Pharmaceutical Companies, Intellectual Property, and the Global AIDS Epidemic

This case is provided at the end of chapter 3 of your text (Luthans and Doh). After reading the case, and performing research on the topic, answer the following questions: 1.) Do pharmaceutical companies have a responsibility to distribute drugs for free or at low cost in developing countries? What are the main arguments for and against such an approach? 2.) What are the principal arguments of pharmaceutical companies who oppose making exception to IPR laws for developing countries? What are the arguments by NGOs and others for a differential treatment? 3.) What impact would you expect South Africa's decision to levy duties on drug imports from Western nations to have on the international distribution of drugs to South Africa? 4.) In June 2002, the WTO extended the transition period during which least-developed countries (LDCs) had to provide patent protection for pharmaceuticals. In your opinion, do you think this is an appropriate change in policy, or a dangerous precedent? What could be some of the negative ramifications of this resolution? What about effects for other industries? 5.) Given the initiatives announced by global development and aid organizations and among pharmaceutical companies themselves, was it necessary to relax IPR rules in order to ensure that adequate supplies of AIDs medications would be available for distribution in the developing world? 6.) What role do MNCs have in providing funding or other assistance to international organizations such as the Global Fund?

Present your answers using APA-format:
Eight to ten pages, double-spaced, using 12-point Times New Roman font. Also, please be sure to cite all scholarly information paraphrased or quoted from your researched sources of information on the case topic. Finally, be sure to include a separate **Reference Page** on which you list all of your research information sources according to correct APA citation style, depending on the kind of source: book, chapter, published article, internet article, etc.

Submit this assignment to your instructor during the **FINAL WEEK** of the quarter via the Assignment Dropbox labeled **Research Paper**. This assignment is worth **275 points** and will be graded based on the Writing Intensive Rubric. Be sure that your paper shows **multiple revisions** with improved focus and clear writing for a general audience. Please remember to check your paper against the criteria in the **Writing Intensive Research Paper Rubric** before submitting it (see link above in this paragraph). Also, please let your Instructor know if you have any questions at all regarding producing or submitting this Research Paper assignment as the course progresses.

In-Depth Integrative Case 1.2

Pharmaceutical Companies, Intellectual Property, and the Global AIDS Epidemic

In August 2003, after heavy lobbying from nongovernmental organizations (NGOs) such as Doctors Without Borders, the U.S. pharmaceutical industry finally dropped its opposition to relaxation of the intellectual property rights (IPR) provisions under World Trade Organization (WTO) regulations to make generic, low-cost antiviral drugs available to developing countries like South Africa facing epidemics or other health emergencies.[1] Although this announcement appeared to end a three-year dispute between multinational pharmaceutical companies, governments, and NGOs over the most appropriate and effective response to viral pandemics in the developing world, the specific procedures for determining what constitutes a health emergency had yet to be worked out. Nonetheless, the day after the agreement was announced, the government of Brazil said it would publish a decree authorizing imports of generic versions of patented AIDS drugs that the country said it could no longer afford to buy from multinational pharmaceutical companies. Although the tentative WTO agreement would appear to allow such production under limited circumstances, former U.S. trade official Jon Huenemann remarked, "They're playing with fire. . . . The sensitivities of this are obvious and we're right on the edge here."[2]

Despite the role of developed and developing country governments, NGOs, large pharmaceutical companies, and their generic competitors in crafting this agreement, it was unclear how it would be implemented and whether action would be swift enough to stem the HIV/AIDS epidemic ravaging South Africa and many other countries.

The AIDS Epidemic and Potential Treatment

In 2008, after over two decades of fighting the AIDS epidemic and raising the public awareness, HIV/AIDS still remained one of the leading causes of death in the world, occupying the 6th position in WHO Top 10 Causes of Death list.[3] According to the World Health Organization (WHO), in 2008 there were approximately 33.4 million people living with AIDS, with 2.7 million newly infected, and 2 millions deaths (see Table 1). Since 1980, AIDS has killed more than 25 million people. HIV is especially deadly because it often remains dormant in an infected person for years without showing symptoms and is transmitted to others often without the knowledge of either person. HIV leads to AIDS when the virus attacks the immune system and cripples it, making the person vulnerable to diseases.[4]

Table 1 Regional HIV/AIDS Statistics, 2008

	Adults and Children Living with HIV/AIDS	Adults and Children Newly Infected with HIV	Adult Prevalence Rate [%]*	Adult and Child Deaths Due to AIDS
Sub-Saharan Africa	20.8–24.1 million	1.6–2.2 million	4.9–5.4	1.1–1.7 million
North Africa and Middle East	250,000–380,000	24,000–46,000	0.2–0.3	15,000–25,000
South and Southeast Asia	3.4–4.3 million	240,000–320,000	0.2–0.3	220,000–310,000
East Asia	700,000–1.0 million	58,000–88,000	<0.1	46,000–71,000
Latin America	1.8–2.2 million	150,000–200,000	0.5–0.6	66,000–89,000
Caribbean	220,000–260,000	16,000–24,000	0.9–1.1	9,300–14,000
Eastern Europe and Central Asia	1.4–1.7 million	100,000–130,000	0.6–0.8	72,000–110,000
Western & Central Europe	710,000–970,000	23,000–35,000	0.2–0.3	10,000–15,000
North America	1.2–1.6 million	36,000–61,000	0.5–0.7	9,100–55,000
Oceania	51,000–68,000	2,900–5,100	<0.3–0.4	1,100-3,100
TOTAL	33.4 million [31.1–35.8 million]	2.7 million [2.4–3 million]	0.8% [<0.8–0.8]	2 million [1.7–2.4 million]

*The proportion of adults [15 to 49 years of age] living with HIV/AIDS in 2008, using 2008 population numbers. The ranges around the estimates in this table define the boundaries within which the actual numbers lie, based on the best available information. These ranges are more precise than those of previous years, and work is under way to increase even further the precision of the estimates.

Source: World Health Organization, UNAIDS, December 2009.

Table 2 Prices (in $) of Daily Dosage of ARV, April 2000

Drug	U.S.A.	Côte d'Ivoire	Uganda	Brazil	Thailand
Zidovudine	10.12	2.43	4.34	1.08	1.74
Didanosine	7.25	3.48	5.26	2.04	2.73
Stavudine	9.07	4.10	6.19	0.56	0.84
Indinavir	14.93	9.07	12.79	10.32	NA
Saquinavir	6.5	4.82	7.37	6.24	NA
Efavirenz	13.13	6.41	NA	6.96	NA

Source: UNAIDS, *2000 Report on the Global HIV/AIDS Epidemic.*

The health of a nation's population is closely correlated with its economic wealth. Poor countries lack resources for health care generally, and for vaccination in particular. They are unable to provide sanitation and to buy drugs for those who cannot afford them. They also have lower levels of education, and therefore people are less aware of measures needed to prevent the spread of disease.[5] There is no cure or vaccine for AIDS. Therefore, public health experts place a high priority on prevention. However, only a small percentage of the funds targeted to prevent AIDS was deployed in developing countries.

Drugs help combat AIDS by prolonging the lives of those infected and by slowing the spread of the disease. These drugs significantly reduce deaths in developed countries. Treatment, however, is very expensive. As with most medicines, manufacturers hold patents for drugs, thereby limiting competition from generic products and allowing firms to price well above manufacturing costs in order to recoup R&D investment and make a fair profit.

In 2000–2001, a year's supply of a "cocktail" of antiretroviral (ARV) drugs used to fight AIDS cost between $10,000 and $12,000 in developed countries, putting it beyond the reach of those in most developing countries, where per capita income is a fraction of this cost (see Tables 2 and 3).[6] This discrepancy provokes strong reactions. Dr. James Orbinski, president of Doctors Without Borders (Médecins Sans Frontières), an international humanitarian nongovernmental organization (NGO) that won the 1999 Nobel Peace Prize, lamented, "The poor have no consumer power, so the market has failed them. I'm tired of the logic that says: 'He who can't pay dies.'"[7]

Table 3 Estimated Number of People in 2002 Who Needed "Triple Therapy" AIDS Treatment, Compared with the Number Who Received Treatment (in thousands)

	In Need of Treatment	Received Treatment
Latin America and the Caribbean	370	196
North Africa and Middle East	7	3
Eastern Europe and Central Asia	80	7
Asia Pacific	1,000	43
Sub-Saharan Africa	**4,100**	**50**

Source: UNAIDS, *2002 Report on the Global HIV/AIDS Epidemic.*

AIDS in Southern Africa

In sub-Saharan Africa, approximately 22.4 million people are living with AIDS. Of the 2 million AIDS deaths globally in 2003, approximately three-quarters or 1.6 million were in sub-Saharan Africa (see Table 1).[8] The disease took a heavy toll on women and children. In 2008, more than 1.8 million children were infected in the region and a disproportionate percentage of infected adults were women.

Most HIV transmission among southern Africans occurred through sexual activity rather than blood transfusion or use of infected needles. As a result of historic and economic factors, there are large numbers of single migrant male communities in southern Africa. These communities, many of whom served the mining industry, are at great risk of AIDS transmission, especially with easy access to alcohol and commercial sex workers (prostitutes).[9]

There is great stigma attached to AIDS in southern Africa. On International AIDS Day in 1998, Gugu Dlamini, a South African AIDS activist, declared on television that she was HIV-positive and was subsequently stoned to death for having shamed her community. Dr. Peter Piot, head of UNAIDS (the AIDS program of the United Nations), pointed out the tragic irony in the situation: Some of those who murdered Dlamini probably had AIDS but didn't know it—25 percent of her community was infected.[10]

In the nation of South Africa, one out of every nine residents has HIV/AIDS. The disease had slashed South African life expectancy from 66 years to below 50, a level not seen since the late 1950s. Large pharmaceutical companies and the U.S. government resisted calls to relax intellectual property laws that were thought to limit the provision of low-cost AIDS treatments. South African president Thabo Mbeki himself had been accused of engaging in "denial" as he had disputed established wisdom regarding the source of and treatment for AIDS.

Table 4 2003 Global Pharmaceutical Sales by Region

World Audited Market	2003 Sales ($bn)	% Global Sales ($)	% Growth (constant $)
North America	229.5	49%	111%
European Union	115.4	25	8
Rest of Europe	14.3	3	14
Japan	52.4	11	3
Asia, Africa, and Australasia	37.3	8	12
Latin America	17.4	4	6
Total	$466.3bn	100%	19%

Source: IMS World Review (2004).

Meanwhile, South Africans continued to die from the disease, and the South African economy also suffered direct and indirect costs from the disease's ravaging effects.[11]

The Global Pharmaceutical Industry, R&D, and Drug Pricing

Most of the global $466 billion of pharmaceutical sales in 2003 were in the developed countries of North America, Japan, and Western Europe (see Table 4). Leading pharmaceutical companies were large and profitable (see Table 5), although all of them have come under pressure from a range of factors—most notably, calls for lower health care costs in most major industrialized countries. Drug discovery is a long, expensive, and uncertain process. In recent years, the development of a new drug, starting with laboratory research and culminating in FDA approval, was estimated to take 10 to 15 years and cost around $800 million on average. Only 30 percent of drugs marketed were reported to earn revenues that matched average R&D costs.[12]

Like most for-profit firms, pharmaceutical companies pursue opportunities with high profit potential. A spokesman for Aventis, a French-German pharmaceutical company, said, "We can't deny that we try to focus on top markets—cardiovascular, metabolism, anti-infection, etc. But we're an industry in a competitive environment—we have a commitment to deliver performance for shareholders."[13] The industry tends to focus on diseases prevalent in its major markets. Drug patents enable companies to charge prices several times the variable manufacturing costs and generate hefty margins to help recover R&D costs and deliver profits. Drugs tend to be relatively price insensitive during the period of patent protection.

Table 5 2001 Financials for Selected Pharmaceutical Companies ($bn)

	Merck	Pfizer	GlaxoSmithKline
Country	U.S.	U.S.	U.K.
Revenue	47.7	32.3	29.7
COGS	29.0	5.0	6.9
SG&A	6.2	11.3	12.2
R&D	2.5	4.8	3.8
Net income	7.3	7.8	4.4

Source: Sushil Vachani, "South Africa and the AIDS Epidemic," *Vilkapala* 29, no. 1 (January–March 2004), p. 104; and company annual reports.

Prices vary considerably across markets, as illustrated by the price of fluconazole, an antifungal agent as well as a cure for cryptococcal meningitis, which attacked 9 percent of people with AIDS and killed them within a month. According to a study by Doctors Without Borders, in 2000, wholesale prices for fluconazole averaged $10 per pill and ranged from $3.60 in Thailand to $27 in Guatemala. Pfizer, which reportedly earned $1 billion annually on fluconazole, claimed the range was narrower ($6). Prices were considerably lower in countries that did not uphold foreign patents for pharmaceuticals. In India, Bangladesh, and Thailand it was sold by generic manufacturers for prices ranging from 30 to 70 cents.[14] (Some of the countries that didn't recognize patents for pharmaceuticals did have laws for patent protection of other products.)

The pharmaceutical industry was criticized for spending large sums on sales, marketing, and lobbying. Pfizer's spokesman, Brian McGlynn, countered, "Yes, we spend a lot of money on advertising and marketing. But we don't sell soda pop. It's an enormous transfer of knowledge from our lab scientists to doctors, through those sales reps."[15] Companies also spent heavily on lobbying governments on issues such as government-managed prescription drug plans for the elderly, which could create pressure to cap drug prices, and on strengthening and enforcing intellectual property protections.

WTO and Intellectual Property Rights[16]

Intellectual property rights (IPR) grant investors rights for original creations. The goal of IPR protection is to stimulate creativity and innovation, and to provide incentives and funding for R&D. Intellectual property rights, such as patents, prevent people from using inventors' creations without permission.

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which was agreed

Exhibit 1 Broad Areas Covered by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

1. Basic principles
   a. National treatment. Equal treatment of foreign and domestic nationals.
   b. Most-favored-nation treatment. Equal treatment of nationals of all WTO members.
   c. Technological progress. Intellectual property rights had to strike a balance between technological innovation and technology transfer. The objective was to enhance economic and social welfare by making both producers and users benefit.
2. How to provide adequate protection.
3. Enforcement.
4. Dispute settlement.
5. Special transitional arrangements. WTO agreements took effect January 1, 1995. Developed countries were given one year to bring their laws and practices in line with TRIPS. Developing countries were given five years and least developed countries 11 years.

Source: WTO, www.wto.org/english/tratop_e/trips_e/trips_e.htm.

to under the Uruguay Round of the GATT (1986–1994), attempted to bring conformity among different nations' protection of IPR. TRIPS covered five basic areas (see Exhibit 1). Patent protection extended a minimum of 20 years. Governments could deny patent protection on certain grounds (e.g., public order or morality) or for certain classes of inventions (e.g., surgical methods, plants, and so on). If the patent holder abused the rights granted by the patent (e.g., by refusing to supply the product to the market), the government could, under prescribed conditions, issue compulsory licenses that allowed competitors to produce the product.[17]

Also under TRIPS, a country that is in a state of medical emergency could resort to two actions: compulsory licensing, under which it could have generic products manufactured while paying a royalty to the patent holder, and parallel importing, which meant importing legally produced copies of a product that were cheaper in a foreign country than in the importing country. However, the WTO guidelines did not define a medical emergency. Developing countries' view of what constituted a medical emergency was substantially different from that held by drug companies and the U.S. government.

Despite being a country with 85,000 AIDS patients,[18] Brazil responded to international pressures and passed a law recognizing patents in 1996. This law specified that products commercialized anywhere before May 15, 1997, would forever remain unpatented in Brazil. The Brazilian government encouraged local companies to produce unlicensed copies of several AIDS drugs, which it bought from them to distribute to its patients free of charge in a policy of universal access. AIDS deaths were halved between 1996 and 1999. Between 1996 and 2000, local production, together with bulk imports, reduced annual treatment costs by 80 percent for double therapy (a cocktail of two AIDS drugs, both nucleosides) and by about 35 percent for triple therapies (two nucleosides and a protease inhibitor or non-nucleoside).[19]

For drugs that had valid patents in Brazil, the government attempted to negotiate lower prices. When negotiations between Merck and the Brazilian government over prices of the drug Stocrin initially stalled, the government threatened to license the drug compulsorily under the provisions of Brazilian law. When Merck learned a copy was being developed in a government lab, it threatened to file a lawsuit. The U.S. government filed a complaint with the WTO, but Brazil refused to budge.[20] President Fernando Cardoso defended the patent-breaking practice, suggesting that this approach was not one of commercial interest, but rather a moral issue that could not be solved by the market alone. The pharmaceutical industry association's position on intellectual property rights was summarized as follows:

> Strong intellectual property protection is the key to scientific, technological and economic progress. Such protection is the *sine qua non* of a vibrant and innovative pharmaceutical industry—and thus to patients—in the United States and around the world. Without such protection, far fewer drugs would be developed, fewer generic copies would be manufactured, and the flow of medicines to the public would be greatly slowed—to the detriment of patients, public health, and economic development throughout the world.[21]

Pharmaceutical companies were worried about more than losing contributions from sales of a drug faced with a knockoff in a specific country. They feared a domino effect—compulsory licensing spreading across developing countries and sharply hurting profits in multiple markets. Even more alarming was the prospect that prices in developed countries might sink either because of a gray market in generics or because of pressure to cap prices as information on the significant price differential between countries became widely available and developed-country consumers clamored for lower prices.

Drug Pricing in Developing Countries: Government, Industry, and NGO Perspectives[22]

Dr. Christopher Ouma, who cared for AIDS patients in a Kenyan public hospital, pointed out that half his patients couldn't pay the $2.60 daily bed charge. He usually didn't tell patients' families about the existence of drugs to treat AIDS. "This is where the doctor's role goes from care-giver

to undertaker," he added. "You talk to them about the cheapest method of burial. Telling them about the drugs is always kind of a cruel joke."[23]

Drug companies had been reluctant to provide AIDS drugs to developing countries at prices much lower than those charged in developed countries. They expressed concern that distributing drugs in unregulated and unreliable environments could risk creating new strains of drug-resistant HIV. In 1997, South Africa passed a law to permit compulsory licensing of essential drugs. Pharmaceutical companies, including Bristol-Myers Squibb and Merck, sued the South African government in an attempt to delay implementation of the law.

The Clinton administration lobbied the South African government to reverse its decision. U.S. Trade Representative Charlene Barshefsky placed South Africa on the "301 watch list," which puts a nation on notice that U.S. trade sanctions will be imposed if it doesn't change its policies.[24]

The *Washington Post* reported, "Critics have accused U.S. trade policy of placing the profits of drug companies above public health, moving to block poor countries from manufacturing the drugs themselves, despite international laws that permit countries to do so when facing a public health emergency."[25] The British newspaper *Guardian* referred to the U.S. government's actions as "trade terrorism" and called for efforts to "defend developing countries against U.S. aggression."[26] The World Bank official who oversaw the Bank's African health investments and its annual $800 million drug procurement said the drug-price structure "shows an increasing disconnect with the needs of the majority of the people in the world."[27]

As the U.S. government began to exert pressure on developing countries through the WTO and unilaterally, AIDS activists and NGOs, such as Doctors Without Borders, Act-Up, Health Action International, and the Consumer Project on Technology, swung into action. They targeted the public appearances of Vice President Al Gore during his presidential campaign. In September 1999, the administration backed off from the threats of placing trade sanctions against South Africa. The administration informed the South African government it would not object to issuance of compulsory licenses for essential drugs provided this was done within WTO guidelines.

In December 1999, President Bill Clinton told members of the WTO that the U.S. government would show "flexibility" and allow countries to obtain cheaper drugs during health emergencies on a case-by-case basis.[28] NGOs immediately called on the U.S. government to end trade pressure on poor countries in health care industry disputes.[29] Over the following year, the U.S. government declared it would not block compulsory licenses in the rest of sub-Saharan Africa and Thailand and elsewhere on a selected basis.

In the summer of 2000, at the 13th International AIDS Conference in Durban, South Africa, Boehringer Ingelheim, a German pharmaceutical company, offered to make its AIDS drug, Viramune, available for free. Bristol-Myers Squibb, Merck, and Glaxo Wellcome made similar offers. NGOs and developing governments, however, criticized the companies for making the announcements without consulting and working with the concerned governments, and for placing restrictions on distribution.[30] Jack Watters, Pfizer's medical director for Africa, defended the conditions of the company's pilot free-drug program in South Africa: "We want to evaluate how much impact the program has on survival." The company was also concerned about corruption and diversion of supplies. He added, "There's no guarantee that the drug will find its way to the people who need it most."[31] NGO activists continued to press the U.S. government, the WTO, and the pharmaceutical industry to make it easier for developing countries to produce or import generics. Some felt that if the pharmaceutical industry really wanted to make its products available it should drop its lawsuit against the South African government.[32]

In spring 2001, three U.S. pharmaceutical companies—Merck, Bristol-Myers Squibb, and Abbott—announced they would sell HIV drugs to developing countries at cost. GlaxoSmithKline offered 90 percent discounts.[33] Merck planned to use the United Nations Human Development Index and offer the lowest prices to countries that received "low" rankings or had an AIDS infection rate of 1 percent or higher. It offered Brazil, which didn't fall in that category, prices about 75 percent higher. Still, this was a steep discount compared to U.S. prices. Merck would sell efavirenz in Brazil for $920 per year per patient (compared to $4,700 in the United States) and Crixivan for $1,029 ($6,000 in the United States).[34] In October 2002, Merck announced further cuts in the price for Stocrin from the (already reduced) price of $1.37 per patient per day to $0.95 per patient per day in the poorest, hardest-hit countries. The price for middle-development countries with less than 1 percent HIV prevalence would be $2.10 per patient per day, down from $2.52.

On September 5, 2002, GlaxoSmithKline announced an additional price cut for antiretroviral drugs and malaria drugs for poor countries. The British company said it would cut the prices of its HIV/AIDS drugs by as much as 33 percent and the prices of its antimalarial drugs by as much as 38 percent in developing countries to help health workers fight two of the deadliest diseases that afflict the developing world. Under the new pricing plan, GlaxoSmithKline said it would supply its AIDS and antimalarial drugs at not-for-profit prices to the public sector, nongovernmental organizations, aid agencies, the United Nations, and the Global Fund to Fight AIDS, Tuberculosis and Malaria. To prevent cut-price drugs from being reimported into the West, Glaxo said it would seek regulatory

approval to provide special packaging for the cut-price drugs.

Indian generic manufacturers, such as Cipla, offered among the lowest prices in the world. Over the years Cipla had developed a range of pharmaceuticals. In 1985 the U.S. FDA approved Cipla's bulk drug manufacturing facilities. Cipla's net income in 2001–2002 was $48 million on sales of $292 million. Its major export markets were the Americas (41%), Europe (24%), and the Middle East and Africa (12% each). In late 2001 Cipla agreed to supply a three-drug antiretroviral combination to Nigeria for $350 per person per year.[35] The Nigerian government initiated a $4 million pilot program covering 10,000 adults and 5,000 children in which it planned to charge patients $120 per year and cover the remaining cost from government funds.[36]

In March 2002 the WHO released its first list of companies that are regarded as manufacturers of safe AIDS drugs. Of the 41 drugs listed, 26 were sold by multinationals and 10 by Cipla.

The Global Fund

In April 2001, while addressing an African summit in Nigeria, UN Secretary General, Kofi Annan, proposed creation of a global fund to combat AIDS. He stressed the need to ratchet up spending on fighting AIDS in developing countries from the current $1 billion level to $7–10 billion. He noted that pharmaceutical companies were beginning to accept that "generic medication can be produced where it can save lives." The previous week pharmaceutical companies had dropped their lawsuit against the South African government over patent laws.[37]

The proposal attracted significant support from world leaders. In May 2001, President George W. Bush announced $200 million in seed money for the fund. The following month, addressing delegates from 180 nations at a UN conference, U.S. Secretary of State Colin Powell declared, "No war on the face of the world is more destructive than the AIDS pandemic. I was a soldier. I know of no enemy in war more insidious or vicious than AIDS, an enemy that poses a clear and present danger to the world." He added, "We hope this seed money will generate billions more from donors all over the world, and more will come from the United States as we learn where our support can be most effective."

The Global Fund, set up as an independent corporation, was broadened to address not just AIDS but tuberculosis and malaria as well. By July 2003, more than $2 billion had been paid in by developed countries (see Table 6). In addition to leading country donors that included the United States, the EU, individual European countries, and Japan, the Gates Foundation contributed $100 million. In April 2002, the Global Fund made its first awards, totaling $616 million, to programs in 40 countries. Slightly more than half was designated for Africa. Experts predicted that the Fund's success hinged on how effective it proved to be as a "hard-nosed judge of its grantees' performance."

Table 6 Leading Donors (Paid to Date) to the Global Fund, July 2004

Country	$m
U.S.A.	623
EU	401
France	304
Japan	230
Italy	215
U.K.	173
Gates Foundation	100

Source: theglobalfundatm.org.

In October 2003, the Fund announced it would slow the pace of its awards to one round per year because it had fallen short of its fund-raising goals and was concerned about running out of money. The Fund announced it had received pledges through 2008 of about $5.2 billion, well short of its $8–$10 billion goal.[38] The decision came as the Fund announced $623 million in grants to 71 disease prevention and treatment programs in about 50 countries. This round of grants, the third, was substantially smaller than the $884 million awarded in January 2003.

By May of 2008 the Global Fund had distributed a total of US$5.67 billion. Around 58 percent of funding in November 2007 was spent on HIV and AIDS.[39] Since the inception of the Global Fund, 50 donor governments have pledged US$20.3 billion up to 2015 and paid in US$14.5 billion. In 2007 and 2008 those 16 member countries of OECD/DAC that are the largest supporters of the Global Fund contributed 96 percent of the contributions of the public donors. Some additional 20 donor governments collectively provided the remaining 4 percent of such resources for the two-year period.[40]

Other Funding Sources

A very large proportion of foreign funding for responses to the AIDS epidemic is provided by donor governments. The American government donates a substantial amount of money for the AIDS epidemic. In 2008 the United States was the largest donor in the world, accounting for more than half of disbursements by governments. It was followed by the United Kingdom, the Netherlands, France, Germany, Norway, and Sweden.[41]

In his State of the Union address in January 2003, President Bush announced the creation of PEPFAR, the President's Emergency Plan for AIDS Relief, a commitment to significantly increase U.S. spending on HIV/AIDS initiatives around the world. PEPFAR was a five-year program which was to direct US$15 billion to countries most in need. PEPFAR was renewed in July 2008 with

the intention of spending $48 billion from 2009 to 2013 on programs to tackle HIV and AIDS as well as tuberculosis and malaria. The U.K.'s Department for International Development (DFID), the world's second biggest bilateral donor for HIV/AIDS, spent about $850 million in 2005/06, and is also a major donor to the Global Fund, committing up to £1 billion of funds for the years leading up to 2015.[42]

The World Bank is the second largest multilateral donor to the HIV/AIDS response in developing countries besides the Global Fund and is one of eight co-sponsors of UNAIDS. By the end of 2006, it had dispersed US$879.22 million to 75 projects to prevent, treat, and reduce the impact of HIV and AIDS. There are also a very large number of private sector organizations involved in the response to AIDS, including corporate donors, individual philanthropists, religious groups, charities, and nongovernmental organizations (NGOs). These organizations vary in size, from small groups such as local churches, to large contributors such as the Bill and Melinda Gates Foundation and corporate donors. Overall, the private sector is by far the smallest of the four main sources of funding for the global AIDS response, accounting for around 4 percent of spending.[43]

Pressure Mounts

In June 2002, two weeks before the 14th International AIDS Conference in Barcelona, the WTO council responsible for intellectual property extended until 2016 the transition period during which least-developed countries (LDCs) did not have to provide patent protection for pharmaceuticals.[44] Previously they'd been expected to comply by 2006. (See Exhibit 2 for a list of least-developed countries.)

The delegates from the 194 countries left the July 2002 International AIDS Conference in Barcelona with cautious optimism. Joep Lange, president of the International AIDS Society, said, "If we can get Coca-Cola and cold beer to every remote corner of Africa, it should not be impossible to do the same with drugs." However the conference wasn't without protests. Activists tore down the European Union exhibition stand, demanding larger contributions to the Global Fund. The World Health Organization estimated that given the public health infrastructure in developing countries, the maximum that could be spent productively each year by 2005 was about $9 billion. This assumed $4.8 billion for prevention and $4.2 billion for treatment. It also estimated that with a commitment of $4.8 billion per year to prevention, 29 million infections could probably be avoided by 2010.

Several challenges remained. Drug prices had fallen significantly, but not low enough for everyone. While the large pharmaceutical companies were selling antiretroviral combinations for about $1,200 per person per year in some developing countries, the lowest generic prices out of India were $209. Health economists estimated that prices needed to fall as low as $30–$40 per person per year for drugs to reach the poorest recipients. Such low prices were unlikely to materialize anytime soon. NGOs, such as Doctors Without Borders, were expected to push for optimizing use of scarce funds by deploying Global Fund allocations for purchase of generics only. Tough decisions needed to be made about the allocation of resources between AIDS and other diseases, and between prevention and treatment of AIDS.

In early August 2003, the South African government reversed its policy on AIDS, signed the Global Fund, and announced production of its first generic AIDS drug. Aspen Pharmacare, a South African firm, announced it would be the initial provider of generic treatments. Backed by many activist groups, including the influential Treatment Action Campaign, revisions to the $41 million deal detailed an operational plan to make the drugs available by the end of September 2003. South African president Thabo Mbeki finally agreed to the long-standing proposal after a recent World Bank report predicted "a complete economic collapse" within four generations if the government didn't act swiftly.

The 2003 WTO Agreement and Its Aftermath

In August 2003, the United States and other WTO members announced that they had finalized a solution to streamline the supply of disease-fighting medications to poor countries. As part of the compromise deal, the United States agreed to language that would allow compulsory licensing only for "genuine health reasons" and not for commercial advantage. This appeared to prompt action.

On December 10, 2003, Britain's GlaxoSmithKline and Germany's Boehringer Ingelheim agreed to expand the licensing of their patented AIDS drugs to three generic manufacturers in South Africa and other African countries as part of an out-of-court settlement with South Africa's

Exhibit 2 Countries Classified as Least-Developed by WTO

Angola	Djibouti	Maldives	Sierra Leone
Bangladesh	Gambia	Mali	Solomon Islands
Benin	Guinea	Mauritania	Tanzania
Burkina Faso	Guinea Bissau	Mozambique	Togo
Burundi	Haiti	Myanmar	Uganda
Central African Republic	Lesotho	Niger	Zambia
Chad	Madagascar	Rwanda	
Congo	Malawi	Senegal	

Treatment Action Campaign. In return, the South African Competition Commission, a government body that monitors free-market practices, agreed to drop a yearlong probe into whether the companies had overcharged for their AIDS drugs. Glaxo and Boehringer Ingelheim already had existing agreements with a fourth generic manufacturer, South Africa's Aspen Pharmacare. Under the settlement pact in South Africa, Glaxo also agreed to cap royalty fees at no more than 5 percent of net sales and to extend the generic licenses to the private and public sectors. It said it would allow the generic licensees to export AIDS drugs manufactured in South Africa to 47 sub-Saharan African countries. The Competition Commission said it had not asked for a fine or administrative penalty against Glaxo, which is the world's largest maker of AIDS medicines.[45]

Shareholder activists have also begun to put pressure on companies to provide more comprehensive reporting about their potential to support efforts to fight AIDS. In March 2004, a consortium of religious investors forwarded shareholder resolutions at four top drug makers, asking the companies to assess how much charity work they are doing for HIV and AIDS in developing countries and to estimate how much the epidemic could affect their businesses. The Interfaith Center on Corporate Responsibility (ICCR) and roughly 30 religious groups requested that pharmaceutical companies offer shareholders a report of their conclusions six months after the annual meetings. Although the boards of directors at Pfizer, Merck, and Abbott said they opposed the measure, Coca-Cola's board said it supported a similar shareholder proposal to assess the business risks associated with the HIV/AIDS epidemic.[46]

2005: Making the WTO Agreement Official and Its Aftermath

At the end of 2005, members of the WTO approved changes to the intellectual property agreement making permanent the August 2003 "waiver" which facilitated access for developing countries to cheaper, generic versions of patented medications.[47] Director-General Pascal Lamy said, "This is of particular personal satisfaction to me, since I have been involved for years in working to ensure that the TRIPS Agreement is part of the solution to the question of ensuring the poor have access to medicines."[48]

According to Doctors Without Borders, prices of first-line treatments have dropped from more than $10,000 to as little as $150 a year since 2000 largely due to competition from generics.[49] Brazil and Thailand have been able to launch successful national AIDS programs because key pharmaceuticals were not patent protected and could be locally produced for very low costs. Still, the method of implementation at the national or regional trade level of TRIPS can cause problems.[50]

In early 2006, Bristol-Myers Squibb (BMY) announced an agreement for technology transfer and voluntary license with generic manufacturers Aspen Pharmacare and Emcure Pharmaceuticals for atazanavir, first approved for combination therapy in the United States in June 2003. Peter R. Dolan, Bristol-Myers Squibb's CEO, highlighted his company's commitment to the global fight against AIDS: Under the deal, the generic company will set prices in Africa and India.

Generic drug manufacturers have lowered the costs of some much-needed drugs to developing countries, but often new drugs were still priced much higher than old treatments, and are hence unavailable in many of the countries with the most need. Doctors Without Borders spoke out in March 2006 against what it calls the standard practice of drug companies marketing less adapted drugs to African, Asian, and Latin American countries, while reserving new and improved drugs for more wealthy countries.[51] The NGO specifically criticized Abbot Laboratories' lopinavir/ritonavir, which was only available in the United States at a cost of US$9,687 per patient per year. Doctors Without Borders worker Dr. Helen Bygrave commented, "It's a cruel irony that although this drug—with no need for refrigeration—seems to have been designed for places like Nigeria, it is not available here."[52]

In December 2005, the WHO released a statement urging countries to adopt a policy of free access at the point of service delivery to HIV care and treatment, including antiretroviral therapy.[53] This recommendation came in the wake of a 2005 endorsement by G8 leaders and UN member states to provide universal access to HIV treatment and care by 2010. After a similar effort, the "3 by 5" program, which aimed to provide treatment for 3 million patients in 50 developing countries by the conclusion of 2005, it had become apparent that charging users at the point of service undermines efforts to provide universal care.

The number of people receiving antiretroviral aid has increased under the 3 by 5 program, but not to desired levels. More than 1 million people in developing countries received antiretroviral treatment in 2005, and expanded treatment helped to prevent 250,000–350,000 deaths.[54]

Pressure Mounts Again

The increasing severity of the AIDS epidemic, compounded by the constant lack of access to drugs, has recently prompted more drastic action among some developing countries. In January 2007 Thailand, a nation with nearly half a million residents infected with HIV, announced its intentions to break the patent on an important AIDS drug (Kaletra) produced by Abbott Laboratories,[55] setting a precedent for other nations such as Brazil, Indonesia, and the Philippines. Abbott retaliated by revoking the introduction of seven new drugs in Thailand.

Doctors Without Borders called Abbott's reaction "callous," and Abbott has since backed down.

The UN and World Bank have openly supported Thailand's landmark patent-breaking decision as part of its serious treatment of AIDS within its new health program.[56] The global impact of Thailand's decision is likely to be magnified by subsequent policy changes by other countries; for instance, Brazil renounced the patent on a Merck AIDS drug in May 2007 (after years of threatening to do so).[57] Although the U.S.-Brazil Business Council warns that this IPR violation might deter future business investment from Brazil, the government still went through with the decision, likely prompted by Thailand's precedent as well as Merck's inability to offer what Brazil viewed as a satisfactory discount on patented drug purchases.[58]

The increased global effort to fight HIV/AIDS has been supported by other organizations. Among others, the Clinton Foundation has recently stepped up its work with drug companies to lower prices of AIDS medications. In October 2003, former president Bill Clinton first announced a landmark program to attack two of the toughest obstacles to treating AIDS in the developing world: high drug prices and low-quality health infrastructures. The Clinton Foundation HIV/AIDS Initiative reached a deal with four generic-drug companies, including one in South Africa, to slash the price of antiretroviral AIDS medicine. In April 2004, Clinton's foundation announced that these special drug prices were being extended from the initial 16 countries in the Caribbean and Africa to any country supported by UNICEF, the World Bank, and the UN-administered Global Fund to Fight AIDS, Tuberculosis, and Malaria. "With these agreements, we are one step closer to making sure future generations can live without the scourge of AIDS," Clinton said in a statement released by his U.S.-based foundation.

In May 2007 the Foundation struck a deal with Cipla and Matrix Laboratories to lower prices on "second-line" AIDS drugs.[59] The Clinton Foundation, which is financed by Unitaid (an organization of 20 nations that donate a portion of airline tax revenues for HIV/AIDS programs in developing countries), provides access to lower-priced AIDS drugs for approximately 65,000 people in 65 countries worldwide.[60]

Under the Clinton Foundation agreement, five generic-drug manufacturers—Pharmacare Holdings of South Africa and the Indian companies Cipla, Hetero Drugs, Ranbaxy Laboratories, and Matrix Laboratories—provide basic HIV treatment for as little as $140 per person per year, one-third to one-half of the lowest price available elsewhere. Diagnostic tests are supplied by five different companies and include machines, training, chemicals, and maintenance at a price that is up to 80 percent cheaper than the normal market price. "This new partnership works to break down some of the barriers—such as price, supply and demand—that are impeding access to lifesaving AIDS medicines and diagnostics in developing countries," said UNICEF Executive Director Carol Bellamy.[61]

AIDS Medicine Development

As reported by Pharmaceutical Research and Manufacturers of America (PhRMA) at the end of 2008, U.S. pharmaceutical research companies were testing 109 medicines and vaccines to treat or prevent HIV/AIDS and related conditions.[62] This showed a substantial effort by the pharmaceutical community to combat the disease, although only 31 medicines to treat HIV/AIDS have been approved so far since the virus that causes AIDS was first identified more than 20 years ago.[63] As noted in PhRMA 2008 Report, an effective HIV vaccine could prevent almost 30 million of the 150 million new infections projected in the coming decades. A highly effective vaccine could prevent more than 70 million infections in 15 years. In 2008, 29 vaccines were in development. In addition to the vaccines, there were 57 antivirals, 4 cancer treatments, 6 immunomodulators, 2 gene therapies, and 12 other medicines in human clinical trials or before the Food and Drug Administration awaiting approval.[64]

Opportunistic infections are a particular problem for patients infected with the HIV virus. Opportunistic infections include candidiasis of the mouth (thrush), the most common opportunistic infection in people with HIV; *Mycobacterium avium* complex (MAC), a bacterial infection that up to 50 percent of people with AIDS may develop; and *Pneumocystis carinii* pneumonia (PCP), the most common AIDS-defining infection in the United States. Examples of HIV medicines and vaccines in the pipeline for HIV-related opportunistic infections include antisense gene therapy that uses two novel technologies to boost immune responsiveness against HIV; and a vaccine that is designed to protect against the three most common types of HIV-1 virus found around the world.[65]

From 2000 to 2007, pharmaceutical research companies contributed more than $9.2 billion to improve health care in the developing world, according to the International Federation of Pharmaceutical Manufacturers & Associations.[66] Despite that progress, AIDS remains a devastating and growing worldwide health problem in developing countries, particularly in sub-Saharan Africa, China, India, and the Russian Federation.

Pharmaceutical Companies and UN Joint Efforts to Combat AIDS

United Nations Secretary-General Ban Ki-moon and other UN officials met in September 2008 with senior executives from 17 companies, including Abbott, Boehringer Ingelheim, Glaxo, Pfizer, Roche, Merck,

Becton-Dickinson, Johnson & Johnson, Gilead Sciences, and Ranbaxy, among others. Companies agreed to invest further in research and development of new HIV-related medicines adapted to resource-limited settings. All participants agreed that increasing access to vaccines, diagnostics, and medicines is essential in scaling up prevention and treatment efforts.[67]

Some progress was noted by UN officials in 2008: As many as 3 million people were on treatment by the end of 2007, up from 1.3 million in 2006. There have been significant price reductions for first-line and pediatric antiretroviral drugs, and some second-line products. Two new classes of drugs have been introduced and new heat-stable formulations and fixed-dose combinations have been developed. There has also been further investment and development of technologies for prevention and diagnosis of HIV and for monitoring the efficacy of antiretroviral therapy in adults and children.[68]

The parties agreed to continuing to hold periodic high-level meetings, under the leadership of UNAIDS, to take stock of progress and to identify new collaborative measures.[69]

Recent Initiatives

In April of 2009 two pharmaceutical rivals, GlaxoSmithKline and Pfizer announced that they intend to create a new company, headquartered in London, to manage their HIV operations with initial working capital of £250m. The lion's share of the business will be owned by GSK, which will take 85 percent to reflect its portfolio of big-selling HIV drugs such as Combivir and Kivexa. The other 15 percent will go to Pfizer, which will contribute potentially promising new treatments. The new company will have 11 drugs on the market and a further six in clinical development. It will have a market share of 19 percent and annual sales of £1.6bn.[70]

GSK's chief executive, Andrew Witty, said the "clear focus" of the joint venture would be in delivering new drugs to build on what he described as the drug industry's remarkable success in tackling HIV over the last two decades. Witty recalled that as recently as 1990, it was extremely difficult to conduct clinical trials in HIV because patients rarely lived long enough to complete studies. He said: "I think it's one of the finest performances of the pharmaceuticals industry to have transformed an incredibly frightening infectious disease into something more manageable."[71]

Speaking in Kenya in July of 2009, Andrew Witty, GSK's chief executive, said the treatment of the conditions in children remains a "significant unmet medical need." Therefore, GSK will create a new Positive Action for Children Fund that will have access to £50m over the next 10 years, and has also granted Aspen Pharmacare, in which it acquired a 16 percent stake in May, a royalty-free license to develop a cheaper, generic version of its HIV treatment abacavir. The company could make more drugs "appropriate for use in an African setting" available for a license, added Mr. Witty. GSK's new fund is designed to work alongside health organizations and pregnant mothers to prevent mother-to-child transmission of HIV in the developing world, especially sub-Saharan Africa. The company will also make £10m available to support a new public-private partnership which will research and develop new drugs.[72]

In September 2009 a group of AIDS treatment activists after a yearlong study of the actions of nine major pharmaceutical companies to address the contagion in the United States, issued a report with the grades for the pharma efforts to fight HIV/AIDS. The report card graded the drug makers overall with a below-average C-minus and recommended improvements. The report gave its highest grade, a B, to Merck, for producing Isentress, the first of a new class of AIDS drugs called integrase inhibitors. It also praised Merck for freezing prices for lower income users. Isentress, approved in 2007, is already used by 11 percent of the more than 550,000 people treated in the United States. The group gave an F to Abbott for raising the wholesale price of Norvir, the first drug proved to increase survival in AIDS patients, by 400 percent in 2003. Norvir is a key ingredient in most AIDS treatment cocktails. The price increase provoked an outcry by many patients and others.[73]

Questions for Review

1. Do pharmaceutical companies have a responsibility to distribute drugs for free or at low cost in developing countries? What are the main arguments for and against such an approach? What are the advantages and disadvantages of giving drugs for free versus offering them at low no-profit prices?
2. What are the principal arguments of pharmaceutical companies that oppose making exceptions to IPR laws for developing countries? What are the arguments by NGOs and others for relaxing IPR laws?
3. What impact would you expect South Africa's decision to levy duties on drug imports from Western nations to have on the international distribution of drugs to South Africa?
4. In June 2002, the WTO extended the transition period during which least-developed countries (LDCs) had to provide patent protection for pharmaceuticals. In your opinion, was this an appropriate change in policy or a dangerous precedent? What could be some of the negative ramifications of this resolution? What about the effects for other industries?

5. Given the initiatives announced by global development and aid organizations and among pharmaceutical companies themselves, was it necessary to relax IPR rules in order to ensure that adequate supplies of AIDS medications would be available for distribution in the developing world?
6. What role do MNCs have in providing funding or other assistance to international organizations such as the Global Fund, UN, and WHO?

Exercise

Although the WTO has now agreed to relax intellectual property rules in order to facilitate the production and distribution of inexpensive generic antivirals, the conditions under which this provision allows for production or importation of generics ("genuine health reasons") are not entirely clear. The WTO is to hold a hearing for interested parties to provide input about how these rules should be implemented. Your group represents the interests of one of the key stakeholders (see table) and will be responsible for arguing that stakeholder's position.

Team	Stakeholder
1	The WTO
2	Doctors Without Borders (NGO)
3	CIPLA (Indian generic manufacturer)
4	GlaxoSmithKline (representing pharma companies)
5	Government of Brazil (representing developing countries)
6	The Clinton Foundation HIV/AIDS Initiatives

Discuss with your group the major points to make to advance your perspectives. Come prepared to make a five-minute presentation summarizing how you would like the WTO to implement the new rules. The WTO group should ask questions during the hearing. It should then take 10 minutes to deliberate and come up with a proposed plan incorporating the interests of all of the stakeholders.

Source: © McGraw-Hill Irwin. This case was prepared by Jonathan Doh and Erik Holt of Villanova University with research assistance by Courtney Asher and Tetyana Azarova as the basis for class discussion. It is not intended to illustrate either effective or ineffective managerial capability or administrative responsibility. The authors thank Sushil Vachani for comments, suggestions, and input.