



AIDS and Developing Countries:

Facilitating Access to Essential Medicines

By Robert Weissman, Essential Action

One in five adult South Africans, one in seven Kenyans, and one in four Zimbabweans has HIV/AIDS. U.S. Surgeon General David Satcher has likened the HIV/AIDS epidemic in Africa to the plague that decimated Europe in the fourteenth century.

Existing treatments, which enable many people with HIV/AIDS in the U.S. and other industrialized countries to live relatively healthy lives, are unavailable to all but a few people in Africa. Life-saving HIV/AIDS drug cocktails cost about \$12,000 a year in many African countries—vastly out of reach of all but a small handful of the growing African population with HIV/AIDS.

Addressing the HIV/AIDS crisis in Africa and around the world will require a massively accelerated prevention

effort. It will also require revitalizing developing countries' decimated public health systems, and making quality health care much more widely available. This, in turn, will require major new investments in public health and the abandonment of structural adjustment requirements to collect "user fees" from people seeking health care. But for millions of people infected with the HIV virus, there is also a crying need to make life-saving drugs more available—and quickly.

Two ways to promote access to essential medicines involve compulsory licensing and parallel imports. The more important of these policy

tools, compulsory licensing, enables any government to instruct a patent holder to license the right to use its patent to a company, government agency, or other party. Zimbabwe, for example, could issue a license to a local company for an HIV/AIDS drug manufactured by Bristol-Myers Squibb. The Zimbabwean firm would then manufacture the drug for sale in Zimbabwe under a generic name, and it would pay a reasonable royalty to Bristol-Myers Squibb on each sale.

Compulsory licensing lowers prices to consumers by creating competition in the market for the patented good. Its impact is similar to the introduction of generic competition at the end of a drug's patent term—prices come tumbling down. Compulsory licensing can

lower the price of medicines by as much as 95% or more.

Parallel imports involve imports of a product from one country and resale, without the authorization of the original seller, in another, thereby allowing the buyer to search for the lowest world price. A Namibian company or government agency, for example, might purchase HIV/AIDS drugs in France—assuming they are sold for a lower price in France—and then resell them in Namibia. Since the price of medicines is sometimes lower in the United States and other industrialized countries, parallel imports can be a tool to enable developing countries to lower prices for consumers.

Both compulsory licensing and parallel imports are permitted under the international trade rules established by the General Agreement on Tariffs and Trade (GATT) and administered by the World Trade Organization (WTO). They are regularly used in industrialized countries, including the United States, Japan, and the European Union. One of the GATT agreements, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), contains the international rules the WTO enforces on intellectual property (patents, copyrights, and trademarks). Industry, especially the pharmaceutical sector, exercised heavy influence over the TRIPS agreement negotiations, and many public interest advocates generally believe the TRIPS agreement inappropriately favors corporations.

In general, the TRIPS agreement requires countries to adopt U.S.-style patent systems, which apply both to products and processes, and last for 20 years. This has compelled many developing countries—which had followed the lead of virtually every industrialized country in enacting weak patent rules while they were still industrializing (many European countries did not recognize patents until the 1970s)—to refashion their patent rules dramatically.

But whatever the TRIPS agreement's biases, and despite the requirements it imposes on signatory countries, it permits compulsory licensing and parallel imports. Yet, despite the WTO-legality of these policy tools, multinational pharmaceutical companies object to the practices, which they perceive as curtailing corporate profits. Under pressure, the Clinton administration retreated from its longstanding, aggressive opposition to developing country efforts to undertake compulsory licensing and parallel importing. The Bush administration has signaled it will follow the revised Clinton policy.

Key Points

- Africa and the developing world are facing an HIV/AIDS crisis equated by the U.S. surgeon general to the plague that decimated Europe in the fourteenth century.
- Combinations of available pharmaceuticals—too expensive for nearly all of the infected people in the developing world—could enable many afflicted with HIV/AIDS to live relatively normal lives.
- Compulsory licensing and parallel importing policies could help developing country governments make essential medicines more affordable to their citizens.

Problems with Current U.S. Policy

Despite the legality of compulsory licensing and parallel importing, and despite the public health emergency enveloping much of the developing world, the U.S. until mid-1999 actively opposed developing country efforts to implement compulsory licensing, parallel imports, or other measures to make HIV/AIDS drugs more affordable and available in their countries.

The U.S. position suddenly changed, however, beginning in June 1999. Although the growing evidence of the scale of the unfolding horror of the HIV/AIDS pandemic in Africa contributed to the shift, what actually changed U.S. policy was protests by AIDS activists. When Al Gore formally announced that he was running for president, his speech was interrupted by activists chanting, "Gore's Greed Kills." Two of his next three speeches were similarly disrupted. Immediately thereafter, the White House began reaching out to activists, indicating it was looking at changing its position.

In June 2000, Gore told the Congressional Black Caucus that policy on access to medicines was shifting. In September, the administration announced it would cease pressuring South Africa to repeal its Medicines Act, which would permit compulsory licensing and parallel imports (and which remains on hold, while an industry lawsuit in South African courts proceeds). During the November-December WTO meetings in Seattle, the Clinton administration announced it would offer special treatment for health-related intellectual property disputes, taking into account health issues as well as commercial concerns. When efforts to make the policy into law as part of the Africa Growth and Opportunity Act floundered—and threatened to impede passage of the Act—the Clinton administration issued an executive order, which stipulated that the U.S. would not challenge TRIPS-compliant policy measures to make AIDS medicines available anywhere in Africa.

In February 2001, with ever-heightening attention on the AIDS crisis and growing interest in what posture the Bush administration would adopt on controversial intellectual property issues, the Bush administration indicated it would continue the Clinton administration's policy regarding not challenging initiatives making AIDS medicines more available, as long as they are TRIPS-compliant.

Even with the revised position, however, significant problems remain with various U.S. policies related to access to essential medicines.

The executive order itself is limited by application only to sub-Saharan Africa and only to AIDS medicines. A pervasive problem in U.S. policy, even after the 1999 policy shift, is the treatment of compulsory licensing as an exceptional policy tool to be used only in emergency circumstances. In fact, the WTO's TRIPS agreement considers compulsory licensing a standard part of the intellectual property regime.

In diverse international trade negotiating fora, the U.S. is seeking to increase the monopoly protections afforded by patents, and diminish the ability of countries to

do compulsory licensing and parallel importing. The U.S.-Jordan Free Trade Agreement, completed in fall 2000 and expected to be considered by Congress in 2001, sharply limits the grounds for compulsory licensing. The published summary of the U.S. negotiating position for the intellectual property portion of the proposed Free Trade Agreement of the Americas (FTAA) contains a variety of measures that would effectively extend patent terms, interfere with compulsory licensing, and otherwise undermine efforts by poor countries to make medicines more accessible.

Generally, the inclusion of intellectual property provisions in multiple trade agreements makes it much harder to ratchet down international patent protection obligations. Even if changes were made so that the WTO TRIPS became less restrictive, for example, this would have little impact on countries that had separate TRIPS or TRIPS-plus obligations in the FTAA or other international trade agreements.

The U.S. is also continuing with challenges to countries' intellectual property laws within the WTO. Arguing that it maintains the right to demand TRIPS compliance, the U.S. has challenged a Brazil law (known as a "local working requirement") that permits local manufacturers to produce products if the patent holder does not produce them locally.

Brazil has, by far, the most successful developing country program of delivering AIDS treatment drugs to people with HIV/AIDS. While the U.S. claims its case against Brazil concerns a narrow technical issue and would not inhibit Brazil's ability to continue its program or issue compulsory licenses, the act of bringing the high-profile case has sent the wrong message.

Throughout the world, many countries continue to believe that issuing a compulsory license will invite U.S. sanctions or WTO litigation. The U.S. has also commenced WTO action against Argentina, disputing a number of technical issues that may significantly impact the country's ability to carry out access-to-medicines policies.

The U.S. has also offered an effective bribe to countries not to undertake compulsory licensing: the U.S. Export-Import Bank announced in July 2000 that it would make \$500 million in loans available to African countries each year, for the purpose of buying HIV/AIDS medicines. Those loans—which of course would have to be repaid—could only be used to buy drugs from U.S. companies, not the far lower-priced drugs available from generic makers in India and other countries.

Key Problems

- The inclusion of intellectual property provisions in multiple trade agreements makes it much harder to ratchet down international patent protection obligations.
 - Washington continues to restrict the space available to developing countries to adopt intellectual property policies that could make HIV/AIDS drugs more affordable.
 - U.S. government positions on intellectual property questions remain too responsive to corporate profits, not public health needs.
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Toward a New Foreign Policy

In May 1999 the World Health Assembly, the policy-making body of the World Health Organization (WHO), passed a resolution that declared public health concerns "paramount" in intellectual property issues related to pharmaceuticals. Although Washington had vociferously opposed earlier efforts to obtain passage of a similar resolution that said public health concerns should take priority over commercial matters, the U.S., after insisting on minor changes, voted in support of the

1999 resolution. It is now time for Washington to bring its foreign policy into full compliance with the accepted notion that public health protection is the most important goal in shaping pharmaceutical patent policy.

First, the U.S. should announce that it will terminate all bilateral pressure on Brazil, Argentina, and other countries related to health-related intellectual property disputes. While it was an advance for the U.S. to agree that countries can adopt TRIPS-legal measures to make medicines more available, it should not seek to press TRIPS monopoly patent protections to their limit.

Second, the executive order about AIDS medicines and policy recognizing that health issues deserve special consideration in intellectual property disputes should be broadened. The U.S. should accept compulsory licensing and parallel importing as integral parts of the intellectual property system and crucial to delivering essential medicines in poor countries. The executive order should be broadened to cover all health-related technologies, not just those related to HIV/AIDS, and all parts of the world, not just Africa.

Third, the U.S. should announce its support for the South African effort to enable compulsory licensing and parallel imports, and urge the pharmaceutical companies that continue to block implementation of the

South African Medicines Act through litigation to drop their lawsuit.

Fourth, the U.S. should stop seeking expansion of TRIPS ("TRIPS-plus") in international trade agreements like the FTAA. There should be no provisions to enhance patent protections in new trade agreements.

Fifth, the U.S. Ex-Im Bank should abandon its drug lending program. The U.S. should instead provide massively stepped-up aid for AIDS treatment and prevention, channeled through appropriate UN agencies.

Sixth, the U.S. should immediately license to the WHO all of the HIV/AIDS drugs that have been developed with government funding and for which the U.S. government holds patent or other intellectual property rights. Existing law permits Washington to take such steps. With a license, the WHO could contract with private generic makers to produce the medicines and distribute them widely in the developing world. Since many of the most important HIV/AIDS remedies—such as ddI—were developed with significant U.S. government funding, the U.S. government controls rights to many important HIV/AIDS treatment pharmaceuticals.

Finally, it should be reiterated that although access to essential medicines is of critical importance, much more must also be done to prevent the spread of HIV/AIDS and to improve treatment of those infected. An essential step in combating the transmission of this disease is to cancel the foreign debts of the poorest countries, since debt servicing siphons off funds from investment in public health. World Bank and IMF structural adjustment programs that impose policies—such as requiring copayments from indigent patients—also make it more difficult for those with HIV/AIDS to gain access to medical care. And African governments must do more to support AIDS education and prevention efforts and to destigmatize people with the disease.

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Key Recommendations

- The U.S. should terminate all bilateral pressure on countries for pursuing intellectual property policies designed to make essential medicines more available to those in need.
- The U.S. should cease efforts to incorporate intellectual property protections in new trade agreements, especially those that contain provisions that go beyond TRIPS.
- The U.S. government should license to the World Health Organization all HIV/AIDS drugs that the U.S. government has played a substantial role in developing to ensure widespread distribution in the developing world.

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