

AIDS and Developing Countries: Democratizing Access to Essential Medicines

By Robert Weissman

One in eight 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 the decimated public health systems of developing countries 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 75% or more.

Parallel imports involve imports of a product from one country and resale, without 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. The U.S. government has adopted a similar view, strongly opposing developing country efforts to undertake compulsory licensing, parallel imports, or other similar measures to make HIV/AIDS drugs and other essential medicines more available and affordable to their people.

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.

Despite the legality of compulsory licensing and parallel imports, and despite the public health emergency enveloping much of the developing world, the U.S. has actively opposed developing country efforts to implement compulsory licensing, parallel imports, or other measures to make life-saving HIV/AIDS drugs more affordable and available in their countries. Although it frequently argues—incorrectly—that compulsory licensing and the other measures are WTO-illegal, the U.S. also takes the position that it has the right and authority to demand that countries do even more to protect intellectual property rights than is required by the TRIPS agreement.

To justify this position, Washington echoes pharmaceutical industry claims that compulsory licensing unfairly impinges on corporate intellectual property rights. The companies' unstated, overarching concern is that the United States and other industrialized nations might follow developing countries in pursuing compulsory licensing and parallel imports to lower consumer prices. These industry claims, however, ignore the fact that compulsory licensing is part of the intellectual property system—it is one of the many limitations on patent rights, and patent holders know this when they receive a patent. In the United States, for example, compulsory licenses are regularly issued on products ranging from pesticides to pollution control devices to computer processing chips. And under WTO compulsory licensing rules, companies receive reasonable royalties when a patented invention is used.

The U.S. also champions the pharmaceutical industry's argument that the high cost of research and development (R&D) requires that companies be given freedom to charge whatever they want. But it is unreasonable to give a blank check to anyone who controls life-saving technologies. And several facts cast doubt on industry claims about R&D and profits, especially in the case of the developing world.

First, governments often finance the key R&D costs of important drugs. In the case of HIV/AIDS, for example, the two leading candidates for compulsory licensing are AZT and ddI, both of which were developed at the National Institutes of Health (NIH) at U.S. taxpayer expense. Both drugs have already generated huge profits for drug companies. Second, the drug companies routinely exaggerate the costs of developing new drugs.

Third, since compulsory licensing will increase company sales (as it lowers prices), this policy tool may not harm industry earnings at all, or it may hurt earnings less than initially appears to be the case. If compulsory licensing expands access to AZT and ddI in Africa and the developing world without undermining high prices in the U.S. and Europe, the companies could come out ahead, since they are currently selling so little in developing country markets.

Fourth, developing country markets are a paltry income source for the multinational drug companies—representing only about 10 % of international sales, 1.6 % in the case of Africa. Lower revenues from developing countries, should they occur, would not affect company

R&D efforts or profitability to any significant extent. Application of the intellectual property system in developing countries won't make much of a dent in company profits one way or another, but it can make a huge difference in people's access to medicines.

Finally, there is a moral issue: should people with HIV/AIDS in poor countries be denied available treatments so that companies can earn higher profits? Neither compulsory licensing nor parallel imports involves companies selling their products at a loss.

These are not just academic arguments. The U.S. has exerted extraordinary pressure on developing countries to prevent them from pursuing compulsory licensing and similar strategies to make drugs widely available. Most notably, Washington has undertaken a massive bullying effort to get South Africa to repeal provisions of its Medicines Act that would help the country make essential medicines more accessible and affordable.

A report from the State Department says, "All relevant agencies of the U.S. government—the Department of State together with the Department of Commerce, its U.S. Patent and Trademark Office, the Office of the United States Trade Representative, the National Security Council and the Office of the Vice President—have been engaged in an assiduous, concerted campaign to persuade the government of South Africa to withdraw or modify" the Medicines Act provisions that give the government the authority to pursue compulsory licensing and parallel import policies. The State Department report explains how "U.S. government agencies have been engaged in a full court press with South African officials from the departments of Trade and Industry, Foreign Affairs, and Health" to pressure them to change the law. Vice President Gore has raised the issue repeatedly with South Africa's former Deputy President (now President) Thabo Mbeki.

The United States has withheld certain trade benefits from South Africa and has threatened trade sanctions (by putting South Africa on the "Special 301 Watch List" of countries receiving heightened U.S. scrutiny regarding trading practices) as punishment for Pretoria's refusal to repeal those provisions of its Medicines Act that offend the multinational drug companies. Washington has also enlisted the French, Swiss, and German presidents to raise the issue with top South African officials.

And South Africa is not alone. Washington has undertaken similar actions against other countries—chiefly, Argentina, Brazil, Thailand, and India—that have enacted or considered intellectual property rules that would make essential medicines more affordable to their citizens.

Key Problems

- Without access to existing HIV/AIDS treatments, millions of people in developing countries are sentenced to preventable deaths.
 - Washington is pressuring developing countries not to adopt compulsory licensing and other intellectual property policies that could make HIV/AIDS drugs more affordable.
 - U.S. government positions on intellectual property questions are responsive to corporate greed, not public health needs.
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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 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 South Africa, Thailand, Brazil, Argentina, India, and other countries for pursuing compulsory licensing policies, parallel imports, or any other WTO-legal policy. Instead, Washington should formally

declare that it accepts the legitimacy of compulsory licensing and should immediately lift all sanctions currently in place against countries in retaliation for pursuing any intellectual property policies designed to make vital medicines more available to those in need.

Second, pending legislation should be altered. The African Growth and Opportunity Act currently conditions new benefits to developing countries on whether they enforce "appropriate policies relating to protection of intellectual property rights." Such provisions should either not be enacted into law or should be revised to clarify that "appropriate policies" include compulsory licensing and other measures that help to make life-saving drugs more widely available.

Third, rather than using the millennial round of WTO negotiations in Seattle this fall to tighten intellectual

property requirements related to pharmaceuticals, the U.S. should lead the way in calling for a review of the existing TRIPS agreement and its effect on access to HIV/AIDS and other essential medicines. Among the pertinent questions: Have TRIPS rules undermined the ability of developing countries to maintain domestic pharmaceutical industries? If so, what impact has this had on consumers? Have TRIPS rules promoted new multinational corporate investment in research to treat and prevent diseases of particular concern to developing countries?

Fourth, 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.

Robert Weissman is editor of Multinational Monitor magazine and co-director of Essential Action, a corporate accountability group. He is coauthor of Corporate Predators: The Hunt for MegaProfits and the Attack on Democracy (Monroe, ME: Common Courage Press, 1999; see <http://www.corporatepredators.org>).

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.
- Aid and trade benefits for developing countries should not be conditioned on their intellectual property rules, as the African Growth and Opportunity Act would require.
- The U.S. government should license HIV/AIDS drugs that it has played a substantial in developing to the World Health Organization for widespread distribution in the developing world.



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