EIR Feature

# South Africa, India Fight Drug Multis on AIDS Treatment

by Ramtanu Maitra

An all-out war has broken out at the Pretoria High Court between the South African government and large multinational drug companies. The Pharmaceutical Manufacturers Association of South Africa, representing 39 drug companies, kicked off the latest battle in the form of a lawsuit to dislodge the 1997 law, passed by the South African legislature, which would allow the government to import and produce generic drugs, including anti-retrovirals, at a much cheaper price than that of the pharmaceutical giants.

The battle in the courts is the latest episode in a war waged by the forces of globalization against the sovereign efforts of South Africa to protect its population from the ravages of the deadly poverty-linked epidemic. The first attack against the law came from U.S. Vice President Albert Gore. In 1998, Gore delivered a threat to South Africa that it would be put *back* on a sanctions list (as imposed during the time of apartheid), for violating the "rights" of pharmaceutical companies to monopolize and control medications under World Trade Organization (WTO) enforcement of patent laws.

Gore's threat was not an anomaly. As a close collaborator of Britain's Prince Philip, who brags that he would "like to be reincarnated as a deadly virus" in order to help curtail the growth of the human race, Gore also advocated reducing the world population to about 2 billion people. It is also the case that since 1974, a highly secret doctrine of U.S. foreign policy, authored by Henry Kissinger as National Security Study Memorandum 200 (NSSM 200), has declared Third World population growth a threat to U.S. national security. However, with a mounting protest in the United States and worldwide, Gore and his allies were forced to back down from their sanctions threat in 2000. Now the pharmaceutical giants of the United States, Britain, and continental Europe have continued the assault in a new form, through their Pretoria lawsuit.

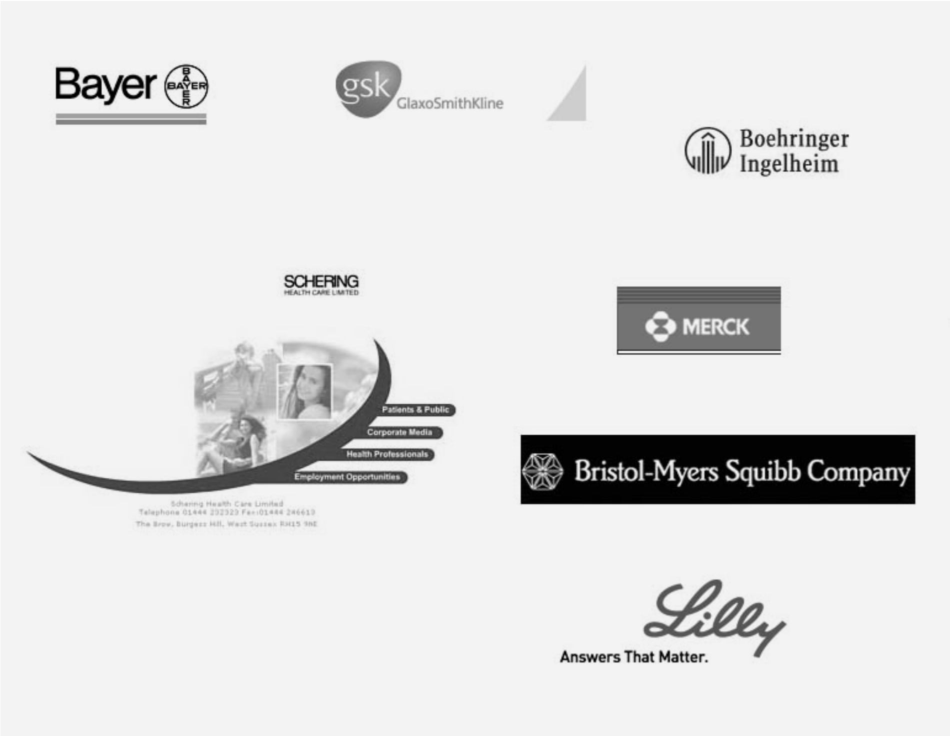
An injunction, currently in force in this lawsuit, is preventing South Africa, now, from producing *any* pharmaceuticals for treatment of AIDS. On March 14, the government of President Thabo Mbeki, under international economic threats clearly reflected in the *Washington Post*'s front-page coverage, put off any move to declare a national AIDS emergency to overcome this blockade.

## Patents or Patients First

The contesting local and international pharmaceutical companies claim, that the South Africa law authorizing generic medications—the Medicines and Related Substances Control Amendment Act—will override their patent rights and put the entire industry "at risk." But the court decided on March 6 to allow a local body, Treatment Action Campaign (TAC), a non-governmental organization (NGO) representing HIV-AIDS sufferers, to submit evidence on behalf of the government's case, documenting the dramatic human costs which result from pharmaceutical companies profiteering off AIDS medications. The TAC hailed the court's decision to include the evidence, as a recognition that this case is not a narrow legal battle over property rights, as the pharmaceutical companies would have it, but a fight for public health and human lives. The court then postponed the case for five weeks to allow the contending companies to prepare their response.

Two international organizations helping the AIDS patients in Africa—Médecins Sans Frontières (MSF, Doctors Without Borders) and Oxfam—and the Congress of South African Trade Unions (Cosatu), have welcomed the court's decision to accept evidence from the TAC.

The multinational companies that are seeking to overturn the law include GlaxoWellcome, Merck, Hoffman-LaRoche AG, Eli Lilly, Bayer, Bristol-Myers Squibb, Boehringer In-




*Some of the multinational pharmaceutical companies which have been the justified target of large demonstrations in Pretoria, South Africa in February and March. Thirty-nine of the multis have sued South Africa to block it from producing inexpensive AIDS treatment drugs.*

gelheim Gmbh of Germany, and SmithKline Beecham.

The trial has brought thousands of activists to the nation's capital. They have come to lodge their protest against the large drug companies and support the law. With more than 4 million people infected with HIV, South Africa, in official World Health Organization statistics, leads the world in cases of the virus. Africa reportedly has about 70% of world's 36 million HIV-positive people.

Despite the fact that patent protection is against the interests of the developing nations, the WTO proscribes worldwide minimal standards for patent protection. Any nation that wants to be part of the global economy by joining the WTO, must abide by the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The drug multis claim that South Africa, in its "Partnership Against AIDS" Program, on the other hand, is attempting to circumvent the TRIPS by identifying the AIDS epidemic as equivalent to a national emergency. There is no question that by not meeting the TRIPS rules, many developing, and developed, countries would be able to develop generic drugs which would be cheaper, and better serve the interest of their people.

## Technological Apartheid vs. South Africa

In 1998, President Nelson Mandela raised hopes among the large AIDS population of South Africa when he signed into law South Africa's Medical and Related Substances Control Amendment Act of 1997. The law included a measure designed to make affordable some of the new miracle drugs that slow down the progression of AIDS. The law demands that the multinational pharmaceutical companies sell their anti-retroviral drugs at a lower price in South Africa and allow the local manufacturers to make generic versions that are affordable to the populace.

Typically, these miracle drugs, marketed by the multinationals, sell at a price of $10,000 to $15,000 per patient per year in the United States. While the multinationals were willing to bring down the price of their drugs in South Africa, they objected strongly to the law, claiming that widespread licensing of its products will lead to a global "gray market" in low-priced drugs and undermine their profits and the incentive to spend on costly research. They sought refuge in the WTO's intellectual property rights among its member nations. However, the global rules of trade dictated by the WTO allow for what is known as "compulsory licensing," if it is done to combat a national emergency. South Africa has made it clear that the AIDS situation has indeed reached national emergency proportions.

Although the Bush Administration in the United States has refrained from opposing the law, the multinationals drew their strength from the U.S. Trade Representative Charlene Barshefsky, saying the South African law was too broad and might be applied to other medicines. Barshefsky denied South Africa special tariff breaks on its exports to the United States. Vice President Al Gore also raised the issue with President Mandela when he visited South Africa in 1999.

In the United States, "friends" of multinational pharmaceuticals swung into action in 1998 to pressure South Africa. Rep. Rodney Frelinghuysen (R-N.J.), whose political donors include a large number of big pharmaceuticals companies in New Jersey, inserted a rider in the House Appropriations Bill in October 1998 to cut off foreign aid to South Africa. So far, South Africa has refused to back down, but by postponing the case for five weeks and allowing the European and American multinationals to push through a temporary injunction preventing the law from taking its effect, Pretoria has sent weak signals.

## New Entrants in the Battle

In early March, at the height of tensions in Pretoria, an Indian drug company, Cipla Ltd., asked the South African government to allow the company to license a three-drug cocktail for marketing at a price of $600 per patient per year (see accompanying article). Desperate to keep the situation under control, U.S. pharmaceutical giant, Merck, quickly offered to slash down the price of its brand-names Crixivan (indinavir sulfate) to $600 per year and Stocrin (efavirenz) to $500 per year in developing countries effective immediately. Another Indian company, Hetero Ltd., based in Hyderabad, has also offered the generic versions of Crixivan and Stocrin at $347 per patient per year, according to Toby Kaspar of MSF, a leading humanitarian organization that provides medical services to the Third World.

According to doctors' descriptions, a typical AIDS cocktail is a combination of any three of about nine protease inhibitors or reverse transcriptase inhibitors. The chemical suppresses the human immunodeficiency virus (HIV), but, as with any chemical therapy, these are toxic and can cause damage to the liver. If the virus mutates to resist the therapy, physicians say, the combinations are changed. In South Africa, the mutation has not been reported yet.

The trouble for the multinationals started when Cipla Ltd. offered to sell the three-drug cocktail to MSF for only $350 for use in Africa. Cipla told the MSF that the company would supply the agency with the drugs at the stated price, as long as they agree to distribute the drug for free. "This is my contribution to fighting AIDS," said Dr. Y.K. Hameid, the owner of Cipla. Dr. Hameid, who was trained as a pharmacist at Cambridge University, said his concern for fighting AIDS stems from a personal interest. "AIDS is going to be a bigger holocaust in India than the earthquake," he said, referring to the recent earthquake in Gujarat, which claimed as many as 30,000 human lives. (In fact, though official World Health Organization [WHO] data report about 1 million cases in India, Indian AIDS groups say there may already be as many or more AIDS cases than in South Africa.)

According to Cipla, the drug cocktail it is offering to the MSF, consists of two 40 mg tablets of stavudrine, two 15 mg tablets of lamivudine, and two 200 mg tablets of nevirapine. Bristol-Myers Squibb holds the patent on stavudrine, GlaxoSmithKline of Britain developed lamivudine, and Boehringer Ingelheim holds the patent rights to nevirapine. Although one of the multinationals, GlaxoSmithKline, refuses to be drawn into a fight, saying that Cipla's offer to the MSF is "partially one of donation," others have maintained a bitter silence.

According to Cipla, some multinationals had committed last year, under the sponsorship of the WHO, to offer AIDS drugs at a reduced price. This was in the glare of the publicity around the July 9-14 International AIDS Conference in Durban, South Africa. But they have not followed through with figures, although experts claim that Senegal has been acquiring the typical three-drug cocktail from these multinationals, at a price of $1,000 per patient per year.

## What Is at Stake?

The fight that is now going on in the Pretoria court is fundamentally a question of "shareholder values" against the value of human life.

For the multinationals, upholding of the law by the South African court might save lives, but it would erode their business in South Africa and weaken their efforts to sell the same drugs at a high price in Europe and the United States, where they earn most of their profits. They also point out that by allowing the "pirate manufacturers" (i.e., those companies like Cipla, Ltd. and other Third World manufacturers that produce low-cost medications) to copy their invention, the court would undermine their drug research. This interference, they complain, would further prevent development of drugs, which may actually cure the disease, or prevent AIDS from occurring.

The "pirate manufacturers," as the multis like to describe Cipla, Hetero, and other such drug producers, claim that the prices that the multinationals charge are heavily padded. The padding includes huge salaries to the executives, who make substantial political donations to powerful politicians who look after the interests of large pharmaceutical companies. The padding also includes international promotion of drugs, advertisements, and campaigns to launch their products in a big way. What exact proportion of their cost can actually be considered as the contribution to the R&D efforts is not clear. The multinationals have not come out with the specifics. What is clear is that they are among the highest-profit large corporations in the world, with average profit rates in 1999 having been reported at over 18%.

Anti-AIDS organizations such as the TAC claim that the case pending before the Pretoria High Court provides an opportunity to learn exactly how the drugs are priced and why they are so expensive.

Cipla also points out that all the attacks of the multinationals against them are not true. Cipla, a well-established drug manufacturer, also spends money on research and development. Cipla claims it has reduced its anti-retroviral prices five times in the last three years, through adoption of new technologies to improve the process. The company also

*In a Tanzanian hospital, one of Sub-Saharan Africa's nearly 30 million AIDS victims is comforted by his wife. In nations with per-capita average incomes of $500 per year, virtually none gets the multi-drug treatments costing $5-15,000 annually.*

claims that the price of the three-drug cocktail it has offered to the South African government for licensing cannot be priced any lower at this point. Its price of $350 offered to the MSF will lose them a lot of money.

The other important issue at stake is the patent law. In developing countries, such as India, Brazil, and Thailand in particular, the new "trade" rules of the WTO now pose a serious threat to local industry and to the millions of poor who depend on cheap, life-saving drugs. The secret of production of cheap drugs has been patent laws such as India's. It should be recognized that in many industrial nations, the protection of inventions through internationally recognized patents was only developed in the last 30 years. The Swiss pharmaceutical industry had fought the patent law for decades, and it was only in 1978 that product patents, which the WTO is implementing internationally, came into existence in Switzerland. Technology exporters profit from patent protection, which shields them from low-cost competition. Technology importers, which constitute most of the developing nations, want access to technical innovations as freely and cheaply as possible.

## Cancel the Debt!

It is also evident that while the prices offered by Cipla or Hetero are significantly lower than what the multinationals are ready to offer, they are beyond what the majority of Africans, or Indians, or Brazilians can pay. In countries where the daily wage of the poor is less than a dollar, an additional expenditure of $350 per patient per year to sustain life is simply ruinous. The epidemic has spread disastrously, in the first place, from poverty, lack of nutrition and sanitation infrastructure, and from the explosive spread of other serious diseases, particularly malaria, since the early 1970s.

It is, therefore, a necessity for the national governments to look beyond the court case. Without cancellation of their debt, which costs them $15 billion a year in debt service, poor African nations do not have the money to buy the drugs and protect their citizens.

Drug giants like Merck have "joined the price war," as the U.S. media like to describe it, but the price of $600 per year per patient for the life-prolonging anti-AIDS cocktails is a cruel joke, in a country where the average annual per-capita income is $530.

At the International AIDS Conference in Durban, the evidence showed that the AIDS pandemic was out of control and accelerating rapidly worldwide. There were already, according to the Durban reports, 25 million cases in Africa; and unofficial estimates ranged to more than 1 million in Russia, perhaps as many as a million between Haiti and the Dominican Republic, which share the Caribbean island of Hispaniola, and up to 5 million in India. All told, the estimates suggest there are may be 40 million cases worldwide.

Addressing that threat, and echoing the call by President Mbeki that the "number-one disease is poverty," the head of the UNAIDS agency, Dr. Peter Piot, opened the Durban conference with a call for the entire foreign debt of the African nations to be cancelled at once, so that its debt service could be used to develop public health capabilities to fight the pandemic. "Developing countries," he said, "who carry 95% of the HIV-AIDS burden, owe in total around $2 trillion."

Dr. Piot, and others, in tying the pandemic to the foreign debt, made a serious connection to the need for a new international monetary agreement which begins by declaring the bubble of international debt to be bankrupt. But what has been done since, such as the Italian moves to cancel debt of the Least Developed Countries, is entirely in collaboration with the growing movement associated with Lyndon H. LaRouche's international call for a New Bretton Woods.

The battle at Pretoria now is necessary and extremely important. But the AIDS epidemic will not begin to be turned back, until a thorough reversal of global economic policies of the past 30 years takes place. This requires India, Brazil, and other nations with such scientific capabilities to save lives, to move immediately for a new monetary system, a New Bretton Woods.

# Cipla Ltd.: A Small Player in a Big Fight

by Ramtanu Maitra

When Cipla Ltd., a major Indian pharmaceutical company, based in Mumbai, offered to sell poor countries an anti-retroviral drug cocktail for $350 per patient per year through the Paris-based doctors' non-governmental organization, Médecins Sans Frontières (MSF), a global debate began. World Trade Organization (WTO) chief, Mike Moore, who often sheds crocodile tears for the poor of developing nations and frets about the high price of anti-HIV drugs, joined the fray and defended the patent system. He said in an interview with the *International Herald Tribune* recently that "were it not for a patent system that rewards companies for risking millions on research, anti-AIDS drugs would not exist."

Maybe so, but the owner of Cipla, Dr. Y.K. Hameid, whose father founded Cipla during British rule, does not agree to what Moore says. He points out that the Cipla experience in India, Brazil, and Thailand "has shown that most of these critical drugs can be produced at costs that put them realistically within the reach of the resource-poor." Hameid footnotes his statement by pointing out that Cipla is not marketing drugs to the Western markets. Cipla "represents the Third World and its needs and aspirations. . . . I also represent the capabilities of a country with a billion population. Please do not link up the problems of the Third World and India with those of the West. . . . We Indians abide by the laws of our land. We have not broken any laws," Hameid adds.

The law that Dr. Hameid refers to is the patent law as it exists in India. India implemented a patent law in 1970, which allows patenting a drug-manufacturing process, and not the product.

## Mahatma's Endorsement

Cipla's concern for producing cheaper life-saving drugs is well known in India, if not internationally. Cipla was established in 1935, and on July 4, 1939, Mahatma Gandhi, considered as the "Father of the Nation," went to the Cipla factory to endorse his support to fight the high-priced British drugs imported by the British Raj. Gandhi left an autographed photograph of himself which Dr. Hameid proudly displays in his office room.

From the time Cipla came to the aid of the nation, then under British rule and gasping for essential medicines during World War II, the company has pioneered the manufacture of more than 250 sophisticated drugs, from the basic stage. It would be grossly unfair to label Cipla as a company good at back-engineering only. In fact, it has a well-developed R&D section and has patented internationally in the area of anti-asthmatic devices.

Cipla came to the limelight in the early 1960s when the foreign-held patents still ruled the roost in India. The U.S. Senate Kefauver Committee had observed in 1962 that drug prices in India were among the highest in the world. It was in this context that the 1970 Indian Patent Act was enacted. The Act obliterated the monopoly that the multinational drug companies enjoyed and it led to the growth of a number of indigenous Indian pharmaceuticals, such as Cipla. Dr. Hameid is deeply concerned that the new patent regime imposed through the powerful instruments of the WTO may bring back the monopoly of the multinationals. "We will not be able to afford the drugs currently being developed by genomics and proteomics. Ultimately, we will be enslaved again," Hameid worries.

The Indian Patent Act of 1970 is one reason why average life-expectancy in India has risen to 64 years, just as cheap pesticides based on foreign formulations are part of the reason why India feeds itself, Dr. Hameid explains. At the European Commission meeting in Brussels last September, Dr. Hameid made an offer to the Health Ministers of Brazil and South Africa, who were also attending the meeting, of technology to manufacture active substances and tablets of the anti-HIV drugs. He also made a similar offer to any Third World or developing country which wanted the technology free of cost. Cipla has offered drug-cocktail essentials to countries that do not have patents, including Brazil, Argentina, many countries in Sub-Saharan Africa, Thailand, Indonesia, China, and the whole of Eastern Europe and Turkey.

Dr. Hameid also fumes about the WTO and its patent regime. In an interview with UPI, he said: "I sincerely believe that the Third World countries and poor countries cannot afford a monopoly. I've never been against patents, I'm just saying that we countries of the Third World—a country like India with a billion population, we simply cannot afford a