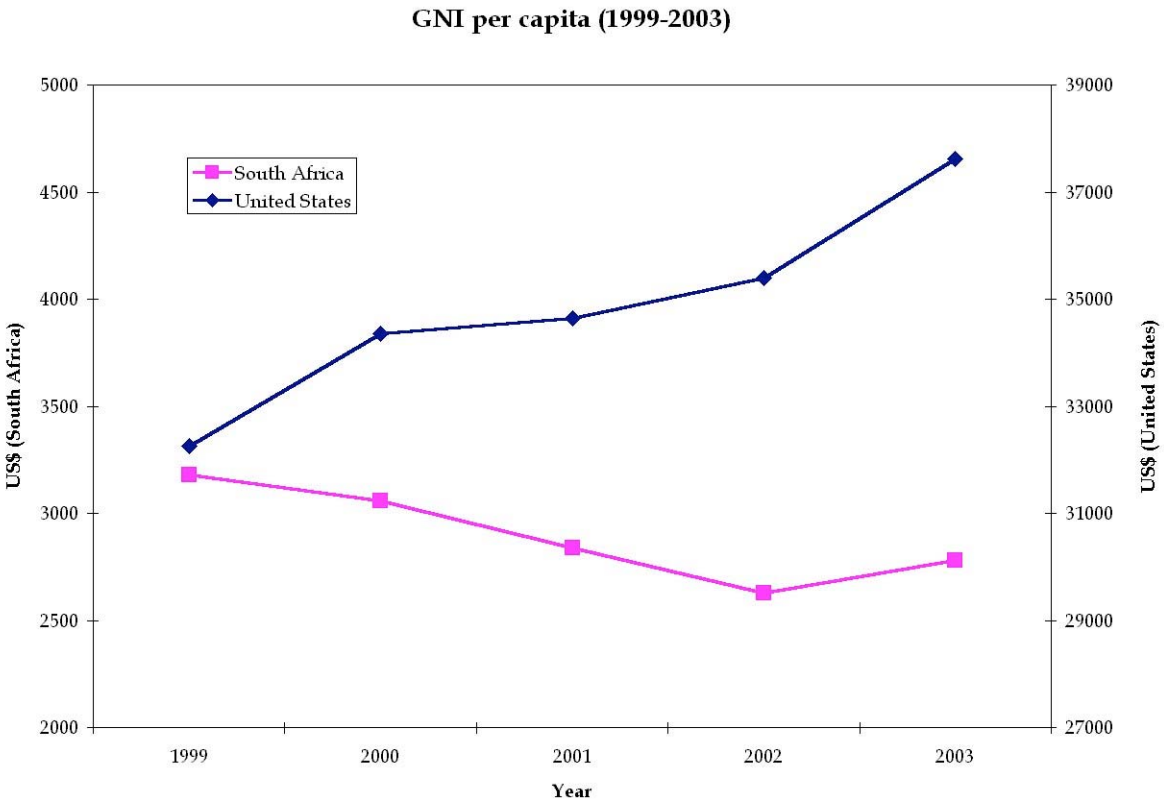
Exhibit 3

Figure 2.1 Estimated worldwide coverage with antiretroviral treatment, end 2003



Source: WHO, World Health Report 22 (2004)

Exhibit 4



Source: World Bank; data available at http://devdata.worldbank.org/data-query

Exhibit 5

NATIONAL DRUG POLICY FOR SOUTH AFRICA (1996)

(excerpt of objectives relating to drug pricing)

4. Drug pricing

AIM

To promote the availability of safe and effective drugs at the lowest possible cost

This aim will be achieved by monitoring and negotiating drug prices and by rationalising the drug pricing system in the public and private sectors, and by promoting the use of generic drugs.

4.1 Rationalization of the pricing structure

! A Pricing Committee with clearly defined functions to monitor and regulate drug prices will be established within the Ministry of Health. Committee members will include health economists, pharmacoeconomists, representatives from the Department of Finance, the Department of Trade and Industry, the Procurement Unit of the Department of Health, the Department of State Expenditure, and consumer representatives.

! There will be total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services, such as dispensers of drugs, as well as private clinics and hospitals.

! A non-discriminatory pricing system will be introduced and, if necessary, enforced.

! The wholesale and retail percentage mark-up system will be replaced with a pricing system based on a fixed professional fee.

! All drugs at the primary care level will be supplied free of charge. At the secondary and tertiary levels a fixed affordable co-payment for drugs supplied by the State will be levied. A system of exemption will be established for patients without the resources to meet such payment to ensure that they are not deprived of treatment.

! A data base will be developed to monitor the cost of drugs in the country in comparison with prices in developing and developed countries.

! Price increases will be regulated.

! Where the State deems that the retail prices of certain pharmaceuticals are unacceptable and that these pharmaceuticals are essential to the well being of any sector of the population, the State will make them available to the private sector at acquisition cost plus the transaction costs involved.

4.2 The use of generic drugs

The use of interchangeable multi-source pharmaceutical products (IMPP), using the international non-proprietary name (INN), or generic name, is a recommended step to reduce drug costs and expenditure. It also contributes to a sound system of procurement and distribution, drug information and rational use at every level of the health care system.

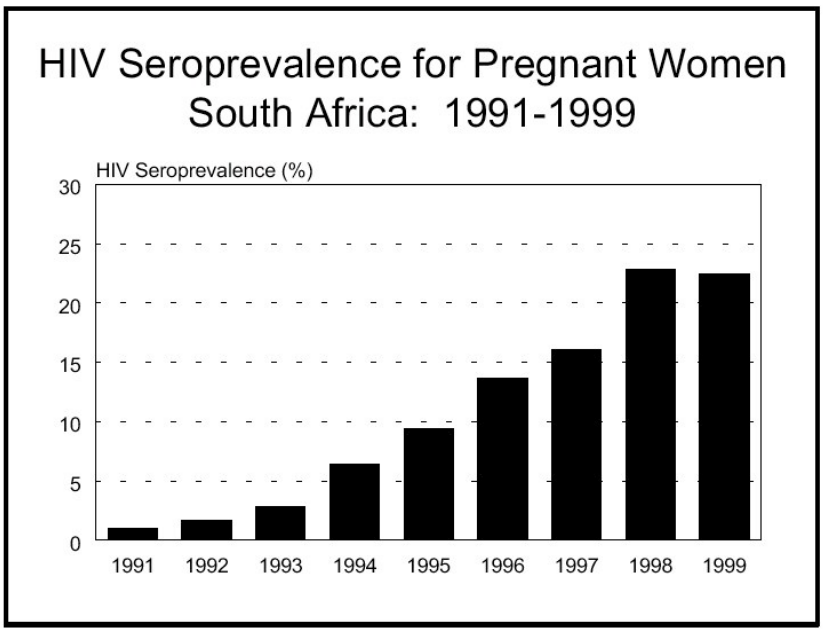
! The availability of generic, essential drugs will be encouraged through the implementation of incentives that favour generic drugs and their production in the country.

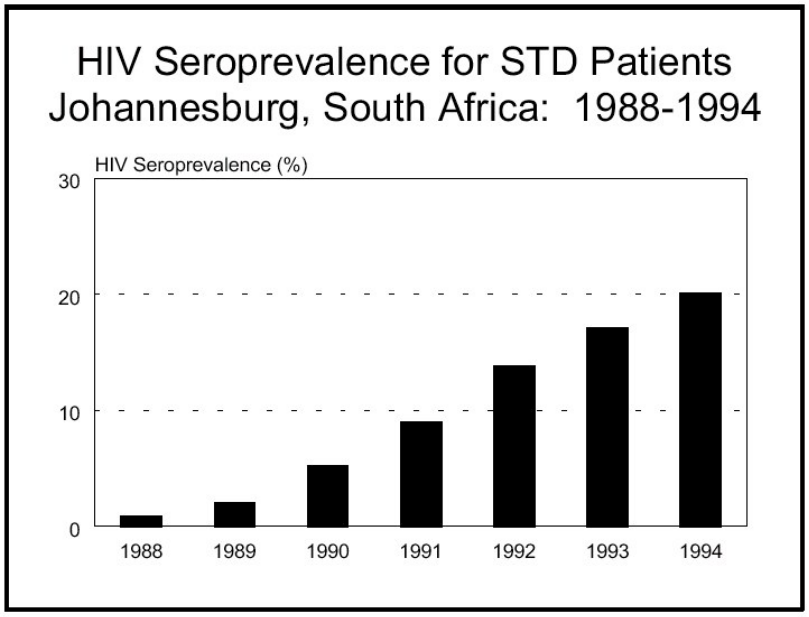
! The policy will aim at achieving generic prescribing in both the public and private sectors. Until this aim is achieved, generic substitution will be allowed, through legislation, in the public and the private sector. It will be incumbent on the pharmacist, prior to dispensing a prescription, to inform the patient on the benefits of generic substitution and to ensure that substitution takes place with the patient's full understanding and consent.

! Patients have the right to make informed decisions concerning their own health, including a choice for generic drugs.

! A regularly updated list of products that cannot be substituted will be prepared and disseminated by the MCC.

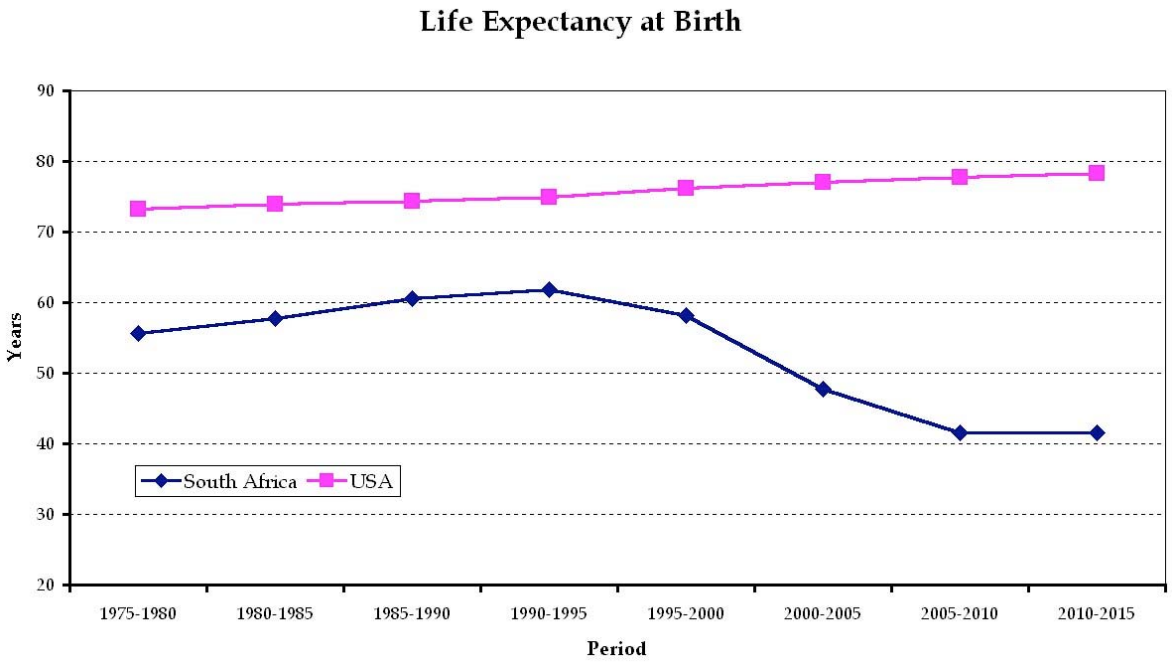
Exhibit 6





Source: International Programs Center, Population Division, U.S. Census Bureau, HIV/AIDS Surveillance Data Base, June 2000

Exhibit 7



South Africa
Life expectancy at birth by sex (years)
Medium variant
1975-2015

Period	Both sexes combined	Male	Female
1975-1980	55.6	52.4	59.0
1980-1985	57.7	54.1	61.6
1985-1990	60.6	56.8	64.8
1990-1995	61.8	57.8	66.3
1995-2000	58.2	53.7	63.1
2000-2005	47.7	45.1	50.7
2005-2010	41.5	41.3	41.6
2010-2015	41.5	42.3	40.5

United States of America
Life expectancy at birth by sex (years)
Medium variant
1975-2015

Period	Both sexes combined	Male	Female
1975-1980	73.3	69.5	77.2
1980-1985	74.0	70.7	77.6
1985-1990	74.4	71.1	78.0
1990-1995	74.9	71.8	78.6
1995-2000	76.2	73.2	79.1
2000-2005	77.1	74.3	79.9
2005-2010	77.8	74.9	80.6
2010-2015	78.3	75.4	81.2

Source: Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat, World Population Prospects: The 2002 Revision and World Urbanization Prospects: The 2001 Revision, http://esa.un.org/unpp

Exhibit 8

Figure 1. The number of orphans is decreasing in all regions except sub-Saharan Africa, where HIV/AIDS has hit the hardest.

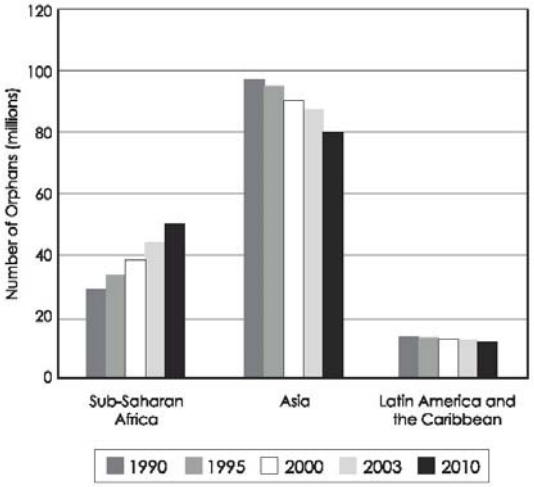
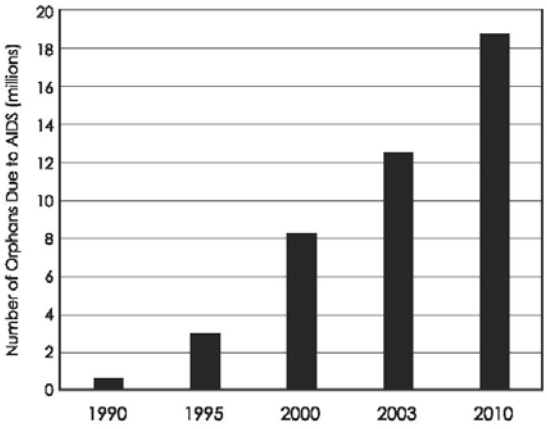
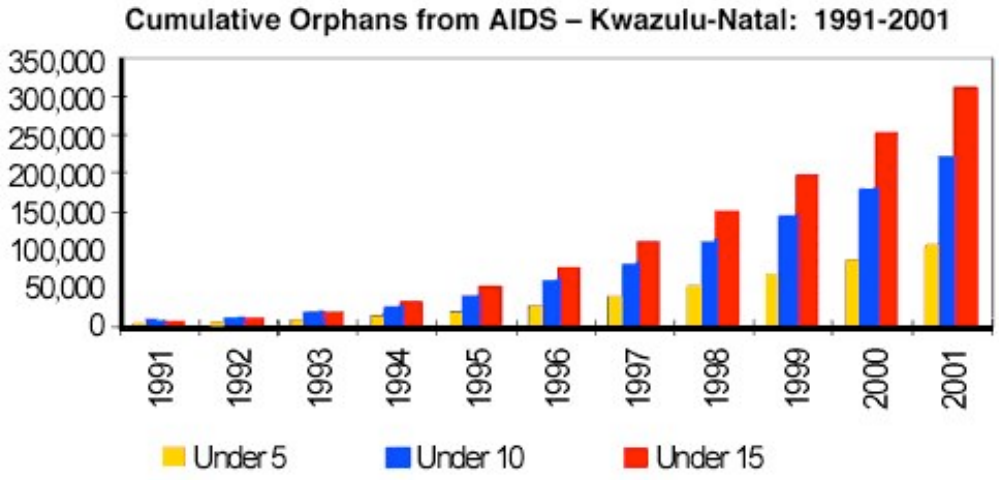


Figure 6. Between 1990 and 2003, sub-Saharan Africa's population of children orphaned by AIDS increased from less than 1 million to more than 12 million.

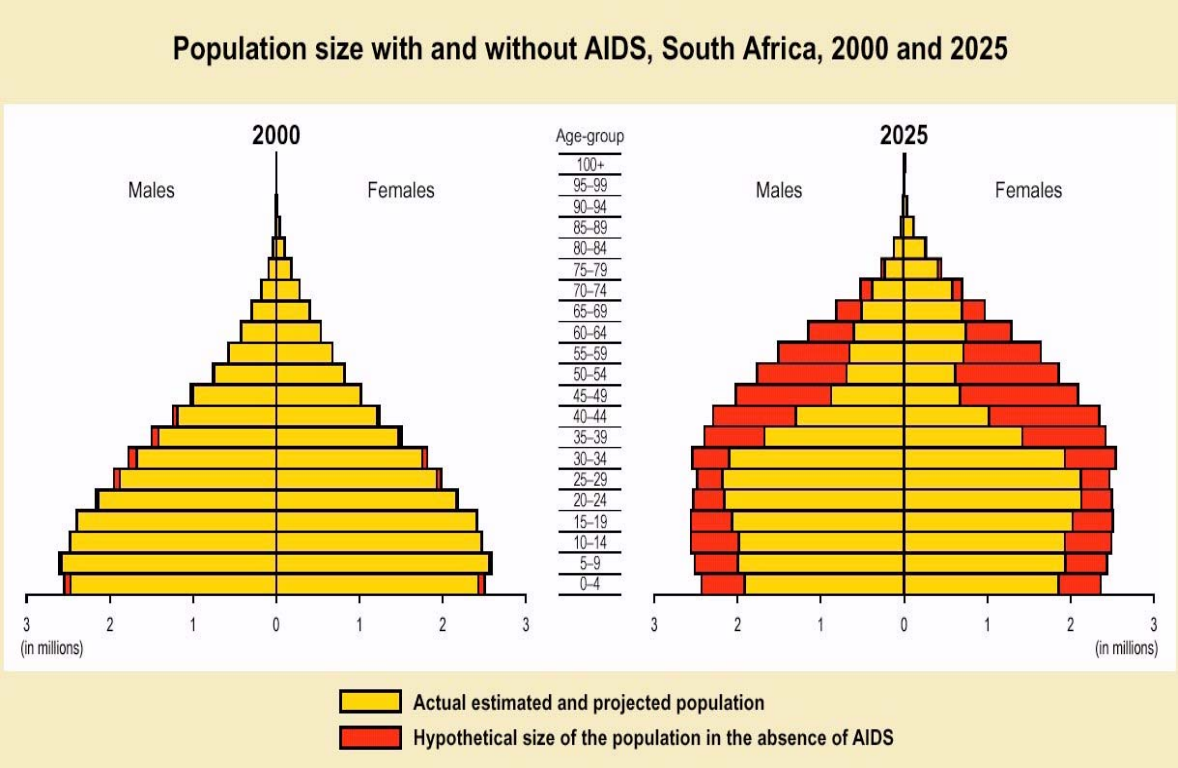


Source: UNAIDS/UNICEF/USAID, Children on the Brink 8, 10 (2004)



Source: Monitoring the AIDS Pandemic (MAP), The Status and Trends of the HIV/AIDS Epidemics in the World 20 (Provisional Report, 1998) (based on data collected by CINDI, South Africa)

Exhibit 9



Source: UNAIDS, 2004 Report on the global AIDS epidemic 43 (2004)

Exhibit 10

SOUTH AFRICAN MEDICINES AND RELATED SUBSTANCES CONTROL AMENDMENT ACT OF 1997

(excerpt from Section 10)

Measures to ensure supply of more affordable medicines

15C. The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may —

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

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

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

Exhibit 11

The New York Times
March 29, 1998, Sunday, Late Edition
Section 3; Page 1; Column 1

South Africa's Bitter Pill for World's Drug Makers

By Donald G. McNeil, Jr. (Johannesburg)

(excerpt)

AMERICANS who need to visit a doctor here notice it right away: the price of the appointment is a pleasant surprise, far less than it would be in the United States. But the prescription afterward is a shock – sometimes double the charge for the doctor's time.

The national Health Department says South Africans, most of whom live in poverty, pay some of the highest drug prices in the world. But its effort to force down prices has set off a pitched battle between the Health Minister – a doctor and Zulu princess named Nkosazana Zuma – and the powerful global pharmaceutical industry. The stakes are so high that President Clinton put the dispute on his agenda last week during a stop in South Africa on his six-nation African tour.

At issue is a new law that gives Dr. Zuma sweeping powers to open the country to cheap imports, encourage the use of generics and sharply curb the markups that pharmacists charge.

The law is crucial to the mission the new Government has assigned her: to turn inside out a health care system that has given high-quality care to whites while forcing most blacks to wait in crowded public hospitals or turn to traditional healers. Not only have prescription drugs consumed a huge portion of the public health budget, but half of all drugs in public hospitals are stolen, winding up in the high-priced private sector. At the hospitals, meantime, the cupboards are so bare that some provincial doctors said recently that they could no longer give AIDS patients expensive antibiotics for brain infections.

None of this, however, is why President Clinton cares about what has come to be known as the Zuma law. Rather, American pharmaceutical companies, which control nearly half of the $2 billion-a-year drug market here through subsidiaries, see it as a threat to their patent rights.

They say the law -- which was signed in December and is now tied up in a court battle over its enforcement -- seems to arm Dr. Zuma with the power to undo international patent protections and give anyone here she chooses the green light to make pirate versions of prescription drugs.

If the law is allowed to stand, the companies worry that other countries will follow suit. And why stop with drugs? American companies have billions in other intellectual property to protect -- from movies to music to

software -- and the principles involved are essentially the same.

"If the Health Minister thought it was in the interest of public health that those $10,000 AIDS cocktails be cheaper, she could just rip off the patents and set up a factory in Cape Town to make them," said a Western diplomat who is fighting the law. "And if the Minister of Health says this is O.K., then the Minister of Education will be able to say, 'Well, affordable computers are in the interest of public education, but Windows is just too darn expensive, so we're going to buy knockoff copies.' "

The Health Ministry denies having any such designs, and insists that it is only trying to cut prices. "The minister has said constantly that we have no intention of abrogating patent rights," said Dr. Ian Roberts, a British consultant to Dr. Zuma who drafted the new law. "We respect the fact that they have an economic value."

On Thursday, Commerce Secretary William M. Daley, visiting with Mr. Clinton, discussed the American objections to the law with Dr. Zuma. Both continue to disagree, a diplomat said, about the meaning of the section of the law that the pharmaceutical companies and the United States Government say they cannot live with.

In this battle, it is hard to spot the good guys – or even a neutral player. There is no consumer lobby here, no Ralph Nader or Consumer Reports magazine, so patients are at the mercy of big business and big government. The local press has been lax, dutifully retyping the propaganda from both sides without explaining the issues to nervous readers. And there has been more than enough brinkmanship to go around.

Merck & Company, the New Jersey-based drug giant, has dropped a $10 million investment, openly blaming the new law. Britain's SmithKline-Beecham said it was rethinking expansion plans. Since the legislation was introduced last May, Bristol-Myers Squibb, Pharmacia & Upjohn and Eli Lilly have all closed their South African factories. While they didn't openly blame the bill, the closures "were partly in response to uncertainty surrounding the legislation," acknowledged Mirryena Deeb, executive director of the Pharmaceutical Manufacturers Association of South Africa.

In Washington, 47 members of Congress recently signed a letter asking the United States trade representative to "pursue all appropriate action" against the law.

And an industry group, the Pharmaceutical Research and Manufacturers of America, lumping South Africa with Argentina and India as "global centers of patent piracy," asked the Commerce Department to put all three on Washington's highest-level list of countries that discriminate against American exports -- the first step toward imposing sanctions. (South Africa got off the list only two years ago, when the Government helped stop a Durban hamburger outlet from stealing the McDonald's name.)

The South African Government, on its side, is threatening to bypass the pharmaceutical companies and import cheaper drugs. If drugs don't get less expensive, Dr. Roberts said, Pretoria could up the ante by mandating the use of generics or even directly setting drug prices.

The battle is greatly affected by the quirky, stubborn personality of Dr. Zuma, whose husband is a power broker in the ruling African National Congress party. More important, Dr. Zuma enjoys the absolutely bulletproof support and affection of President Nelson Mandela.

The dispute is also bitter, and driven by deep suspicions. Virtually everyone interviewed quietly suggests – off the record – that the other side is hatching a plot. Some examples: The Health Ministry is the tool of a World Health Organization cabal that thinks patents on medicines are unethical – or a tool of Indian pharmaceutical companies that want new markets for their pirate products. The A.N.C. health specialists are Marxists who want revenge on multinationals that evaded sanctions in the apartheid era. The American drug companies are being misled by their

local subsidiaries, which have formed cozy cartels to keep profits up.

The two sides disagree even about whether medicines here are cheap or expensive, and they interpret the same words in the law differently. A great deal will depend on how Dr. Zuma enforces the law. That is, assuming it withstands a pending challenge in the courts here and a threatened one before the World Trade Organization, and that the Government doesn't bend to American and European pressure to amend it.

* * *

The Government says that drugs here are exceedingly expensive. For example, the same drugs in pharmacies in next-door Zimbabwe are frequently half the price or less, because many are Zimbabwe-made generics. Prices in New York can also be cheaper. A tablet of Amoxicillin, a commonly prescribed antibiotic, sells for 50 cents here, compared with 30 cents in New York and just 4 cents in Zimbabwe.

Dr. Roberts, the health ministry consultant, did his own study in 1996 of drug expenditures as a percentage of gross domestic product. It showed South Africa as No. 2 in the world, after Portugal.

But the South African drug makers' association replies that public hospitals, which buy 80 percent of the nation's drugs, pay rock-bottom prices through competitive bidding. Its studies show public-sector prices equal to or below those obtained by international aid agencies. The problem, the drug makers say, has to do only with the other 20 percent of the drugs, earmarked for private pharmacies and "dispensing doctors."

These two views are not necessarily mutually exclusive. Nor is it the case that the high prices affect only the well-to-do. The poor are victims because the huge profits available in the private sector leach drugs off hospital shelves, forcing patients at times to do without or to pay more.

The drug makers blame the distributors for this situation. The drugstore industry has long had a cartel arrangement typical in South Africa -- wholesalers mark up about 21 percent and pharmacies mark up 50 percent more. (In the United States, the distribution chain typically marks prices up only 25 percent, pharmaceutical makers said.) Drugstores don't post prices and there are no discount chains.

Dr. Roberts calls the 50 percent markup a "perverse incentive" to sell the most expensive drug. The new law authorizes replacing the markup with dispensing fees that will result in the same modest profit on a cheap prescription as on a costly one.

But the most important change in the law is probably the simplest: Pharmacists must tell customers when a cheaper generic exists, and must sell that medicine unless the doctor or the patient forbids it. (As elsewhere in the world, 95 percent of the most commonly prescribed drugs here have generic equivalents.)

The law also forbids manufacturers from offering cash, vacations or other incentives to doctors who prescribe their drugs. And it requires doctors who sell drugs, often as a lucrative sideline, to get licenses to do so.

The figures are disputed, but some experts estimate that fewer than 20 percent of prescriptions here are for generics, compared with more than 50 percent in Britain and the United States.

* * *

FEARS, real or otherwise, are also at the center of the fighting over so-called parallel imports. Typically, a multinational company makes the same pills in several factories around the world, then designates which lots go to which countries, setting different prices in each. South Africa wants to buy a drug wherever it is cheapest. "That's free trade, isn't it?" said a World Health Organization doctor.

* * *

TWO adorable 3-year-old orphans in the nursery at the Cotlands Baby Sanctuary and Hospice here drop their lunch bowls as a visitor enters to run and hug his knees. Like many HIV-positive children, they have swollen glands below their ears, but otherwise seem healthy and happy. Minutes later, the head nurse, Kathy Volkwyn, almost bursts into tears as she answers a whispered question. "Yes," she says, "these babies are probably all going to die."

For Cotlands, the cost of drugs is an enormous issue. The anti-AIDS cocktail that could keep the children alive costs an unthinkable $1,000 a month. Cotlands -- which by South African standards is quite good at fund-raising -- can barely pay the $40 a month it takes to treat each child's ear infections with Ciprobay, a patented antibiotic for which no generic exists.

"We have a hard time paying for milk and nappies," said Reva Goldsmith, the assistant director. "Many medicines become out of the question."

Dr. Zuma's law may bring at least some of those medicines within reach. But things could definitely get worse if the dispute with the big drug companies goes too far.

The companies are most upset at one scrap of a phrase in Paragraph 15C(a) of the law. "To protect the health of the public," it says, the Health Minister may approve the use of more affordable drugs, "notwithstanding anything to the contrary contained within the Patents Act," a reference to the 1978 Patents Act of South Africa, which binds the country to international patent protections.

Drug companies, members of Congress, the American ambassador here and some European governments have all told the South African Government that they think the paragraph abrogates all patent rights.

MR. ZUMA says it does not, but she adamantly refuses to change the wording. The Government's official position is that the provision only authorizes parallel imports. Parallel importing honors patents, even if it snubs the patent holder's right to control worldwide prices.

Feeling increasingly threatened, the drug makers are becoming increasingly threatening, openly hinting that they may refuse to sell here their future discoveries for treating AIDS or cancer.

Asked if the companies were literally threatening to let people die if the law stands, Mrs. Deeb, of the local manufacturers' association, hemmed a bit, then answered: "In so many words, yes. It's very clear – when countries start tampering with patent rights, the new innovations aren't released there."

Drug makers shun India, she said, citing a hypertension drug that must be consumed immediately upon unwrapping, before sunlight begins to make it toxic. In India, she said, it is sold on the street in jars. "If they can't control how it's made and sold, they won't sell," she said. "They can't afford the liability lawsuits."

Asked if such harsh threats were really a wise tactic, she answered: "Health is a very emotive topic. When one party is totally unreasonable, the other becomes totally unreasonable. It becomes tit-for-tat. It's playground tactics, I'm afraid."

Exhibit 12

February 2, 1998

Ms. Charlene Barshefsky
United States Trade Representative
600 17th Street
Washington, D.C. 20508

Dear Ms. Barshefsky:

We are writing to urge that the Administration respond to a law recently enacted by the Government of South Africa which effectively abrogates the intellectual property rights of foreign pharmaceutical companies operating in South Africa. These rights are guaranteed by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to which South Africa is a signatory.

The new law contains at least two egregious provisions. First, it permits the parallel importation of patented products and second, it allows for the administrative expropriation of patented technology.

Both provisions are violations of the TRIPS Agreement. Article 28 of the Agreement obligates member countries to prohibit parallel imports of patented products and Article 27 prohibits discrimination on the enjoyment of patent rights based on the field of technology.

As South Africa seeks to establish itself in the world market, it needs the assistance of the international community to create jobs and economics opportunity. Weakening intellectual property protection in any field is certain to lessen, rather than enhance South Africa's ability to attract vitally needed foreign direct investment.

We hope to work with the South African government in its pursuit of equitable social reforms, including those within the health sector. However, the implications of this law are so great that in the absence of its repeal, we must urge you to pursue all appropriate actions, including if necessary with the WTO.

Sincerely,

Congressman Bob Menendez (D-NJ), Ranking Member, House Subcommittee on Africa
Congressman Edward Royce (R-CA), Chairman, House Subcommittee on Africa
Senator Bob Toricelli (D-NJ)
Senator Frank Lautenberg (D-NJ)
Congressman Chris Smith (R-NJ)

Congressman Howard Coble (R-NC)
Congressman Tom Lantos (D-CA)
Congressman Rodney Frelinghuysen (R-NJ)
Congressman Frank Pallone (D-NJ)
Congressman Donald Payne (D-NJ)
Congressman Bob Franks (R-NJ)
Congressman Jim McDermott (D-WA)
Congressman Scott Klug (R-WI)
Congressman Rob Andrews (R-NJ)
Congressman Steve Rothman (D-NJ)
Congressman Ken Calvert (R-CA)
Congressman Steve Chabot (R-OH)
Congressman Mark Sanford (R-SC)
Congressman Bill Pascrell, Jr. (D-NJ)
Congressman Carrie Meek (D-FL)
Congressman Sam Gejdenson (D-CT)
Congressman James Traficant (D-OH)
Congressman Dan Burton (R-IN)
Congressman Gary Ackerman (D-NY)
Congressman Brad Sherman (D-CA)
Congressman Eni Faleomavaega (D-AS)
Congressman Gerald Solomon (R-NY)
Congressman Martin Frost (D-TX)
Congressman Elton Gallegly (R-CA)
Congressman Frank LoBiondo (R-NJ)
Congressman John Hostettler (R-IN)
Congressman John Peterson (R-PA)
Congressman Merill Cook (R-UT)
Congressman Jim Davis (D-FL)
Congressman John Porter (R-IL)
Congressman Edolphus Towns (D-NY)
Congressman Jim Saxton (R-NJ)
Congressman David Price (D-NC)
Congressman David Drier (R-CA)
Congressman Don Manzullo (R-IL)
Congresswoman Carolyn Maloney (D-NY)
Congressman Stephen Horn (R-CA)
Congressman Robert Wexler (D-FL)
Congresswoman Julia Carson (D-IN)
Congressman Michael Pappas (R-NJ)
Congresswoman Juanita Millender-McDonald (D-CA)
Congressman Dana Rohrabacher (R-CA)

Exhibit 13

June 25, 1999

The Honorable James E. Clyburn
Chairman, Congressional Black Caucus
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Thank you for your letter on behalf of the Congressional Black Caucus inquiring into the issue of affordable AIDS medicines in South Africa. I share with the Caucus an abiding interest and affection for the people of South Africa and of Africa as a whole, and I am happy to bring you abreast of developments in our efforts to resolve our differences with South Africa over trade in pharmaceuticals.

I want you to know from the start that I support South Africa's efforts to enhance health care for its people --including efforts to engage in compulsory licensing and parallel importing of pharmaceuticals -- so long as they are done in a way consistent with international agreements.

As you know all too well, AIDS has reached epidemic proportions in South Africa. More than three million South Africans are HIV positive, and the virus is spreading at an astonishing, horrifying speed -- infecting more than a thousand people a day. AIDS is tearing apart communities and wiping out families, turning wives into widows and children into orphans. At the current pace, more than 2.5 million South African children will lose both parents to AIDS in the next ten years. And the financial means to battle the crisis is itself a casualty; South Africa's economic growth is slowed by 1 percent each year due to the impact of HIV/AIDS.

That is why I put the issue of AIDS at the top of my agenda during my trip to Cape Town last February for a session of the U.S-South Africa Binational Commission. Then-Deputy President Thabo Mbeki and I had a lengthy discussion on the crisis. He has launched an important campaign of awareness and prevention, but he knows he needs to provide effective treatment to those for whom prevention is no longer an option.

In 1997, in an effort to enhance health care for all South Africans, the National Assembly passed amendments to the Medicines Act that granted the government broad, but unspecified authority to provide more affordable drugs to its people. Out of concern that this new law might be used in ways that violate patent rights, more than 40 pharmaceutical firms -- about one third from South Africa, one third from Europe, and one third from

the U.S. -- challenged the law in South African courts, claiming the law violates the South African Constitution. After more than a year, that case is still pending.

Clearly, there is a global consensus on the need to protect intellectual property. That is why the 134 nations of the WTO concluded the WTO/TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement to establish international standards for intellectual property protection.

The Administration has shared its own concerns with South Africa over the more vague provisions of the Medicines Act. We have asked the Government of South Africa to clarify the actions it would take under the Act, and assure us the actions would comply with international agreements and not undermine legal protections for patent holders.

Under her independent authority mandated by Congress, the United States Trade Representative named South Africa to the "watch list" during her Special 301 Annual Review in 1998. Naming a country to the "watch list" -- the lowest designation in the review -- triggers no sanctions or threat of sanctions, but calls for bilateral efforts to resolve the issue. It is also important to note that naming South Africa to the watch list was not done solely in response to pharmaceuticals, but extended to other issues, including protections for computer software, CDs, and other intellectual property.

As you may know, the pharmaceutical industry recommended this year that South Africa be elevated two levels to the designation "Priority Foreign Country." Such a designation would have required the Government of South Africa to resolve this issue to the USTR's satisfaction within a set time, or face trade sanctions. I believe that such an action would have undercut our cooperative efforts to resolve this issue with South Africa, and I urged the USTR to reject the industry recommendation. In the end, USTR maintained South Africa on the "watch list," where it had been the previous year.

In my meeting with then-Deputy President Mbeki here in Washington in August of last year, he and I agreed to seek a solution that addressed the need to bring better health care to South Africans and, at the same time, account for the legitimate interests of manufacturers. I proposed to then-Deputy President Mbeki that -- to speed the availability of lower-cost pharmaceuticals in South Africa -- we work toward a resolution within a framework that included parallel importing and compulsory licensing, consistent with international agreements.

Our efforts to resolve the issue have been slowed by the ongoing litigation, but my view is the same now as it was then: I support South Africa's effort to provide AIDS drugs at reduced prices through compulsory licensing and parallel importing, so long as they are carried out in a way that is consistent with international agreements.

During our meeting in Cape Town in February of this year, then-Deputy President Mbeki and I again reviewed the issue and agreed to continue our efforts to resolve our differences. I am confident that we will reach a mutually satisfactory agreement.

Meanwhile, I thank you for your support of the U.S.-South Africa friendship, and for the commitment of the Congressional Black Caucus to confront the growing crisis of AIDS in Africa.

Sincerely,

Al Gore

Exhibit 14

World Trade Organization WT/MIN(01)/DEC/2
Ministerial Conference, Fourth Session 20 November 2001
Doha, 9 – 14 November 2001 (01-5860)

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. 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.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

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

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Exhibit 15

World Trade Organization

WT/L/540
2 September 2003
(03-4582)

IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Decision of 30 August 2003*

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

* This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[87];

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[88] to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members[89] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s)[90] has made a notification[2] to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed[91];

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

---

87 [Fn. 1] This subparagraph is without prejudice to subparagraph 1(b).

88 [Fn. 2] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

89 [Fn. 3] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

90 [Fn. 4] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

91 [Fn. 5] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision[92];

(b) the compulsory license issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the license shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website[93] the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify[94] the Council for TRIPS of the grant of the license, including the conditions attached to it.[95] The information provided shall include the name and address of the licensee, the product(s) for which the license has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the license. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory license is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a

---

92 [Fn. 6] This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

93 [Fn. 7] The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

94 [Fn. 8] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

95 [Fn. 9] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

compulsory license is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(a) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(b) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting

Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

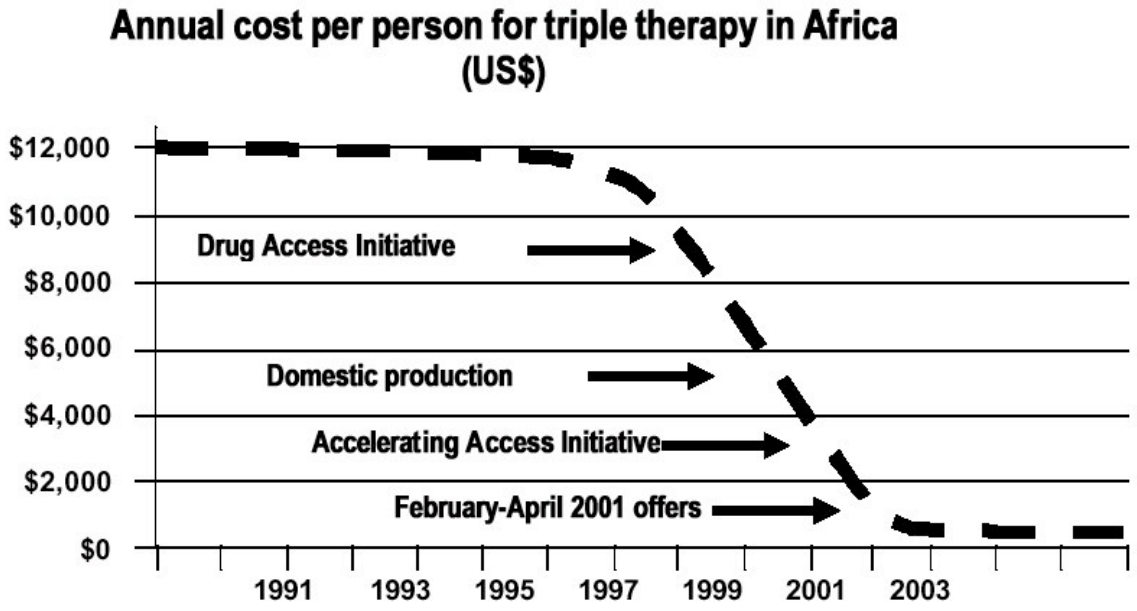
(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or

controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

Exhibit 16



Source: UNAIDS, Report of the Executive Director, 2000-2001, Doc. No. UNAIDS/PCB(12)/02.2, 33 (May 3, 2002)

Exhibit 17

The Global Fund – Pledges as of Oct. 20, 2004

DONOR	TOTAL PLEDGES TO DATE				TOTAL PAID (USD)
	AMOUNT		IN USD	PERIOD	
Countries					
Andorra	USD	100'000	100'000	2002	100'000
Australia	AUD	25'000'000	17'416'875	2004-2006	13'827'500
Austria	EUR	1'000'000	1'075'900	2002	1'075'900
Barbados	USD	100'000	100'000	2003	100'000
Belgium	EUR	41'183'222	48'365'501	2001-2007	29'707'866
Burkina Faso	USD	75'000	75'000	2002	75'000
Cameroon	USD	100'000	100'000	2003	
Canada	USD	100'000'000	100'000'000	2002-2005	100'005'530
	CAD	70'000'000	55'118'110	2005	
China	USD	10'000'000	10'000'000	2003-2007	4'000'000
Denmark	DKK	295'000'000	44'795'810	2002-2004	44'795'810
EU	EUR	460'500'000	557'749'291	2001-2006	451'837'961
France	EUR	550'000'000	674'956'619	2002-2006	305'498'491
Germany	EUR	300'000'000	363'224'518	2002-2007	95'367'375
Greece	EUR	250'000	307'882		
Hungary	USD	10'000	10'000	2004	10'000
Iceland	ISK	15'000'000	206'299	2004	206'299
Ireland	EUR	30'000'000	33'295'430	2002-2004	33'295'430
Italy	USD	200'000'000	200'000'000	2002-2003	215'160'273
	EUR	200'000'000	246'305'419	2004-2005	
Japan	USD	259'993'443	259'993'443	2002-2004	246'520'013
Kenya	KES	653'550	8'273	2001	8'273
Korea	USD	500'000	500'000	2004	
Kuwait	USD	1'000'000	1'000'000	2003	1'000'000
Liberia	USD	25'000	25'000		
Liechtenstein	USD	100'000	100'000	2002	100'000
	CHF	100'000	77'190	2004	77'190
Luxembourg	EUR	4'000'000	4'497'320	2002-2004	4'497'320
Mexico	USD	100'000	100'000	2003	
Monaco	USD	88'000	88'000	2002-2003	88'000
Netherlands	EUR	135'000'000	162'372'322	2002-2005	99'564'440
New Zealand	NZD	2'250'000	1'359'200	2003, 2004	1'359'200
Niger	USD	50'000	50'000		

Nigeria	USD	10'000'000	10'000'000	2002-2003	9'080'914
Norway	NOK	373'300'000	53'536'383	2002-2004	53'536'383
Poland	USD	30'000	30'000	2003-2004	30'000
Portugal	USD	1'000'000	1'000'000	2003-2004	1'000'000
Russia	USD	20'000'000	20'000'000	2002-2006	8'750'000
Rwanda	USD	1'000'000	1'000'000		
Saudi Arabia	USD	10'000'000	10'000'000	2003-2006	5'000'000
Singapore	USD	1'000'000	1'000'000	2004-2008	200'000
South Africa	ZAR	20'000'000	3'039'814	2003	2'000'000
Spain	USD	100'000'000	100'000'000	2003-2006	50'000'000
Sweden	SEK	616'000'000	75'195'191	2002-2004	75'195'191
Switzerland	USD	10'000'000	10'000'000	2002-2003	10'000'106
	CHF	3'000'000	2'343'384	2004	2'343'384
Thailand	USD	5'000'000	5'000'000	2003-2007	2'000'000
Uganda	USD	2'000'000	2'000'000		
United Kingdom	GBP	259'000'000	452'131'963	2001-2007	178'581'238
United States[2]	USD	1'969'480'000	1'969'480'000	2001-2008	982'725'000
Zambia	ZMK	83'500'000	25'000	2002	25'000
Zimbabwe	USD	158'462	158'462	2003	158'462
Total			**5'499'313'599**		**3'028'903'549**
Foundations and Not-for-profit Organizations					
Gates Foundation	USD	150'000'000	150'000'000	2002-2003	150'000'000
Int'l Olympic Committee	USD	100'000	100'000	2001	100'000
Other					105'967
Total			**150'100'000**		**150'205'967**
Corporations					
Eni S.p.A.	USD	500'000	500'000	2002	500'000
Winterthur	USD	1'000'000	1'000'000	2002	1'044'225
Other					32'325
Total			**1'500'000**		**1'576'550**
Individuals, Groups & Events					
Mr. Kofi Annan	USD	100'000	100'000	2001	100'000
Amb. D. Fernandez	USD	100'000	100'000	2001	100'000
Health Authorities of Taiwan	USD	2'000'000	2'000'000	2002, 2004	1'000'000
Real Madrid Soccer Match	USD	112'487	112'487	2002	112'487
Treatment Action Campaign	USD	10'000	10'000	2003	10'899
Other - pledged	USD	50'000	50'000	2003	50'000
Other - unpledged					750'562
Total			**2'372'487**		**2'123'948**
Grand Total			**5'653'286'086**		**3'182'810'014**

Source: The Global Fund, http://www.theglobalfund.org/

Exhibit 18

Aspen Pharmacare (South Africa), Stock Quotes 1995 - 2004

Merck (U.S.), Stock Quotes 1995 – 2004 (for comparison)

Source: BigCharts.com (October 13, 2004)

Exhibit 19

Media Releases by the South African Competition Commission

COMPETITION COMMISSION
MEDIA RELEASE NO. 29 OF 2003
16 October 2003

Competition Commission finds pharmaceutical firms in contravention of the Competition Act

The Competition Commission has found that pharmaceutical firms GlaxoSmithKline South Africa (Pty) Ltd (GSK) and Boehringer Ingelheim (BI) have contravened the Competition Act of 1998. The firms have been found to have abused their dominant positions in their respective anti-retroviral (ARV) markets.

In particular the Commission has found the firms have engaged in the following restrictive practices:

1. Denied a competitor access to an essential facility
2. Excessive pricing
3. Engaged in an exclusionary act

The Commission has decided to refer the matter to the Competition Tribunal for determination.

Menzi Simelane, Commissioner at the Competition Commission, says," Our investigation revealed that each of the firms has refused to license their patents to generic manufacturers in return for a reasonable royalty. We believe that this is feasible and that consumers will benefit from cheaper generic versions of the drugs concerned. We further believe that granting licenses would provide for competition between firms and their generic competitors."

"We will request the Tribunal to make an order authorising any person to exploit the patents to market generic versions of the respondents patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty. In addition, we will recommend a penalty of 10% of the annual turnover of the respondents' ARVs in South Africa for each year that they are found to have violated the Act."

Simelane said these practices violate the Competition Act of 1998's prohibitions against excessive pricing (section 8(a)), refusing access to essential facilities (section 8(b)) and exclusionary acts that have an anticompetitive effect that outweighs technological, efficiency or other pro-competitive gains (section 8(c).

"Indeed the very goals of our Competition Act - promoting development, providing consumers with competitive prices and product choices, advancing social and economic welfare and correcting structural imbalances - have been made difficult in this context by the refusal of the respondents to license patents."

The original complaint in this matter was filed by Hazel Tau and others alleging that GSK and BI were charging excessive prices to the detriment of consumers for their patented ARV medicines.

GSK and BI hold patents on certain antiretroviral (ARV) medications used to treat HIV/AIDS. GSK holds patents in South Africa on AZT (branded as Retrovir), Lamivudine (branded as 3TC) and AZT/Lamivudine (branded as Combivir). BI holds patents in South Africa on Nevirapine (NVP) (branded as Viramune).

* * *

COMPETITION COMMISSION
MEDIA RELEASE NO. 33 OF 2003
16 December 2003

Competition Commission Concludes an agreement with pharmaceutical firm

The Competition Commission has concluded a settlement agreement with pharmaceutical firm GlaxoSmithKline South Africa (Pty) Ltd (GSK) and is in discussions with Boehringer Ingelheim (Pty) Ltd (BI) regarding a settlement agreement.

The settlement agreement is the result of negotiations following the Commission's announcement in October 2003 that GSK and BI had, in its view, contravened the Competition Act of 1998. From its investigation into the complaints by Hazel Tau and others, the Commission concluded that GSK and BI had abused their dominant positions in their respective anti-retroviral (ARV) markets. This was denied by GSK and BI.

The Competition Commissioner, Menzi Simelane, said he was happy that all parties concerned had agreed to the terms of the settlement agreements as he believed that the agreements addressed the competition concerns raised by the Commission.

"The terms of the agreements are substantially similar to the successful outcomes which we would have hoped to achieve at hearings before the Tribunal, namely the issuing of licenses to generic manufacturers of antiretroviral drugs. It has been a particularly difficult case and we are happy that the matter has been amicably resolved."

Simelane said the Commission had not asked for the imposition of a fine or an administrative penalty.

"We think it is far more important to have broadened access to cheaper ARVs for people with HIV/AIDS through price reductions by generic manufacturers. The introduction of generic substitutes should result in a drastic reduction in the prices of antiretroviral drugs.

"As the agreements provide for more than one generic manufacturer, there will be competition amongst them, which should push prices even lower. GSK will be making financial sacrifices by licensing the ARVs to generic manufacturers at a royalty rate of only 5%, for both the public and private sector. GSK has also reduced Aspen Pharmacare's royalty by 25% and it will retain all the royalties at the same 5%."

In terms of the settlement agreement GSK has undertaken to:

- extend the voluntary licence granted to Aspen Pharmacare in October 2001 in respect of the public sector to include the private sector;
- grant up to three more voluntary licences on terms no less favourable than those granted to Aspen Pharmacare, based on reasonable criteria which include registration with the Medicines Control Council and the meeting of safety and efficacy obligations;
- permit the licensees to export the relevant antiretroviral drugs to sub-Saharan African countries;
- where the licensee does not have manufacturing capability in South Africa , GSK will permit the importation of the drugs for distribution in South Africa;
- permit licensees to combine the relevant ARV with other antiretroviral medicines; and
- charge royalties of no more than 5% of the net sales of the relevant ARVs.

* * *

Exhibit 20

Financial Mail (South Africa)
November 21, 2003, Page 18

Glaxo Battle Comes to SA

By Claire Bisseker

A two-year battle waged internationally by the California-based Aids Healthcare Foundation (AHF) against GlaxoSmithKline (GSK) has moved to SA soil. AHF is leading a class action suit against the drug giant on behalf of local people with Aids.

The action brings to a head a long-standing dispute between the two organisations, in which AHF has brought several legal petitions against GSK in the US. It has tried to have the patents on the drugs AZT and 3TC set aside, has petitioned the US Food & Drug Administration to withdraw approval for GSK's antiretroviral (ARV) drug Trizivir and has filed a false advertising suit against GSK.

None of these legal challenges has borne fruit, but in May AHF successfully lobbied major GSK shareholders in the US to vote down GSK CEO Jean-Pierre Garnier's US$ 36m pension package. It argued that the amount could provide ARVs to more than 100000 Ugandans for a year.

Last week AHF president Michael Weinstein announced in Durban that the non-profit organisation would seek civil damages against GSK on behalf of South Africans who could not afford ARVs because of GSK's anticompetitive pricing policies.

He says AHF will drop the class action if Glaxo establishes a R1bn fund to treat people with Aids. AHF treats more than 12000 people in its HIV clinics worldwide.

Its case is buoyed by the competition commission's finding earlier this month that GSK has abused its dominant market position by pricing its ARVs too high. Though only the competition tribunal can make a legal ruling, Weinstein says AHF is announcing its intention to launch a civil suit now so as to put pressure on GSK to settle the matter favourably out of court.

Last week, GSK hit back. In a statement, it accused AHF of launching legal challenges against it "in retaliation" for GSK's failure to meet its demands for big donations. Weinstein says that more than a year ago, GSK offered AHF $ 1m in response to a request for donations, but he turned down the amount as it was "ridiculously small" (given that GSK's sales of ARVs amount to $ 2bn/year) and because "it would have bought AHF's silence". Last month he asked GSK to donate $ 50m worth of ARVs for developing countries, but the company declined.

"I have no shame in asking GSK for money to help us help our patients," says Weinstein. "We get free drugs from Boehringer Ingelheim and Gilead but Glaxo, with its huge PR apparatus, has tried to slander us for looking for money."

GSK official Vicki Ehrich says "it is a tragedy that an organisation with almost no investment in SA should attempt to distract the attention of all concerned and divert valuable resources from the needs of those affected by HIV."