The FTAA, Access to HIV/AIDS Treatment, and Human Rights
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FTAA Summit: Reject Tighter Patents on AIDS Drugs
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I. Introduction

Less than a year after the signing of the 2001 Declaration on the TRIPS Agreement and Public Health in Doha, Qatar, parties to the proposed thirty-four-country Free Trade Area of the Americas (FTAA) are revisiting the relationship between intellectual property rights and access to essential medicines. In Doha, 142 member states of the World Trade Organization (WTO) agreed that the minimum patent protections required by the WTOs Trade Related Aspects of Intellectual Property Agreement (TRIPS) cannot and should not be enforced in a manner that limits states right to take measures to protect public health. The Doha Declaration reaffirmed what was already recognized by numerous experts and by TRIPS itself, which is that states must have the flexibility to relax patent protection, and thus lower drug prices, in times of public health emergency. Nevertheless, the draft negotiating text of the FTAA contains proposals which, by exceeding TRIPS in their protection of pharmaceutical patents, narrow the space for public health interventions and thus undermine the global consensus reached in TRIPS and Doha.

The FTAAs TRIPS-plus provisions pose a significant danger to developing countries facing public health emergencies such as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS). Millions of people are infected or affected by HIV/AIDS in Latin America and the Caribbean, many of them subjected to violence, abuse, discrimination, and other human rights abuses. The Doha Declaration recognizes that an effective response to the AIDS epidemic requires flexibility in reconciling public health objectives with private intellectual property rights. As FTAA countries approach the Seventh Ministerial Meeting in Quito, Ecuador in October 2002, they should resist pressure from the Office of the United States Trade Representative (USTR) to adopt a TRIPS-plus patent regime that undermines the Doha Declaration and constrains their efforts to promote the health and human rights of their citizens.

II. Epidemic at a Crossroads

An estimated 1.8 million adults and children are living with HIV in Latin America and the Caribbean. The Caribbean is home to some of the world's highest HIV infection rates after sub-Saharan Africa, with adult HIV prevalence exceeding 4 percent in some countries. For many in the region, the consequences of HIV infection have been the loss of their basic rights and freedoms in addition to their right to life. High-risk populations like injecting drug users and men who have sex with men have experienced increased stigmatization and discrimination as a result of their association with HIV/AIDS. Discrimination against HIV-positive pregnant women, for example in the delivery of health care services, has been reported in Nicaragua and elsewhere in the Americas. In many cases these women represent the poorest, least educated sectors of society and are already marginalized from available public health and welfare services.

Latin America and the Caribbean still have an opportunity to avert an AIDS epidemic of the nature and scale witnessed in sub-Saharan Africa. In Brazil, extensive prevention efforts combined with state-funded antiretroviral treatment have, in the face of widespread poverty, reduced AIDS-related mortality by more than 50 percent since 1996. This reduction has resulted in a U.S. $472 million savings in hospital and treatment costs for AIDS-related opportunistic infections and, according to Brazil's Ministry

of Health, an overall shift in negative attitudes towards people living with HIV/AIDS. The cornerstone of Brazil's treatment program has been the local production of generic equivalents of brand name HIV/AIDS drugs, which has driven down the cost of antiretroviral treatment.

Brazil's national AIDS strategy is within the reach of many Latin American and Caribbean countries. The public sectors in Argentina, Costa Rica, and Uruguay, all parties to the FTAA agreement, have already begun to provide free and universal antiretroviral treatment to their HIV/AIDS populations. Barbados, also a party to the FTAA and estimated to have a 1.2 percent HIV prevalence rate, is preparing to implement a national HIV/AIDS care and treatment program. Although these countries face significant resource constraints, they have both greater resources and smaller AIDS-affected populations than many sub-Saharan African countries. Moreover, Brazil's experience has demonstrated that generic production can reduce drug prices to well below those charged by multinational pharmaceutical companies. These factors have led the Joint United Nations Program on HIV/AIDS (UNAIDS) to conclude that by stepping up their responses to HIV/AIDS now, countries in Latin America and the Caribbean can avert more extensive AIDS epidemics.

III. TRIPS and Doha

Countries wishing to emulate Brazil's relative success face an international patent system that restricts the production of generic equivalents of patented HIV/AIDS drugs. Under TRIPS, member states of the WTO are required to grant pharmaceutical companies twenty-year monopolies on all technological innovations and to submit to a binding system of WTO dispute resolution. Countries who are or will become TRIPS-compliant and who wish to lower drug prices by introducing available generic drugs into their domestic markets must either obtain the consent of patent-holders or work within the framework set forth in the TRIPS agreement. Among the mechanisms specified in TRIPS are compulsory licensing, whereby states authorize generic production without the patent-holder's consent, and exclusions on patent admissibility for certain products. TRIPS permits countries facing a national emergency or other circumstances of extreme urgency to issue compulsory licenses without first attempting to obtain the patent-holder's consent, which is normally required.

When the body governing TRIPS, the TRIPS Council, met in June 2001, several African countries insisted on an examination of the tension between the emerging global intellectual property regime and the global health crisis. Representatives of these countries were concerned that key provisions of TRIPS, such as those governing compulsory licensing and national emergencies, be interpreted in a manner supportive of their need to address rapidly expanding AIDS epidemics. The pharmaceutical industry, backed by a few developed countries, maintained that protection of monopoly patents furthered public health objectives by creating an incentive for companies to invest in pharmaceutical research and development. Yet the issue before the TRIPS Council was not the existence of patents themselves, but the duration and scope of patent protection in the context of acknowledged public health emergencies. Indeed, TRIPS itself recognized that for countries to ensure an affordable supply of essential medicines, they sometimes needed to be able to make exceptions to full patent protection.

The initiative of African countries led in November 2001 to the Declaration on the TRIPS Agreement and Public Health (the Doha Declaration), which clarified that TRIPS does not and should not prevent Members from taking measures to protect public health. Instead, TRIPS can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. The Doha Declaration was agreed to by 142 WTO member states including the United States. It encourages states to make full use of the TRIPS provisions allowing for protection of public health interests, such as the following:

- Each provision of TRIPS is to be interpreted in light of the agreements objectives and principles. Objectives include, for example, the the transfer and dissemination of technology, and principles include the idea that members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition (Article 5(a))
- Member states have the right to grant compulsory licenses and to determine the grounds for granting

such licenses. As noted above, compulsory licenses authorize production of a patented product without permission from the patent-holder, subject to payment of a reasonable royalty. (Article 5(b))

- Member states have the right to determine what constitutes a national emergency. When an emergency is declared, a government need not attempt to obtain authorization from the patent-holder before issuing a compulsory license. The Declaration specifies that public health crises may qualify as national emergencies. (Article 5(c))
- Each member state is free to establish its own regime for the exhaustion of patents. This means that TRIPS does not extend patent protections to secondary sales of patented products. Countries can also allow parallel imports, or cross-border trade in a product without permission of the patent-holder. Because patent-holders sell at different prices in different markets, countries with limited resources can buy drugs at the lowest world price and then redistribute the drugs domestically. (Article 5(d))

The principal thrust of the Doha Declaration is that any expansion of intellectual property rights must be balanced by the right of access to health care. Specifically, the Declaration reinforces the right of member states to use generic drugs and market competition to make the provision of medicines possible in situations of public health crisis.

The Doha Declaration has been applauded and affirmed by a broad global consensus. In April 2002, the United Nations Commission on Human Rights passed by consensus a resolution welcoming the Doha Declaration and agreeing that the TRIPS Agreement does not and should not prevent World Trade Organization members from taking measures to protect public health. The World Health Organization similarly lauded the Doha Declaration in a statement to the TRIPS Council in March of this year: The Declaration enshrines the principle WHO has publicly advocated and advanced over the last four years, namely, the re-affirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPS Agreement in order to protect public health and promote access to medicines.

In addition to signing the Declaration, the United States further codified its commitment to Doha in its 2002 Trade Promotion Authority (TPA) Act, which specifies respect for the [Doha] Declaration as one of the objectives of the TPA. Meanwhile, the United States and other developed countries have continued to make use of the framework affirmed by the Doha Declaration for their own domestic purposes. When faced with an anthrax scare, both Canada and the United States used the threat of compulsory licensing to negotiate heavily discounted rates on Ciprofloxacin, an antibiotic that treats anthrax. President Bush recently introduced rules to quicken the approval of generic drugs in the U.S. market.

IV. After Doha: TRIPS-plus in the FTAA

Despite the global consensus reached in TRIPS and Doha, the USTR is currently negotiating bilateral and multilateral agreements that go beyond TRIPS in their protection of pharmaceutical patents. The FTAA is the largest and perhaps most significant of these independent agreements. The USTR is negotiating objectives and the draft text of the FTAA disclose several ways in which the current FTAA draft would undermine the right of member states to protect public health:

Restrictions on compulsory licensing

Recent bilateral agreements such as the U.S.-Jordan Free Trade Agreement, as well as certain proposals in the FTAA draft, restrict the grant of compulsory licenses a method at the center of the Doha Declaration to public parties. TRIPS contains no such bar. A prohibition on licenses to private parties would impede the production of necessary medicines in countries where the government lacks the capacity to produce medicines itself.

The FTAA draft also contains proposals that would preclude countries from exporting products created under compulsory licenses. This prohibition would nullify the benefit of compulsory licensing to countries where neither public nor private sector has the capacity to produce necessary medicines. The Doha Declaration explicitly requires the TRIPS Council to find an expeditious solution by which countries that lack production capacity can nonetheless take advantage of compulsory licenses. An FTAA prohibition on export of compulsorily licensed products would render such a solution impossible in the Americas.

Expanding patent protection
Several proposals in the FTAA draft would widen the already-expansive protections provided to patent-holders. For example, the draft includes proposals for patent extensions to offset delays in marketing approval for pharmaceuticals. TRIPS already requires twenty-year patents on all technological innovations; extensions for marketing approval would lengthen that period of monopoly protection even more, delaying further the generic competition on which the Doha Declaration centers.

Other proposals in the draft would heighten the penalties for patent violations. The USTR has recommended punitive compensation, criminal sanctions, and injunctions where the burden of proof would lie on the infringing party. Such strict penalties could deter countries from fully exercising the very exceptions that Doha seeks to uphold.

Biasing the regulatory regime
Some proposals in the FTAA draft would require state agencies granting marketing approval for generic drugs i.e., the U.S. Food and Drug Administration and its equivalents to predicate marketing approval on the expiration of existing patents. This requirement, which is not present in TRIPS, would delay one of the prerequisites for generic drug distribution until patent expiration, and thereby make it more difficult for generic drugs to reach the market immediately after a patent expires. The requirement would push health and safety agencies into the task of patent enforcement, would be redundant with judicial remedies for patent infringement (which TRIPS already requires), and would further extend protection afforded by patents at the expense of public health.

The USTR has also advocated five-year protection of undisclosed pharmaceutical test data, which is the data submitted by drug companies to show a drug′s efficacy. So long as this data is not available, generic manufacturers must either wait to introduce a generic product or replicate the studies themselves. For the first five years of any patented drug′s existence, this protection would delay any country seeking to exercise its Doha-affirmed right to issue compulsory licenses.

Creating investors rights that hamper public health
The draft chapter of the FTAA dealing with investment would further empower foreign investors against governments in ways that threaten governments' ability to exercise their rights under Doha. For example, some proposals would prohibit governments from imposing performance requirements on investors. A common performance requirement is a commitment to engage in technology transfer which, in turn, is among the objectives of TRIPS whose importance Doha reasserted.

Certain FTAA proposals would also expand investor protections against expropriation. At their most extreme, such proposals could increase the compensation due to a patent-holder in the event of compulsory licensing from reasonable royalties, which are granted under TRIPS, to the full market value of a patent. Finally, some FTAA proposals would grant companies standing to sue governments in FTAA-specific tribunals for alleged violations of the investment chapter of the agreement. This new legal remedy would be over and above TRIPS' existing requirement that states provide domestic adjudicative relief for intellectual property infringements. As in other areas of the FTAA, these dramatic expansions of protections for patent-holders are likely to deter member states from successfully exercising their right to protect public health under Doha.

V. What′s Wrong with TRIPS-plus?
The advent of TRIPS-plus does not correspond with any new consensus about the appropriate balance between private intellectual property rights and public health. On the contrary, experience and research have only reaffirmed the potential dangers to public health of excessive patent protection. The Commission on Intellectual Property Rights, which was convened by the United Kingdom government and included a wide cross-section of experts, found in September 2002 that the international intellectual property system was a constraining factor on access to health care and health care technologies. The Commission stressed that profits from the global intellectual property system do little to stimulate research on diseases that particularly affect poor people. The Commission explicitly affirmed the Doha

Declaration, and encouraged developing-country governments to use compulsory licensing and generic competition to increase access to essential medicines.

At the same time, HIV/AIDS has continued to push middle and low-income nations across the world to the brink of national emergency. At the XIV International AIDS Conference in Barcelona in July 2002, UNAIDS cautioned that without effective treatment and care, the five million people newly infected by HIV in 2001 would die by decades end. Months later, the National Intelligence Council (NIC) estimated that the number of HIV-infected people in five next wave countries Nigeria, Ethiopia, Russia, India, and China would, by 2010, exceed the number of cases in central and southern Africa. The NIC singled out Brazil's treatment program as a source of hope in the AIDS struggle, noting that Brazil's successful emphasis on treatment and the expanded use of antiretroviral drugs has raised hopes for improving the length and quality of life for HIV/AIDS patients. Yet as the international medical humanitarian organization Medecins Sans Frontieres has recently observed, hundreds of thousands of people with HIV/AIDS in developing countries in the Americas do not have access to antiretroviral treatment simply because they cannot afford it.

The FTAA's TRIPS-plus proposals are particularly troubling given that the USTR itself, in the negotiating objectives section of the TPA, purports to be complying with the Doha Declaration. In fact, each of the foregoing TRIPS-plus proposals erodes the Doha Declaration by narrowing and deterring the exceptions whose full use Doha encourages. They do so despite a continued, widespread consensus that TRIPS exceptions provide an essential tool in the provision of affordable HIV/AIDS medicines. By advocating TRIPS-plus provisions in the FTAA, the USTR is clearly betraying its public commitment to helping developing countries fulfill their obligation to protect public health.

The FTAA is not the only context in which the USTR is advocating TRIPS-plus patent protections. Public health flexibilities may also be endangered by bilateral trade and/or intellectual property agreements between the U.S. and individual countries. The U.S. is currently negotiating such agreements with Chile, Singapore, a block of Central American countries, and Morocco, among others. TRIPS-plus measures would raise the same concerns if imposed country by country as they would if incorporated in multilateral agreements like the FTAA.

VI. TRIPS-plus and Human Rights

AIDS is a fatal disease. The cost of impeding access to available and affordable AIDS medication is the sickness and premature death of millions of adults in the prime of their lives, with disastrous consequences for their children and their communities. In some countries, AIDS is threatening to wipe out generations of food producers and contribute to famine and further death. While access to affordable antiretroviral therapy is not a complete solution to these problems, it prolongs the lives of parents and extended families members, strengthens their ability to support their families and communities, and reduces much of the discrimination and stigma associated with the disease. As Brazil's experience has shown, antiretroviral therapy also enhances AIDS prevention efforts by creating an incentive to be tested for HIV and receive lifesaving information about the virus transmission.

The International Covenant on Economic, Social and Cultural Rights (ICESCR) has been ratified by all thirty-four parties to the FTAA except Barbados and the United States. Article 12 of the ICESCR guarantees the right of everyone to the highest attainable standard of physical and mental health, which has been interpreted by the United Nations to include a system of urgent medical care in cases of accidents, epidemics and similar health hazards, as well as the provision of essential drugs for prevalent diseases. In its near-unanimous resolution 2001/33 of April 2001, to which the United States abstained, the United Nations Commission on Human Rights (CHR) recognized that access to medication in the context of HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

States parties to the ICESCR have both the right and the obligation to ensure that their intellectual property regimes facilitate such access. In a November 2001 Statement on Intellectual Property and

Human Rights, the U.N. Committee on Economic, Social and Cultural Rights emphasized that any intellectual property regime that makes it more difficult [for a state party] to comply with its core obligations in relation to health, food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party. Similarly, a May 2001 World Health Assembly resolution entitled "Strengthening health systems in developing countries" noted that lack of access to essential medicines was a significant factor perpetuating health care inequality and recognized the sovereign right of each country to adopt national policies appropriate to the specific needs of its people. States that attempt to introduce generic competition into their markets in order to facilitate access to HIV/AIDS medication are therefore endeavoring to fulfill their obligations under the ICESCR.

As a signatory to the ICESCR, the United States has an obligation not to take actions that defeat that treaty's object and purpose (see Vienna Convention on the Law of Treaties, article 18). The entire international community also has an obligation, according to CHR resolution 2001/33, to facilitate, wherever possible access in other countries to pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS and to ensure that the application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable pharmaceuticals and medical technologies. The efforts of the United States to discourage other nations from guaranteeing access to affordable HIV/AIDS drugs contravene its obligations as an ICESCR signatory.

VII. Conclusion

Though developing countries face inordinate barriers in their struggles against AIDS, one glimmer of hope has been the development of safe, effective anti-retroviral drugs by governments, research institutes, and private pharmaceutical companies. These drugs are a vital part of the limited arsenal countries have in preventing and managing the medical effects of AIDS and thereby securing the human rights of their citizens. By insisting on a particular patent regime at the behest of multinational pharmaceutical companies, one that goes beyond even what is contained in TRIPS, the USTR is betraying an international consensus reached at Doha and arbitrarily interfering with developing countries' good faith efforts to improve and lengthen the lives of their citizens.

Recommendations

To the United States' trading partners:

- Undertake a thorough review of the implications of mandatory intellectual property standards for programs and policies related to HIV/AIDS prevention and treatment. Pending such a review, resist pressure by the United States Trade Representative to include proposed TRIPS-plus provisions in the FTAA or in bilateral trade agreements.

To the United States Trade Representative:

- Refrain from using bilateral trade negotiations and WTO dispute resolution mechanisms to discourage countries from fulfilling their public health objectives as contemplated in the Doha Declaration. Promote flexibility in determining appropriate levels of national patent protection rather than making access to United States markets conditional upon a TRIPS-plus patent regime.

To all parties to the FTAA:

- Include a provision in the FTAA stipulating that nothing in the agreement may be interpreted so as to limit states' right to take measures to promote public health. Specify that the FTAA should and will be interpreted in conformity with the Doha Declaration.