



# FTAA: Protectionism for US Drug Industry

## AFFORDABLE AIDS MEDICINE DENIED IN LATIN AMERICA

November 2003 • Health GAP (Global Access Project) briefing document

Contact: [info@healthgap.org](mailto:info@healthgap.org) • [www.healthgap.org](http://www.healthgap.org) • +1 267.475.2645 tel

**Summary:** The intellectual property rights provisions proposed by the United States Trade Representative (USTR) in the draft text of the FTAA pose a serious threat to access to affordable medicines and public health in Latin America and the Caribbean. If adopted, these provisions would require FTAA countries to uphold a much higher standard of protection and enforcement of intellectual property rights (IPRs) on medicines than is already required of them by the World Trade Organization (WTO). The USTR has sought in every bi- and multilateral negotiation to undermine generic competition and the availability of affordable medicine.

Countries in the region have used the generic medications to protect public health. One such example is Brazil's free AIDS drug program, which treats more than 110,000 people with HIV primarily with generic medicines. By using affordable, high quality generics, mortality rates have declined by over 60% in Brazil. Tougher protection for patents on medicines jeopardizes the expansion and replication of life-saving drug access initiatives.

IPRs should be excluded from the FTAA. All FTAA countries are WTO members, and already protect and enforce IPRs according to the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). In order to protect public health and promote access to medicines for all, countries should support the removal of IPRs from FTAA negotiations, as well as from negotiations of other regional and bilateral free trade agreements (FTAs) in the Western Hemisphere.

### **Background: the access crisis**

Of the 42 million people living with HIV worldwide, 1.9 million live in Latin America and the Caribbean. Approximately 400,000 of these people are estimated to be in urgent need of antiretroviral treatment in order to stay alive. The deadly gap in access to medicines is not limited to HIV treatment. AIDS is only one example of larger crisis in access to affordable treatment for public health problems in the region.

At the Doha Ministerial in November 2001, the WTO's 146 Member States signed the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration).

High drug prices associated with patent monopolies are a key barrier to achieving broader treatment access in public and private health sectors. The Doha Declaration states that WTO rules regarding IPRs, established in the TRIPS Agreement, "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."<sup>1</sup> This declaration affirmed the right of all WTO Members to put public health first when implementing TRIPS by permitting exceptions to patent monopolies to create generic competition and decrease the cost of medicines.

**Compulsory licensing**—licensing the manufacture of a patented medicine to companies without the consent of the patent holder—is the most important of these public health tools. Compulsory licensing results in reduced medicine prices because it stimulates generic competition before a patent expires. The Doha Declaration asserted that WTO Members could grant compulsory licenses and also determine the grounds upon which compulsory licenses should be granted.

Developed country WTO Members, in particular the U.S., working with the U.S. pharmaceutical lobby, have frequently exerted bilateral pressure on poor countries to prevent the use of

compulsory licensing and other flexibilities to promote access to medicines. The end result is that no developing nation has ever been able to issue a compulsory license.

The Doha Declaration also reaffirmed that WTO Members could **parallel import** medicines. Parallel importation is importation, without the consent of the patent-holder, of a product marketed in another country by the patent-holder or by another authorized party. The U.S. has also exerted negative trade pressures on countries seeking to exercise their right to do parallel importation of medicines.

### ***The United States Trade Act of 2002***

This Trade Act lists among "the principle negotiating objectives of the United States regarding trade related intellectual property" the following objective: "...to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001."

The Doha Declaration represented a major step forward: it gave countries assurance that, despite years of trade sanctions and the threat of sanctions from wealthy countries protecting the interest of pharmaceutical companies, WTO Members support a pro-public health interpretation of TRIPS.

Finally, the Doha Declaration extended the timeline for Least Developed Countries (LDCs) to 2016 for protecting patents on pharmaceuticals (without prejudice to an LDC's right to request additional TRIPS extensions from the WTO).

### ***Threats to affordable medicines access***

Although the U.S. signed the Doha Declaration, the USTR has used every opportunity to reverse and undermine this policy in each subsequent bi- and multilateral trade negotiation—including the FTAA. The USTR aggressively pursues regional and bilateral trade rules that create higher standards of protection and enforcement of IPRs than required by TRIPS.

<sup>1</sup> 20 Nov 2001. Declaration on the TRIPS Agreement and Public Health. WT/MIN(01)/DEC/7

U.S. law mandates that USTR negotiate the IPR provisions of trade agreements in a manner that respects the Doha Declaration (see Box 1). But the USTR consistently violates this obligation. The public negotiating position of the USTR on IPRs shows clearly that the USTR is seeking TRIPS-plus rules in the FTAA, without consideration for the public health impact.<sup>2</sup>

Generic competition is already facilitating increased access to HIV treatment in the region. This competition has been possible because many medicines used in HIV treatment are not on patent in the region. However, as countries are required to respect patents on newer medicines, generic competition will only be possible through compulsory licensing. The FTAA and CAFTA would undermine countries' right to grant compulsory licenses and reduce the cost of medicines. Two examples of price reductions attained in the Western Hemisphere would be impossible to duplicate in the future if the IPR rules of FTAA and CAFTA are accepted as written:

1. **Negotiations in June 2003** between the Pan-American Health Organization (PAHO), drug companies, and Andean countries resulted in significant price reductions for generic antiretrovirals—to about \$400 per year.

2. **In October 2003, the Clinton Foundation** negotiated a price reduction in the generic combination of nevirapine, lamivudine (3TC) and stavudine (d4T) to \$132 per patient per year, available in the Caribbean as well as in four African countries.

**All FTAA member countries are WTO Members already obligated to uphold the TRIPS rules on IPRs. The position of the United States Trade Representative (USTR) is to commit the Western Hemisphere to new, tougher protection and enforcement of intellectual property rights, despite the negative impact on public health and access to medicines. The United States is doing this to delay or prohibit competition from generic drug manufacturers, and to protect the US pharmaceutical industry. The cost of this policy is the lives of people with AIDS in central and South America.**

***The following TRIPS-plus provisions in the FTAA will jeopardize public health and access to medicines if adopted by FTAA countries:***

• **Extension of the patent term: The U.S. is seeking longer patent terms than the twenty years already required by TRIPS, to compensate for delays in securing marketing approval. This extension of the patent term will keep less expensive generic products off the market, longer. The U.S. has already secured this provision in the U.S.- Chile FTA.**

• **5 years of exclusivity for test data:** The U.S. is seeking a hemisphere-wide minimum of 5 years of exclusive rights for test data. Originator companies submit test data to national drug regulatory authorities to establish the safety and efficacy of their product. Manufacturers seeking to manufacture generic medications must have access to these data in order to prove bioequivalence. TRIPS requires protection against the “unfair commercial use” of test data, but it does not require the granting of exclusive rights for originator companies.

Granting 5-years of data exclusivity would have the affect of establishing a 5-year ban on compulsory licensing (see Box 3). This TRIPS-plus ban will function as a 5-year patent monopoly—even where patents do not exist.

• **New compulsory licensing restrictions:** WTO Members have the freedom to determine the grounds upon which to grant compulsory licenses. This principle was reaffirmed by the Doha Declaration. The U.S. issues compulsory licenses regularly, but would undermine the effective use of this public health tool in the FTAA and CAFTA. The U.S. wants to limit compulsory licensing to government use for only three circumstances: non-commercial use, situations of national emergency or other situations of extreme urgency, and to remedy anticompetitive practices. Compulsory licensing to remedy excessive pricing or other forms of patent abuse would be prohibited.

• **Blocking export of compulsorily licensed pharmaceuticals:** On August 30, 2003 the WTO reached a temporary agreement that permits countries to issue compulsory licenses to export generic versions of patented medicines to countries that have no or insufficient domestic manufacturing capacity. Proposed FTAA text would prohibit compulsory licensing for export altogether.

FTAA countries that cannot produce medicines themselves would be unable to obtain low cost drugs from a foreign manufacturer in a country where a patent is on file. This is in direct conflict with the August 30 WTO agreement.

• **Linking drug regulatory approval to patent status: The U.S. is lobbying for the expansion of the authority of national drug regulatory bodies, so they have the power to deny approval for generic products if there is a patent claim on file. Patent holders have existing judicial means through which to assert their claims; linking the work of drug regulators to patent claims would only serve to increase the risk that bogus patent claims would delay the market entry of generics.**

#### **Data exclusivity in Guatemala**

In Guatemala, patent barriers on HIV medicines do not exist. However, the USTR pressed the Guatemalan government in April 2003 to consent to a TRIPS-plus standard of 5 years of exclusivity on pharmaceutical test data. This standard will block the entry of low cost generics and undermine access to life-saving medicines.

**Recommendations:** The WHO, public health experts, activists, and others have all recommended that the terms of the Doha Declaration set the maximum level of obligation for protecting and enforcing IPRs for poor countries.

The standard for intellectual property protection established by TRIPS and reaffirmed by the Doha Declaration is stringent enough. The principle endorsed by the Doha Declaration—that public health and access to medicines take priority over pharmaceutical companies' commercial interests—will be undermined by USTR's negotiating objectives. Therefore IPRs should be removed from FTAA negotiations, as well as other trade agreements in the region.

<sup>2</sup> e.g. “FTAA Negotiating Group on Intellectual Property: Public Summary of U.S. Position”