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ROBERT E. KENNEDY

The Pharmaceutical Industry and the AIDS Crisis in Developing Countries

This case contains excerpts from recent articles on the AIDS crisis in Africa.

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Patents Pending: AIDS Epidemic Traps Drug Firms in a Vise: Treatment vs. Profits --- Suit in South Africa Seeks To Block Generic Copies; U.S. Reverses Its Policy --- Activists Warn Mr. Papovich

The Wall Street Journal, March 2, 2001, by Helene Cooper, Rachel Zimmerman and Laurie McGinley

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Can the pharmaceuticals industry inflict any more damage upon its ailing public image? Well, how about suing Nelson Mandela?

That's how scores of international AIDS activists are portraying a lawsuit by 40 drug makers that will be heard beginning Monday in a Pretoria courthouse. The suit seeks to overturn a law that Mr. Mandela signed when he was president of South Africa. Under the law, South Africa can import cheap, generic versions of patented medicines -- including powerful new drugs for treating AIDS -- without permission from the patent owner.

As the case heads for court, many drug-company executives privately say they wish the lawsuit -- and the Scrooge-like picture it paints of their industry -- would disappear. But publicly the companies say they're going forward because the South African law strikes at the heart of their most precious commodity: patents.

"It's never good to be embroiled in a suit with your customers," says Harvey Bale, director general of the International Federation of Pharmaceutical Manufacturers Association, a Geneva-based trade group. But despite the bad press, he says, the industry must protect its patents, which he calls "the foundation of research and development."

The pharmaceuticals industry is locked in a tightening international public-policy vise. On one hand, drug companies want desperately to be seen as helping fight the global AIDS crisis. Witness the unprecedented offer last year by several companies to cut prices of many AIDS drugs in Africa. But the companies also remain unwavering in their defense of patents, even if it means suing poor nations that want to make or buy bootleg generics because they can't afford brand-name drugs.

The stakes for the industry are far higher than the market for AIDS drugs in Africa. Their fear: If the South African law is allowed to stand, other countries will be emboldened to pursue similar legislation. "It is quite likely to be a slippery slope," says Mark Groombridge, a research fellow at the Cato Institute, a

Professor Robert E. Kennedy prepared this case. HBS cases are developed solely as the basis for class discussion. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

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conservative think tank. "If the question is AIDS today, why not heart disease and cancer drugs tomorrow?"

Moreover, the U.S. companies fear that if poor countries are allowed to buy low-priced drugs, American consumers will demand the same. Indeed, many of the activists and lawmakers who support cheap generic drugs overseas are also lobbying to drive down prices in the U.S. -- just as insurers and employers are mounting their own crusade to cut skyrocketing drug prices. Drug makers currently derive the lion's share of their annual profits from the $126 billion U.S. market, where they have the greatest freedom to price drugs at a premium.

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The South Africa law, which was passed in December 1997, authorizes two controversial practices. One, called *parallel importing* -- a form of "gray market" retailing -- allows importers to buy drugs from the cheapest sources available, regardless of whether the patent holders give their approval. The other practice, called *compulsory licensing*, permits the South African government to license local companies to produce cheaper versions of drugs whose patents are held by foreign companies.

For the industry, these provisions were tantamount to a direct assault on their livelihood. In February 1998, the consortium of 40 drug companies, led by a South African pharmaceuticals trade group, filed suit. Its key legal claim was that the statute, the Medicines and Related Substances Act of 1997, is unconstitutional because it gives sweeping power to South Africa's health minister to ignore the country's patent laws. . . .

In general, industry officials say that treating AIDS -- as well as malaria, tuberculosis, malnutrition and other medical woes prevalent among the world's poor -- is a global problem that can't be solved just by attacking pharmaceuticals prices and profits. Drug-company executives claim that their enormous business simply presents an easy target for activists, for whom marshalling a world-wide crusade against poverty and disease would be a much tougher task.

"There are issues associated with infrastructure, with providing proper care and treatment, distribution systems have to be in place -- all these things are needed to ensure access to medicines," says Greg Reaves, a spokesman for Merck & Co., Whitehouse Station, N.J., one of the companies in the lawsuit.

For its part, the South African government says it will vigorously defend the Medicines Act -- which hasn't been implemented because of the lawsuit. Joanne Collinge, a spokeswoman for South Africa's Ministry of Health, says the statute reflects the government's position that equal access to health care is a constitutionally protected right. "We have a constitution that says there will be accessible health care, and that means affordable medicines," she says. "The problems in getting universal access are so deep we need major structural intervention."

Several weeks after the South African law was passed, in early 1998, members of a U.S. drug-industry lobbying group trooped across town to ask the trade office to take action against South Africa. According to an official in the trade office, the industry group framed the matter simply as a fight over intellectual-property rights, and didn't even mention how it might affect the treatment of AIDS. . . .

To pressure South Africa to amend its law, the U.S. in 1998 denied Pretoria's request for additional benefits under the Generalized System of Preferences, a trade scheme that allows poor countries to export products to the U.S. at reduced duties. Then, a year later, Rep. Rodney Frelinghuysen, a New Jersey Republican, speaking on behalf of drug companies with operations in his state, attached an amendment to South African aid legislation, holding up payments for a few months until the U.S. demonstrated it was pressuring South Africa on the Medicines Act.

In April 1999, the U.S. trade office also cranked up the heat. In its annual Watch List, published that month, it cited South Africa for the Medicines Act, which the U.S. said could potentially "abrogate patent rights." The list doesn't necessarily lead to U.S. trade sanctions, but it does send a warning signal to international investors. . . .

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Meanwhile, back in Washington, activists met with Mr. Papovich and other U.S. trade officials at an office building near the White House. Says Eric Sawyer, a founder of the AIDS activist groups Act Up New York and the Health Gap Coalition: "We were slamming on the table, accusing them of genocide." The trade officials' response, Mr. Sawyer says, "was to look as though they had been slapped across the face." The activists warned Mr. Papovich that more disruption was to come.

They made good on their threats, pestering Mr. Gore at campaign stops across the country. Finally, in July, Mr. Gore announced that the White House was reversing its policy. Essentially, the trade office adopted a sort of "Don't ask, don't tell" stance, under which the U.S. agreed to look the other way if South Africa began to make or import generic AIDS drugs. . . .

Two months later, Mr. Papovich was on hand to witness another demonstration. A dozen activists managed to enter the trade office after one of them tricked security guards by pretending to sprain an ankle. Mr. Papovich, on his way to deliver a speech on Capitol Hill, passed the activists on the stairs. From his taxi, he watched, horrified, as the activists unfurled a huge banner from a second-floor window, reading: "Essential Drugs for All Nations."

By then, a cosmic change was under way inside the trade office. Public health and the AIDS crisis were starting to dominate discussions on how to protect intellectual property. The arguments presented by the drug industry started receiving an increasingly skeptical audience among trade officials. . . .

A few months later, during the disastrous December 1999 meeting of the WTO in Seattle, the U.S. trade office issued a statement. The new South Africa policy, it said, would be extended to all poor countries.

Drug companies were dismayed, but not surprised. By then it was clear that the activists' power was surging, while their own influence appeared to be waning. They bided their time. When President Bush took office, some drug companies hoped their campaign efforts on behalf of the new president would lead to a reversal of Mr. Papovich's new stance. They didn't overtly lobby, however, knowing the potential for public-relations damage. Last week, the trade office issued a statement saying it is "not considering a change in the present flexible policy." Administration officials privately say this was an easy decision to make, and it isn't likely to be reversed.

"The HIV/AIDS crisis is a terrible tragedy for countries, families and individuals," said the statement, which was written by Mr. Papovich and approved by the Bush administration. "Consistent with our overall effort to protect America's investment in intellectual property, [the Bush administration will] work with countries that develop serious programs to prevent and treat this horrible disease."

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Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa

New York Times, February 6, 2001, By DONALD G. McNEIL Jr.

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In a move that could force big drug multinationals to cut the prices of their AIDS drugs in poor countries, an Indian company offered today to supply triple-therapy drug "cocktails" for $350 a year per patient to a doctors' group working in Africa.

The Indian company, Cipla Ltd. of Bombay, a major manufacturer of generic drugs, made the offer to Doctors Without Borders, which won the Nobel Peace Prize in 1999 for its work in war-torn and impoverished areas. In Africa the group sets up small pilot programs to develop models for broader approaches to combat AIDS, and would distribute the Cipla drugs free.

As part of its program, Cipla would also sell the drugs to larger government programs for $600 a year per patient, about $400 below the price offered by the companies that hold the patents. "This is the way to break the stranglehold of the multinationals," said Dr. Yusuf K. Hamied, chairman of Cipla, who will meet with the doctors' group on Feb. 15 to discuss strategy. . . .

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The normal cost of the AIDS cocktail in the West is $10,000 to $15,000 a year. Last May five multinationals, backed by the World Health Organization and other United Nations agencies, offered to sell their components to poor nations at sharply reduced prices [about $1,000 per patient per year].

But Cipla and other makers of generic drugs in Brazil, Thailand and other countries have not been part of the talks with W.H.O., a situation that Cipla hopes to change. . . .

Cipla is offering to sell the agency as many doses as it is wants at $350 a year. Dr. Hamied said that his company would lose money at that price, but that he would supply "10,000 doses or 20,000 or 30,000, however many they want." The $600 price to governments is near Cipla's break-even point, he said, but costs could drop with greater production. If that happens, he would cut prices further.

In India he sells the same cocktail for about $1,100 a year. But he denied that he was trying to grab market share in Africa. "What do I want with market share?" he asked. "I don't have a monopoly, and the only way to make real money in drugs is with a monopoly. In this disaster, there is room for everybody."

Wide distribution of the drugs in Africa is not without critics, given the attendant need for careful monitoring. Some experts argue that it would be better to spend the money on providing clean water, controlling malaria and increasing the use of condoms. But Doctors Without Borders says that the dangers and side effects of the drugs pale beside the immensity of the epidemic itself, and that Western testing standards are overcautious.

The typical AIDS cocktail is a combination of any three of about nine protease inhibitors or reverse transcriptase inhibitors. The chemicals suppress the human immunodeficiency virus but, as with any chemical therapy, they are toxic and can damage the liver. In the West, doctors carefully monitor the levels of the drug in the blood, test for organ damage and check the levels of the virus in the bloodstream. If the virus mutates to resist the therapy, the combinations are changed. Careful monitoring may not be possible in many African settings. But with 25 million Africans infected with the AIDS virus, Doctors Without Borders and other agencies argue, imperfect treatment is better than none.

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DEAL ON AIDS DRUGS FUELS PUSH FOR MORE FUNDS INDIAN FIRM AGREES TO PROVIDE TREATMENT CHEAPLY TO CHARITY

The Boston Globe, February 8, 2001, by John Donnelly

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WASHINGTON - An Indian pharmaceutical company's dramatic cut in the price of an AIDS drug cocktail to $350 annually per patient has stunned the pharmaceutical industry and raised questions about whether wealthy governments would now put much more funding into halting the pandemic. . . .

"This announcement must have really shocked people," said Jamie Love, director of the Washington-based Consumer Project on Technology, who helped negotiate the Cipla deal. "It certainly must have shocked those people paying $15,000 for that cocktail." But while AIDS activists hailed Cipla's decision, Doctors Without Borders' programs will first reach only a few thousand patients in Africa, a continent with 24 million HIV-infected people.

Now that the price has dropped significantly, both activists and pharmaceutical representatives yesterday said that rich governments should take the opportunity to exponentially increase funding to fight the most devastating epidemic since the bubonic plague in the 14th century.

"The United Nations and wealthy governments now need to step up to the plate," said Daniel Berman, who coordinates Doctors Without Borders' campaign for medicines. Some pharmaceutical officials are also calling on African governments to boost funding, but fragile economic conditions there present problems.

"How can the developing countries begin to take responsibility for themselves to purchase something they can't afford?" said Amir Attaran, director for international health research at the Center for

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International Development at Harvard University. "This verges on a let-them-eat-cake mentality, where we're now saying, 'The drugs are cheap, let them have these cheap drugs.' It isn't feasible even at $350 per year, which is more than the GDP per capita of many countries." "Rich countries," Attaran said, "are completely AWOL." . . . .

Mark E. Grayson, a spokesman at Pharmaceutical Research & Manufacturers of America. . . said the question of intellectual property rights vs. competition between drug makers and companies that produce generic knock-offs is only part of the picture.

"A lot of things have to be done. Offering drugs is just one part of the pie," he said. "Governments themselves need to contribute. In 1999, South Africa had a $16 million budget to buy drugs and they didn't spent a third of it, and yet they spent $4 billion on fighter planes. Zimbabwe is spending $1 million a day on troops in the Congo and nothing on AIDS treatment."

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Offer to Sell AIDS Drugs at a Discount In Africa Is Met With Caution, Uncertainty

The Wall Street Journal, February 23, 2001,

by Alix Freedman and Rachel Zimmermanin New York, and Danny Pearl in Bombay, India

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An offer to sell AIDS drugs at an extreme discount in Africa has yet to find a major buyer, largely because international relief agencies are still wrestling over how to provide the life-saving medicines on a vast scale.

Two weeks ago, Cipla Ltd. of Bombay, India, jolted the drug industry and the public-health community with its surprise offer to sell a combination of three AIDS drugs at the much-reduced price of $600 per patient per year to governments that want to buy the therapy. Cipla said it would lower the annual price even more -- to $350 a patient -- to Doctors Without Borders. . . .

But Cipla has yet to receive any orders. "We thought, in our naivete, we'd have people calling us and saying `fantastic,' " says Amar Lulla, Cipla's joint managing director. "It was stupid naivete."

Indeed, as the initial euphoria over the offer has died down, the potential buyers of Cipla's drugs say they are deeply frustrated by the complexity of buying and distributing the medicines where they are desperately needed.

For instance, there is uncertainty over the role Doctors Without Borders will play. In an interview this week, Bernard Pecoul, a top official at the group, stressed that it has no intention of becoming a global distributor of AIDS drugs; it plans to place a limited order with Cipla (as well as with other drug firms) for its pilot programs involving no more than 6,000 AIDS patients in 20 countries.

"It is not at all part of our mandate to cover the world and be in charge of distributing AIDS drugs -- that's much more the mandate of U.N. agencies," said Dr. Pecoul, who directs the group's campaign to increase access to essential medicines, such as lower-cost antibiotics. . . .

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Fighting AIDS in Africa

The New York Times, February 25, 2001,

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The recent announcement by the Indian drug company Cipla that it would sell AIDS therapy for $600 a year or less to African countries is a step toward commuting the death sentences now hanging over the 25 million Africans infected with H.I.V., the virus that causes AIDS. . . .

Bush administration officials recognize that AIDS has become a foreign policy issue for the United States. Secretary of State Colin Powell has called AIDS an economic and national security problem and

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said Congress has been generous. But Congress's allocation amounts to only $315 million this year for all AIDS programs worldwide -- vastly inadequate to prevent the catastrophic scenarios looming in Africa. An effective prevention program throughout Africa -- the very minimum necessary -- would cost $1.5 billion, according to the United Nations program on AIDS. [sic][1] Relieving the pain of AIDS sufferers and treating their infections would cost a similar amount, and providing drugs to attack the AIDS virus would cost even more.

The Cipla offer has greatly increased the possibility that poor nations will be able to treat AIDS, especially if it provokes brand-name drug makers to lower their prices, as it seems to be doing. A year of therapy costs $10,000 or more in the United States, but several multinational drug companies have negotiated far lower prices with some African countries, as low as $1,000 a year, and now Cipla will sell generic drug cocktails for less. But even at $600 a year, these drugs are out of reach for most Africans. Wealthy nations are going to have to pay for the drugs -- which could initially cost $3 billion a year for Africa, and more as a greater number of patients are reached. The West must help African nations improve their health care delivery systems so they can properly administer these drugs -- an effort that would reap many other health benefits as well.

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New Regimen: AIDS-Drug Price War Breaks Out in Africa, Goaded by Generics--- Merck, Others Plan to Slash Costs of Key Medicines In Bid for High Ground --- Weighing Patents and People

The Wall Street Journal, March 7, 2001, by Mark Schoofs and Michael Waldholz

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An extraordinary price war is breaking out in the market for AIDS drugs in poor countries, as pharmaceuticals giants seek to blunt a growing threat from generic-drug companies and recoup some moral high ground amid the crippling epidemic.

Merck & Co. yesterday confirmed it is slashing the prices for two of its important AIDS-fighting drugs in Africa by 40% to 55%, on top of sharp reductions the company already pledged last year. In a significant development, it also plans to offer the reduced prices to other poor countries beyond Africa.

Bristol-Myers Squibb Co. and GlaxoSmithKline PLC also plan to implement a new round of sharp cuts, people familiar with the matter said. They come at a time when two generic companies based in India are now fighting with each other to claim the low-cost mantle.

"This is extraordinary news," says David Nabarro, a high-ranking World Health Organization official who was alerted to the move yesterday. "This is part of a trend we hope will increase availability." . . . .

The latest pricing moves reflect increasing concern by pharmaceuticals executives that generic competitors are winning a public-relations battle that could eventually undermine international patents -- their most precious asset. . . .

Pharmaceuticals executives worry that the vilification of the industry will become so widespread that governments will become emboldened to take away drug-company patents, not just in poor nations, but even in wealthier ones, as well. In the U.S., for instance, politicians and health advocates have complained strenuously about the high cost of medicines.

"If we don't solve the drug access problem, then our intellectual property is at risk," says Raymond Gilmartin, Merck's chairman and chief executive. He adds that the companies "need to demonstrate that intellectual property is not an obstacle" to access in developing countries.

The current pricing free-for-all was triggered last month when Cipla Ltd., a leading generic drug maker in India, promised to sell a combination of three AIDS drugs to Africa at $600 per patient per year, about 40% below the discounted price of a similar regimen offered by the giant drug makers.

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[1] This math appears to be incorrect. Twenty five million people at $600 per patient per year totals $15 billion.

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Now a second Indian manufacturer, Hetero Drugs Ltd. has just announced it will sell the same cocktail of drugs for $347 a year. Hetero's entry into the AIDS pricing fray is being hailed by AIDS activists, partly because they say it will bring more pressure on all drug companies, generic or patent-based. The Indian company has already entered an agreement with a large South African generics firm, Aspen Pharmacare Ltd., to distribute Hetero's drugs -- if the South African government wins its lawsuit with the pharmaceuticals companies and allows for the importation of generic drugs. . . .

The Indian generic companies face many hurdles. They can produce and sell patent-protected drugs in India because that country doesn't recognize international patent laws. In order to sell the drugs to Africa, the Indian companies must somehow get around patent laws -- even those with weak protections -- in Africa. . . .

Merck, on the other hand, says its new offer is available immediately to any government, charitable organization, or employer in poor nations.

Executives say this round of price cuts will be different from last May's. Back then, it also restricted the offer to Africa, and insisted that the U.N. help oversee the process. Now, it plans to roll out the offer to poor nations beyond Africa, although it hasn't yet specified which ones. Merck's only demand is that it receive guarantees that their drugs won't be re-exported to any other nation.

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Still, Merck officials continue to fret that lowering prices for poor nations will be used by health advocates to demand lower prices for AIDS drugs in the U.S. "We're making a big assumption here," says Mr. Gilmartin, "that the American people and Congress will look at our discussions in Africa and recognize that they should not be a part of the debate about prices in other parts of the world."

Meanwhile, several other major drug makers, also discouraged by the small numbers of Africans who have benefited from the first round of price cuts, say they are seriously considering new reductions similar to Merck's. Glaxo had previously reduced its Combivir drug by 90% to $2 a day, a price that was available only to governments. But Jean-Pierre Garnier, Glaxo's chief executive, says the company is now offering the same price to "clinics, employers -- essentially centers in contact with thousands of AIDS patients in Africa." . . . .

Moreover, three other major AIDS drug providers, Roche, Bristol-Myers and Boehringer-Ingelheim, are all considering their own new set of reduced prices. . . .

All the companies maintain the new drug charges are about as low as they can go without huge volume buying. Still, AIDS activists, who have become skeptical of drug-company statements over the past few years, are likely to say the companies can discount further. Expecting that, Mr. Gilmartin says the price "will never be low enough" to satisfy activists. "I don't expect to get any credit," he says. "But we will make a difference."

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Cipla Tries to Skirt South Africa AIDS-Drug Battle

The Wall Street Journal, March 9, 2001, by Robert Block

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JOHANNESBURG, South Africa -- The South African government has been tossed a hot potato by Indian drug maker Cipla Ltd., which has asked for legal permission to supply the country with low-cost generic copies of patented AIDS medicines.

The gambit by Cipla Chief Executive Yusuf Hamied for a "compulsory license" for eight antiretroviral drugs used to treat AIDS would sidestep a landmark legal battle between South Africa and 39 international pharmaceutical companies over drug patent rights. The lawsuit, which opened this week, has been postponed until April 18 to give the drug makers time to challenge a 1997 law that allows the government wide discretion to limit patent rights to import cheaper medicines.

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Cipla's request tests claims by the drug companies that the legislation under dispute is unnecessary because patent law allows the government alternatives, such as granting compulsory licenses in emergencies, to achieve the same goal. But the request also could prove to be a trial of the government's allegations that the drug firms' reluctance to provide affordable medicines is at the heart of its own poor response to the country's AIDS epidemic. An estimated four million South Africans are believed to be infected with HIV, the virus that leads to the disease.

Some critics suggest that the government, which only a year ago was pilloried for questioning the link between HIV and AIDS and dismissing AIDS drugs as "toxins," might be using the lawsuit to shift blame to the drug companies to restore its own credibility. They said the government risked slipping back into disrepute if it squandered the Cipla opportunity.

A few government officials say they are worried that should Cipla win its bid to supply the country with cheap AIDS drugs, the government won't have the budget to distribute them. "We are in real danger that Cipla could open the door on the AIDS-drugs barrier in this country and we will not be able to walk through," said one Health Ministry official.

Cipla's Mr. Hamied said neither the government nor any of the drug companies that own the patents he plans to copy have tried to contact him. Mirryena Deeb, the head of the Pharmaceutical Manufacturers Association of South Africa, a trade group party to the lawsuit against the government, said at a news conference yesterday that her organization had no plans to challenge Cipla's request.

"On the contrary, we welcome it because it proves what we have been saying all along: that we are only against [the 1997 law] and not access to cheaper drugs," she said. But she added that some PMA members, including the large international firms, might challenge the application in their individual capacity.

Cipla told the Registrar of Patents in a letter on Wednesday that it deserved a compulsory license because the large pharmaceutical companies had failed to meet demand "on reasonable terms." Now the government must examine its argument and hear challenges by patent holders.

But Stephen Saad, Chief Executive of Aspen Pharmacare, South Africa's largest generic drug manufacturer, says the government could at any time declare AIDS a national emergency and grant compulsory licenses to make generic AIDS drugs. He said Aspen has a contract with one of Cipla's Indian rivals to make three generic AIDS drugs in South Africa. "We're just waiting for the government to give the word. It's just not coming," he said.

Health Minister Manto Tshabalala Msimang says she ruled out that option after African health ministers concluded last year that national emergencies could only be temporary, which isn't sufficient time to deal with the AIDS problem.

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The Catalyst: Behind Cipla's Offer Of Cheap AIDS Drugs: Potent Mix of Motives --- Altruism, Local Politics and The Bottom Line Intersect At Indian Generics Firm --- Waiting for Government Call

The Wall Street Journal, March 12, 2001, by Daniel Pearl and Alix Freedman

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BOMBAY, India -- Yusuf K. Hamied is a man with impressive humanitarian credentials. His pharmaceuticals company, Cipla Ltd., runs a free cancer-care hospital in India. His apartment near London's Hyde Park boasts a series of paintings of Mother Teresa that bear her signature. When a devastating earthquake recently struck India's Gujarat state, Dr. Hamied ordered his company's warehouses opened, on a holiday, to supply free medicine.

And yet, even Dr. Hamied's friends say it wasn't simply compassion that drove the generic-drug pioneer to make his attention-grabbing offer last month to sell AIDS drugs at deep discounts, a move that has set off an extraordinary price war for supplying the life-saving medicines to Africa and developing

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nations elsewhere. The developing world is home to the vast majority of the globe's 35 million people infected with HIV, the virus that causes AIDS.

One friend, Bombay patent lawyer Narendra Zaveri, says Dr. Hamied's offer was "very much a business deal" designed to build Cipla's brand name outside India. Others say Dr. Hamied wanted to impress Indian government officials with his ability to cut prices, as part of an effort to preserve the legal rights of India's generic-drug companies to make and market copies of newly developed drugs.

Regardless, Cipla's offer to sell a triple-combination of "antiretroviral" AIDS drugs to the international aid group Doctors Without Borders at less than $1 a day per patient is transforming the debate over how to provide critical medicines to poor nations. . . .

Multinational pharmaceuticals companies dismiss Cipla and its peers as patent "pirates." But the big multinationals are nonetheless responding with discounts for developing nations that the drug giants themselves would have labeled impossible just a few months ago. And other Indian generic-drug makers are fueling the pricing battle as they try to outdo Cipla. . . .

"Whatever you may say, what we have started has been a crusade," says the mercurial 64-year-old Dr. Hamied. "It has unwittingly developed into this." . . . .

How much the crusade will help AIDS patients is still unclear. Cipla's offer to Paris-based Doctors Without Borders so far seems largely symbolic, since the group lacks the resources, infrastructure or desire to be a global drug distributor. Doctors Without Borders is unsure whether it will be able to get the funding to buy Cipla's drugs. If it does, the group says it plans to set up only small pilot projects to dispense them.

Campaigns to get cheap drugs into African nations also face legal and logistical hurdles as well as questions about who will verify that the knockoffs work like the originals. Dr. Hamied hasn't extended the $350-a-year offer to governments, which might buy large volumes of drugs, but he says he is willing to sell them the three-drug regimen for $600 a patient per year. That price appears to be comfortably profitable for the Indian drug maker, whose overall AIDS-drug sales have been paltry thus far. . . .

But, as with the large drug companies' offers, many wonder if Cipla's proposals will have impact beyond their publicity value. "That's the question we all have," says Denis Broun, a former U.N. pharmaceuticals specialist who has advised Dr. Hamied over the past year. Saving lives with the AIDS drugs requires specially trained doctors and nurses and careful tracking of patient dosages, says Dr. Broun, who now works for Management Sciences for Health, a nonprofit consulting group based in Boston. Dr. Hamied, he believes, is mostly concerned with influencing patent laws in India.

"He is pretty cleverly using the AIDS issue to push his views, and show their validity," says Dr. Broun. "He is pursuing, internationally, an Indian objective."

Dr. Hamied says that his sole motive for offering to supply cheap AIDS drugs is simply "my social obligation to society."

In India, Cipla's agenda hasn't always been to push down drug prices. It and other big generic companies recently asked the government to slap 35% import duties on lamivudine, an AIDS drug known as 3TC, that Dr. Hamied's company also makes. And Cipla is engaged in a bitter dispute with the Indian government over India's price-control regulations. When the government ordered Cipla to reduce prices of certain drugs, the company went to court instead. . . .

It was, in part, a foreign patent holder's attempts to stop Cipla from making Propranolol, a heart-disease drug, that spurred the company to political action 30 years ago. Cipla went to then Prime Minister Indira Gandhi, according to later testimony by Dr. Hamied, and asked: "Should millions of Indians be denied the use of a life-saving drug just because the originator doesn't like the color of our skin?" With the prime minister's support, India enacted a new patent law in 1972 that protected only the process for making a drug, leaving the product itself fair game for copying. . . .

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Cipla is "a company with a sustainable competitive advantage," its promotional video proclaims. But by 2005, that competitive advantage could end. International trade rules require India to put a strong pharmaceuticals patent law in place by then. To get ready, some Indian companies have moved aggressively into research. Meanwhile, Cipla has been duplicating foreign drugs at a furious pace. (The new patent law probably won't cover drugs patented before 1995, as long as generic versions are already on the market.) . . . .

Cipla is the market leader in AIDS drugs in India, which has an estimated HIV-positive population of 3.7 million. It sells the drugs at a cost of $1,090 a year for a typical combination treatment. . . .

Even now, after years of rival seminars for doctors, sponsored by Cipla and by Glaxo PLC (now part of GlaxoSmithKline PLC), the entire Indian market for antiretrovirals barely amounts to $3 million, according to Bombay market-data provider Org-Marg Research Ltd. Glaxo estimates that no more than one in 300 HIV-positive Indians is on antiretroviral drugs. . . .

Most Indians don't have the choice, since a year's supply of the cheapest antiretroviral combination available costs more than India's average per capita annual income. And the hidden costs are even higher. Shahrukh Irani, a wine salesman in the city of Pune, shows a February bill for his HIV-positive 12-year-old daughter: $110 for two-drug combination, $170 for a liver test, blood tests, urea test, and viral-load test to keep track of the drug's effects and side effects, another $130 for doctor's bills and incidental expenses. . . .

Export markets pose other problems for Cipla. For the past two years, it has tried to sell the AIDS drugs to South Africa. It has a 40-person office there and took a small booth at last year's AIDS conference in South Africa. One analyst estimated Cipla could take in $100 million if it could get into South Africa. But few markets have patent laws as lax as India's.

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Dr. Hamied says it was the devastating Jan. 26 earthquake in Gujarat that finally persuaded him to act. He told one friend that he started thinking about the unavoidable deaths, and then about all the AIDS deaths that could be avoided in Africa. During a Feb. 6 conference call with Doctors Without Borders, to iron out technical issues involved in purchases of other drugs, Dr. Hamied turned the subject to the AIDS drugs and said, "I'm thinking of offering a $350 price to subsidize your distribution costs," Doctors Without Borders officials recall. Cipla sent the organization a faxed confirmation letter the next day, offering the $350 price, so long as the drugs were distributed free of charge. Mr. Love made sure the news became public.

A week later, Dr. Hamied had a thick stack of press clippings on his desk, and a fax from Unaids asking him to speak at a U.N. Special Assembly session on AIDS in June. But the following week he found himself frustrated with the U.N's response to his $350 offer. Rather than rushing to embrace his overture, U.N. agencies were just asking for further details about the offer: like how long Cipla would supply drugs at that price. The U.N. was "only working with the multinationals, so good luck to them," Dr. Hamied concluded. . . .

One issue Dr. Hamied wants the WHO to work on is quality assurance. Two other Indian companies, Hetero Drugs Ltd. and Aurobindo Pharma Ltd., are pushing to export AIDS drugs through governments and international organizations. Hetero says Cipla has a problem because its AIDS drugs haven't been fully tested on human beings to show they are equivalent to the patented originals. Cipla says the other companies have a problem because their drug factories don't have full international quality checks.

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Pill-Poppers: The right and wrong way to combat AIDS in Africa.

Andrew Sullivan

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Let's see if I can paraphrase the current consensus about drug companies and AIDS in Africa. Oh, why bother when I can simply quote Anthony Lewis? Here he is:

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In the United States and Europe, the anti-retroviral drugs that have made aids a containable disease for many sufferers cost either the patient or the society $10,000 to $15,000 a year. It has been widely assumed that poorer countries cannot afford them, and in any event do not have health systems that could use them effectively.... [Tina Rosenberg in The New York Times Magazine] showed that those assumptions are false. Brazil now makes the drugs itself and has cut the cost by nearly 80 percent; government commitment has produced clinics to supervise the treatment effectively. Many lives, and much money, have been saved. The big drug companies are frantically resisting the precedent. And they have great lobbying power in the United States, achieved by campaign donations.

Voilà! AIDS in the developing world, described by Lewis as "the most profound and immediate threat to life on earth," is easily solved. Only the evil drug companies, abetted by evil Republicans, stand in the way--companies whose only argument is their ability to buy politicians using campaign cash. The only problem with this line of thought is that the drug companies, not all of which are "big," actually do have an argument, and the closer you look, the stronger it is.

Start with a simple question: Ever wonder how we have drugs to treat HIV in the first place? Lewis doesn't address this, but those of us who are alive today because of those drugs have had reason to figure it out. You could argue that anti-AIDS drugs are the gift to the world of legions of brilliant scientists and researchers. But that misses the point. The reason we have a treatment for HIV is not the angelic brilliance of anyone per se but the free-market system that rewards serious research with serious money. Ever wonder why the vast majority of such treatments come from U.S.-based companies? Because European pharmaceutical companies have been clobbered by socialized medicine and have moved much of their research and production to the United States. (Ten years ago, half of the ten top-selling drugs in the world were made by European companies. After a decade of price controls and regulation, Europeans now make only three of the top 25.) Ever wonder why Indian scientists are working in U.S.-based labs rather than in India? Because our free-market system gives them incentives to discover rather than reasons to flee. The knockoff companies in India and Brazil so beloved by the left are at best copiers of American products and at worst thieves. They're the Napsters of the drug world--only worse, because they charge for what they steal rather than give it away for free.

So the hard question is: How do we maintain the system that gave us these drugs in the first place while getting them to the largest number of infected people? It seems to me that the recent offer by Merck to sell key anti-retrovirals at one-tenth their Western price is an admirable, if partial, answer. HIV, after all, is not like cancer. It is an epidemic, spreading exponentially across the globe. Waiting for patents to run out and prices to drop in the natural course of events is a death sentence for a generation or more. As long as the domestic markets remain unmolested by populists and regulators, a massive discount from the major pharmaceutical companies for poor countries overseas is actually a stunningly generous gesture. Drug companies, after all, are not designed to cure diseases or please op-ed columnists. They're designed to satisfy shareholders. At least that was the shareholders' assumption when they invested.

What if the drugs are still too expensive? Well, that's where governments and international organizations come in. If we wanted to, we could go a long way toward funding discounted HIV meds for the developing world from Western taxpayers' pockets. In saved lives and rescued economies, it would pay for itself. Besides, in times like this it's simply the right thing to do. But such aid should come with realistic caveats. It's vital to ensure that these meds are taken in the right amounts at the right times--or else they will be ineffective in the patient and generate incurable viral strains in the process. Believe me, ensuring this is harder than it sounds. For almost eight years now I've juggled more than 30 pills a day--with food, without food, at night, in the morning, and on and on. Every year or so the regimen changes. I have more than ten prescriptions to keep track of. Most of the time, you feel sick and exhausted after a dose--a subtle but deep incentive to put off taking it, forget, or just give up. I'm not whining, I'm just making a point. Even with educated, motivated patients, 80 percent adherence is an achievement--and 80 percent still means new drug-resistant viral strains gain a niche in the population at large.

Now think of the consequences of doling out hundreds of pills to people who can barely afford a decent meal or a regular trip to the doctor. Keeping track of the drugs will be hard enough. If Western food aid results in massive theft, corruption, and reexportation, can you imagine what Africa's kleptomaniac dictators could do with expensive HIV meds? Sure, Brazil has shown that drugs can be

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successfully administered in controlled circumstances. But Brazil is currently an exception to the rule. Elsewhere our best bet is modest, controlled treatment centers where anti-HIV drugs are delivered with medical monitoring and advice. If these work, let's expand them.

For those without access to these drugs, we can also do a lot, and quite cheaply. For people with AIDS there are plenty of relatively inexpensive post-patent drugs with simple dosings to treat the opportunistic infections that prey on depressed immune systems. This can relieve at least some of the pain and suffering, even if it cannot solve the underlying problem.

This means, tragically, that most people with HIV right now will die of it. That is an appalling prospect--as appalling as the thousands who die of dysentery for lack of clean drinking water or who are killed in war, lost in childbirth, or ravaged by malaria. In the face of this, there is the duty to do all we possibly can. But there's also an imperative not to engage in rituals of easy blame, or to attempt something that cannot realistically be achieved, or to demonize those who are a critical part of the solution. In the current debate, it's worth remembering one simple thing: Most African and Western governments have done virtually nothing to halt this global epidemic and are still balking at major aid. The American private sector, which has been responsible for the lion's share of HIV research, is now offering to pay for 90 percent of the cost of drugs for the developing world at the expense of future profits and research. Now you tell me who the real villains are.

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Patently Wrong: It's been a rough couple of weeks for property rights, and AIDS victims.

National Review Online, March 21, 2001 , By Neil Seeman,

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Not all AIDS activists are blockheads or Communists, just the influential ones. First there's Cuban dictator Fidel Castro, who this week assailed the United States and its pharmaceutical companies for trying to protect their patent rights, Reuters reported. Castro — whose country's AIDS policy consists of collaring HIV-sufferers and shepherding them off to lepers' colonies — expressed "strong support" for South Africa's efforts to import and produce generic AIDS medicines.

Next we have the bombastic South African president, Thabo Mbeki, who continues to eschew the premise that HIV causes AIDS. (In a letter last year to Western leaders, Mbeki suggested that the West's criticism of "dissent[ing] AIDS" scientists smacked of "racist apartheid tyranny.") This self-styled "conscientious AIDS-objector" has abjured the concept of intellectual property, too. Now the Europeans are in tow. This week, the European Union passed a resolution calling on 39 drug companies to drop their lawsuit against South Africa's Medicines Act, which authorizes the manufacture of AIDS medicines by domestic drug companies, despite patents held by U.S. and European firms.

All in all, it's been a rough couple of weeks for property rights — and for AIDS sufferers. As urgent as South Africa's need may be for AIDS treatments today, it will surely need more and better ones tomorrow. The only way to ensure that such drugs become available in the long term is to give drug companies the proper incentives to produce them.

Besides, cheap, generic "AIDS cocktails" are hardly the panacea South Africa so desperately needs. Drugs will only help those who know how to take them properly. And that's asking a lot in South Africa, where, according to a new survey by the research firm ACNielsen, half the population agrees with Mbeki's conspiracy theories about AIDS. Last year, Mbeki asked his minister of health, Manto Tshabala-Msimang, to distribute a document alleging that AIDS had been secreted to Africa 23 years ago by "the Illuminati" as part of a Western plot to take over the world. Because of such fear-mongering, 50 percent of South Africans, the ACNielsen survey found, now believe that Mbeki's misinformation about AIDS has "made it more difficult for health workers to persuade people to take precautions against the disease."

As Andrew Sullivan has observed, it requires considerable stoicism to take some 30 AIDS pills a day — "with food, without food, at night, in the morning, and on and on." Chances are, that's going to be tough when your president says that taking the drugs won't help much, and when having sex with a 12-year-old virgin is widely regarded by your peers as a far more effective way to fight the killer disease.

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If AIDS activists really wanted to make a dent in Africa's AIDS pandemic, then they might want to take on the campaign of misinformation racking the continent. (President Sam Nujoma of Namibia continues to insist that AIDS is a racist plot concocted by white people.) Instead, the AIDS lobby has chosen to heap all manner of abuses upon "Big Pharma," accusing Western drug manufacturers of putting "profits before lives." But that isn't what's really going on here.

Under the WTO pact to which South Africa is a party, a nation may license the production of patented goods without the patent holder's consent — but only after several attempts, over a reasonable length of time, to arrange for such production on fair commercial terms. In emergencies, that condition may be waived, but inventors must be compensated financially. South Africa's Medicines Act skates around these rules. The health minister enjoys unfettered discretion to junk any domestic or international patent obligations deemed to stand in the way of the people's welfare.

Little wonder, then, that these 39 foreign drug manufacturers have sued Pretoria to block the implementation of the law. Should the drug companies lose in court, Americans will start to wonder why AIDS medications — many of them subsidized at taxpayers' expense — are so much cheaper in Pretoria than they are in Poughkeepsie. True, AIDS has ravaged South Africa — the country leads the world in the number of HIV sufferers, with 4 million cases. That is a tragedy. But it is no reason for it to wink at property rights.

Evidently this argument doesn't cut the mustard with AIDS activists the world over. Dr. Nils Daulaire, head of the Global Health Council in Norway, said this week that "the world is ready to move on from squabbling about patent issues."

Dr. Naulaire may be right. But if the world gives up on patents, the pharmaceutical companies will give up on AIDS. This isn't because these companies covet pornographic profit margins, but because they are businesses that need to recoup the hundreds of millions of dollars which they invest in researching and marketing new drugs.

Writing recently in the New York Times, reporter Sheryl Gay Stolberg noted that the international blitzkrieg now raining down on the pharmaceutical companies serves as a call to arms for AIDS activists in America and beyond. Now that "AIDS is back on the front page…the activists are back in business, drawing strength from their old enemy," she wrote. The new fight contains "echoes of the past," a.k.a. the 1980s. That was when the AIDS lobby spouted lies like, "AIDS is an equal-opportunity disease" that kills straight people at the same rate as gays. Or the mantra of the "condom code," which said that you could have sex with as many people as you liked so long as you wore a condom. That kind of misinformation lulled people into a false sense of complacency — and killed thousands. The Left's attack on "Big Pharma" may have an equally pernicious effect.

The next time a drug-company executive debates whether to commit his company's resources to finding a cure for AIDS or, say, inventing a jazzy, new nicotine patch, he may choose the latter. Call a nun a "killer" enough times, she may soon start to believe it.

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Exhibit 1 Financials for Major Pharmaceutical Firms (million USD)

	Merck	GlaxoSmith-Kline PLC	Bristol-Myers Squibb	CIPLA
Revenues	37,859	12,798	18,840	171
Gross Profit	17,342	9,789	13,898	--
Research and Development	2,309	1,887	1,890	--
R&D (% of sales)	6.1%	14.7%	10.0%	--
Operating Profit	9,524	3,848	5,327	28

Source: Adapted from Yahoo!Finance and the Wall Street Journal

Exhibit 2 Pricing of AIDS Drugs

The most recent prices for AIDS drugs per patient per year in the U.S. and Africa offered by large drug makers and two Indian generic drug companies.

	U.S. Price	Latest Company Offer in Africa	Cipla	Hetero
Zerit (Bristol-Myers)	$3,589	$252	$70	$47
3TC (Glaxo)	3,271	232	190	98
Crixivan (Merck)	6,016	600	N.A.	2,300
Combivir* (Glaxo)	7,093	730	635	293
Stocrin (Merck)	4,730	500	N.A.	1,179
Viramune (Boehringer)	3,508	483	340	202

Source: Data collected from CIPLA web site, and pharma company and Doctors Without Borders' press releases accessed through Yahoo!Finance.

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