



“Free Trade” and Medicines in the Americas

by Robert Weissman, Essential Action

The U.S. is aggressively pushing for negotiation and completion of the Free Trade Area of the Americas (FTAA) agreement, a proposed trade deal involving the economies of 34 countries in the Western Hemisphere, stretching from Canada to Chile. It is effectively an effort to expand NAFTA, the North American Free Trade Agreement, to include all of North, Central, and South America and the Caribbean (except for Cuba).

FTAA negotiations are under way with a scheduled completion date of 2005. Although the negotiating text remains secret, it is clear that the agreement will be modeled on NAFTA. The U.S. has released a summary of its negotiating objectives for the agreement, indicating what Washington would like to achieve.

According to its summary position statement, the U.S. wants to include provisions that would require countries to adopt rules concerning intellectual property rights (IPRs) even more favorable to patent holders than required by the World Trade Organization (WTO).

These new obligations would dramatically limit each country's ability to constrain pharmaceutical pricing to ensure that essential medicines are affordable and accessible. In a variety of ways, the U.S. proposals would limit the ability of countries in the Americas to promote generic competition, including through compulsory licensing. Generic competition is the most important means (along with direct price controls) to reduce drug prices.

Compulsory licensing enables any government to grant a license to a company, govern-

ment agency, or other party to use a patent without the authorization of the patent holder. The Costa Rican government, for example, could issue a license to a local company for an HIV/AIDS drug manufactured by Bristol-Myers Squibb. The Costa Rican firm would then manufacture the drug for sale in Costa Rica under a generic name and would pay a reasonable royalty to Bristol-Myers Squibb on each sale.

The generic competition created by compulsory licensing can lower the price of medicines by as much as 95%. For example, two Indian generic drug makers have offered to supply triple-drug combinations to people

with HIV/AIDS for \$350 per person per year. Aside from very limited discount programs that appear to be available only to African countries, the cost of the same “drug cocktails” produced by brand-name companies is \$10,000 to \$15,000 per person per year.

AIDS is not the only disease causing large numbers of preventable deaths in developing countries, but it is certainly one of the most devastating. Although the HIV/AIDS epidemic in Latin America and the Caribbean is nowhere near as serious as it is in Africa, infection rates are still high. The UN estimates that 1.4 million people have HIV/AIDS in Latin America, with 150,000 people newly infected with HIV in 2000 and more than 80,000 dying from AIDS.

If compulsory licensing brought prices for triple-drug treatments down to even \$500 per person per year, most countries could provide pharmaceutical treatments to their HIV/AIDS populations. Although poor, these countries are considerably wealthier than African nations, and their HIV/AIDS populations are considerably smaller. Thus, universal access to treatment in the region is certainly within reach.

Brazil has led the way in showing how generic production can drive down prices and enable developing countries to make drug treatments universally available. It manufactures generic HIV/AIDS drugs (which are not patent-protected, because Brazil has only recently adopted a WTO-style patent system for pharmaceuticals). By doing so, it can guarantee pharmaceutical treatment to every person with HIV/AIDS.

Brazil has shown that developing countries can administer an effective HIV/AIDS treatment program, providing drugs to those with HIV/AIDS and maintaining high rates of compliance with treatment regimes. It has proven that generic production drives down prices: its cost for drug cocktails is far below that of the multinational pharmaceutical firms, and the price continues to decline. And the Brazilian experience—where infection rates are now roughly half what the World Bank had predicted in 1994—strongly suggests that treatment is an important component of prevention; healthier people are less likely to spread HIV, and people are more likely to be tested for HIV and then adopt safer practices if they know that those with HIV/AIDS have hope of being treated. However, the U.S. thrust in the FTAA negotiations significantly diminishes the prospect of other countries in the Americas emulating Brazil's public health accomplishments in curbing HIV/AIDS and other diseases.

Key Points

- Generic competition is crucial to reducing the price of medicines in developing countries.
- The U.S. is pushing a negotiating agenda for the FTAA that would dramatically limit each country's ability to undertake compulsory licensing, an important tool to promote generic competition.
- The U.S. negotiating position would make it difficult for other countries to emulate Brazil's success in providing treatment to all persons with HIV/AIDS.

Problems with Current U.S. Policy

It is not possible to know exactly what the U.S. is advocating in FTAA negotiations because Washington has only released a summary of its negotiating objectives. Draft FTAA texts remain secret. However, the U.S. summary proposals, along with the recently completed U.S.-Jordan free trade agreement (FTA), provide some insight into the positions for which Washington is lobbying. These include both the basic framework of the WTO's Trade-Related Aspects of Intellectual Property (TRIPS) and a series of ill-advised "TRIPS-plus" measures, which would require countries to adopt intellectual property rules that extend or grant new monopolistic patent and intellectual property claims and diminish the public's rights regarding intellectual property.

Perhaps the most worrisome U.S. initiative would directly limit the grounds for compulsory licensing. Under the U.S.-Jordan FTA, compulsory licenses to achieve a public health aim—even in case of a national emergency—can only be granted to "government entities or legal entities operating under the authority of a government." Under the more permissive TRIPS arrangement, by contrast, compulsory licenses could as a matter of course be granted to private parties for commercial, nonpublic use, so long as TRIPS procedures and rules, including payment of reasonable compensation to the patent holder, are obeyed. TRIPS contemplates compulsory licensing as part of the basic schema of the intellectual property system, not as a limited exception.

If the U.S.-Jordan FTA provisions are adopted as part of the FTAA, it would still be permissible for Argentina, say, to issue a compulsory license to procure lower-priced AIDS or cancer drugs for its public health service. But it would not be possible for a private Argentine drug company to obtain a compulsory license to make lower-priced AIDS or cancer drugs available generally on the market. The narrowing of scope for compulsory licensing would tend to make governments less certain about their authority to use this critical public health tool and more worried about facing domestic lawsuits from industry if they do attempt compulsory licensing—thus inhibiting action to advance public health interests.

A second troubling proposal contained in the U.S. summary of its negotiating objectives for the FTAA would link marketing approval for a drug—based on a finding of safety and efficacy (or bioequivalence to a safe and efficacious product) granted by U.S. Food and Drug Administration (FDA)-equivalent agencies—to patent expiration. Under the U.S. proposal, unless they were sure there were no patent claims on a drug, FDA-equivalent agencies could not grant marketing approval to generics.

There should be no linkage between marketing approval and patent term. If a generic company markets an on-patent drug without license, under TRIPS, the patent holder has adequate remedy under the law. Stated differently, linkage can only serve to protect invalid intellectual property claims since valid claims receive protection through normal judicial means.

A third TRIPS-plus proposal from the U.S. would create new restrictions on the use of "undisclosed" pharmaceutical test data, the study data submitted by drug companies to show that a product is safe and efficacious. To gain marketing approval, generic companies typically show that their product is bioequivalent to a patented product (that is, that the generic is chemically similar and works the same in the human body) and then rely on the patented product's safety data to earn approval.

In many instances, if a generic company cannot use the already-generated registration data, it will not introduce a generic version of the patented product. The price of generating the data may be too high or may take several years to replicate. If the company does choose to regenerate the data, consumers suffer from the delay in the introduction of the generic product that occurs while the generic firm reconducts the relevant tests.

In those countries that establish set terms for registration data exclusivity, the period of exclusivity typically runs shorter than the patent term. Thus, registration data protections are not normally an impediment to the introduction of generics. They are an issue, however, for new drugs that are not patent-protected or in cases of compulsory licensing. If a compulsory license is granted for a drug for which registration data exclusivities remain in force, the data exclusivity can block the generic from gaining marketing approval. An effective system of compulsory licensing must also permit the use of registration data, and this does not appear to be contemplated in the U.S. negotiating position, which seeks to establish for the entire hemisphere a minimum exclusivity period of five years for registration data. In contrast, TRIPS is quite vague on registration data, requiring protection of the data against unfair commercial use but imposing no clear mandates.

A fourth problem with the U.S.' negotiation position is that it calls for patent extensions to offset delays in marketing approval for pharmaceuticals. The result would again be extended monopoly protection for drug manufacturers and further gouging of consumers. TRIPS obligates member countries to grant 20-year patents. Those patents provide a two-decade monopoly on inventions. Patent terms seek to create a balance between providing incentives for inventors and enhancing the public interest by maintaining and promoting competition. The 20-year term manifests such a balance—albeit one tilted in favor of the corporate patenting sector—taking into account the known delays sometimes associated with marketing approval. Adding additional time to the patent term after a balance has been struck improperly favors patent holders.

Key Problems

- If the U.S.-Jordan Free Trade Agreement serves as a model, the FTAA will sharply limit the grounds for issuance of a compulsory license.
 - The U.S. negotiating objectives for the FTAA inappropriately seek to link marketing approval to patent status.
 - The U.S. is attempting in the FTAA negotiations to extend patent terms and create new intellectual property protections that will undermine Latin American and Caribbean country efforts to promote access to affordable medicines.
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Toward a New Foreign Policy

The FTAA negotiating countries are all members of the World Trade Organization and have already committed themselves to adhere to TRIPS. TRIPS establishes a comprehensive international standard for intellectual property protection, with a heavy tilt toward the interests of intellectual property holders. The only reason to include intellectual property provisions in the FTAA is to force countries to adopt TRIPS-plus obligations—many of which are dangerous and injurious to public health.

Key Recommendations

- The U.S. should drop its efforts to include TRIPS-plus provisions in the FTAA.
- Because all FTAA negotiating countries are already members of the WTO and are bound by TRIPS, there is no reason to include any intellectual property provisions in the FTAA.
- The U.S. should stop working to expand monopolistic intellectual property rights and begin to explore protections for the public's rights regarding intellectual property.

Even inclusion in the FTAA of rules identical to the WTO's would be harmful, because if positive changes were achieved in the WTO intellectual property rules, the FTAA countries would still be required to adhere to the old, more restrictive rules. By contrast, if harsher rules were adopted at the WTO, the FTAA countries would be required to adhere to them due to their WTO membership. These overlapping obligations can complicate and sometimes thwart positive reform of international trade rules to enhance public rights.

More than just access to HIV/AIDS medicines is at stake in the FTAA negotiations. People in Latin America and the Caribbean, as well as generally throughout the developing world, are regularly denied access to needed medicines because of price. (Of course, similar problems are not unknown in the U.S.)

Although per capita income is dramatically less in Latin America than in the U.S. or the other rich countries in the Organization of Economic Cooperation and Development (OECD), drug prices in Latin America are comparable to or even higher than those in OECD nations. A pharmaceutical pricing study conducted by Health Action International analyzing more than a dozen frequently prescribed drugs concluded, "The average retail prices of 11 out of 13 dosage forms are higher in Latin America than in the OECD." There are many reasons for these price discrepancies, including the maintenance of price control regimes in many OECD countries and the brand-name companies' differential drug pricing, with higher prices charged in some developing countries where the targeted market is limited to wealthy consumers. The most effective way for Latin American and Caribbean countries to address these pricing problems is through compulsory licensing and promoting generic competition.

It is time for the U.S. to endorse compulsory licensing and to begin to conceptualize ways to expand the public's rights regarding intellectual property. The agree-

ment between the U.S. and the United Kingdom to put basic data about genes in the public domain, rather than allowing this information to be monopolized by private companies, is an example of how public rights can be protected. International agreement is needed in several other areas: to prohibit patents on life forms (the U.S. wants to allow such patents in the FTAA); to guarantee minimum rights for educators, researchers, and others concerning a wide range of "fair use" issues regarding intellectual property for public benefit; to resolve particular difficulties or uncertainties in TRIPS that make compulsory licensing difficult for smaller countries (notably, a requirement that compulsorily licensed products be made primarily for domestic consumption); and to ensure that health and other vital public interests take priority over commercial considerations in the crafting of intellectual property policy.

Washington's foremost challenge is to ensure that no harm is done in intellectual property trade negotiations; this means foregoing intellectual property provisions (especially TRIPS-plus conditions) in the FTAA. Current official U.S. policy is that all health-related concerns regarding intellectual property can be addressed through a "flexible policy," by which the U.S. will review its actions in individual cases to ensure that health is not undermined. But even if it is administered in good faith, such a policy is insufficient on numerous grounds. It does not provide countries with the certainty they need to proceed with compulsory licensing and the promotion of generic competition. It ignores how the very existence of baseline rules tilted against compulsory licensing and access to medicines makes it harder for developing countries to pursue compulsory licensing. Even if the U.S. chooses not to enforce those rules, other countries can still choose to enforce the rules and thus undermine access to generic medicines. And Washington's current flawed policy is based on a very narrow understanding of when legitimate health interests conflict with intellectual property rules.

Finally, provisions of the FTAA outside of the intellectual property sphere pose a series of threats to public health. The services provisions may facilitate the privatization of public health services, and the investment provisions might give corporations standing to sue to block the implementation of environmental and public health regulations or to deny the issuance of compulsory licenses. Protecting public health must be prioritized over commercial interests in these areas as well.

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