



6 East 39th Street, 8th Floor
New York, NY 10016

Tel: 212.679.6800
Fax: 212.679.7016

doctors@newyork.msf.org
www.doctorswithoutborders.org

May 1, 2002

Chair of the Committee of Government Representatives on the Participation of Civil Society
c/o Secretaria del Area de Libre Comercio de Las Americas (ALCA)
Apartado Postal 89-10044
Zona 9, Ciudad de Panama
Republica de Panama

Sent Via E-mail to soc@ftaa-alca.com

To Whom It May Concern:

We are pleased to submit these comments on the Draft Free Trade Area of the Americas (FTAA) Agreement on behalf of Doctors Without Borders/Médecins Sans Frontières (MSF) in response to the Notice of Issuance by the FTAA Committee of Government Representatives on the Participation of Civil Society of a Third Open Invitation for Public Comment. These comments focus entirely on the potential negative consequences of FTAA on access to essential, life-saving medicines in developing countries in the Americas.

MSF is an independent, international medical humanitarian organization that delivers emergency aid to victims of armed conflict, epidemics, natural and man-made disasters, and to others who lack health care due to social or geographic marginalization. MSF operates over 400 medical relief projects in nearly 90 countries throughout the world. The organization was awarded the 1999 Nobel Peace Prize. That same year, MSF launched an international Access to Essential Medicines Campaign, which grew directly out of the frustration of MSF doctors and nurses who were increasingly unable to treat their patients because the medicines they needed were too expensive, no longer effective, or simply did not exist. Too often in the countries where MSF works, we have been forced to watch our patients die because they cannot afford the drugs that could improve, extend, or save their lives, and for us this is simply unacceptable. MSF currently has a field presence in many countries in the Americas, including Bolivia, Brazil, Colombia, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, and Peru.¹ Teams provide medical care for people with HIV/AIDS, malaria, Chagas' disease, leishmaniasis, trachoma, and other diseases, as well as primary care, maternal/child health care, and other services for displaced and homeless populations and for indigenous people.

¹ Additional MSF offices in the region are in Argentina, Canada, Costa Rica, and the U.S.

UNDERMINING THE ACHIEVEMENTS OF DOHA

The 4th Ministerial Conference of the World Trade Organization (WTO), which took place in Doha, Qatar, in November 2001, was a breakthrough in the international debate about the impact of the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) on access to medicines. One hundred and forty two countries adopted a Declaration on the TRIPS Agreement and Public Health, driven largely by developing countries, which firmly placed public health needs above commercial interests and offered much needed clarifications about key flexibilities in the TRIPS Agreement related to public health. The very fact that public health, and in particular access to medicines, has been singled out as an issue needing special attention in TRIPS implementation acknowledges that health care and health care technologies must be treated differently from other commodities and gives countries leeway for taking measures to counter the negative effects of excessive intellectual property protection on health. The FTAA threatens to undermine the achievements in Doha. In particular, the U.S. negotiating position gives rise to serious questions about their true motives in agreeing to the Doha Declaration.

The Doha Declaration must remain a ceiling for international trade negotiations on intellectual property rights as they relate to public health technologies, and FTAA negotiators must not renege on the agreement reached in Doha.

PATENTS, PRICES & PATIENTS: THE EXAMPLE OF HIV/AIDS

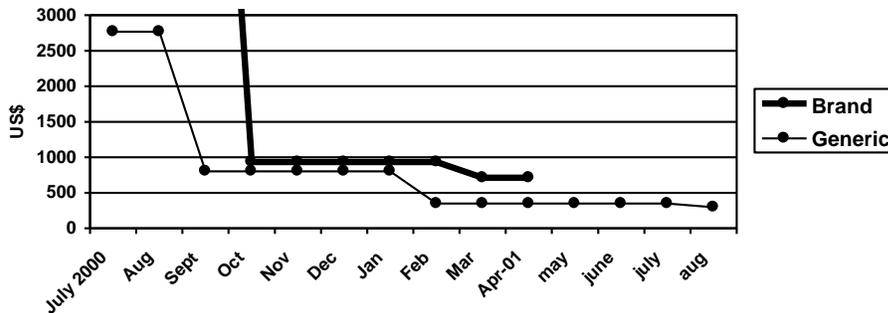
According to the World Health Organization, there are currently 1.8 million people living with HIV/AIDS in Latin America and Caribbean, and 110,000 AIDS deaths were recorded in the region in 2001. The Caribbean is the second-most affected region in the world, after sub-Saharan Africa. In several Caribbean countries, HIV/AIDS has become a leading cause of death.² The AIDS epidemic is having major consequences for tropical infectious diseases in the region, such as Chagas' disease (American trypanosomiasis) and tuberculosis. Hundreds of thousands of people with HIV/AIDS in developing countries in the Americas do not have access to antiretroviral therapy—which, in wealthy countries such as the U.S., has dramatically extended and improved the lives of people living with HIV/AIDS, reducing AIDS-related deaths by over 70%³—simply because they cannot afford it.

Price is not the only reason that people do not get the medicines they need, but it is a major barrier. As MSF and other non-governmental organizations have been pointing out for over two years, the high cost of medicines is often linked to patents. Patents give their owners a monopoly to use, manufacture, sell, and import the patented product and therefore to sell it at the most profitable price, which may not be the most equitable price in most developing countries. As shown in the table below, generic competition is crucial to ensuring downward pressure on drug prices—as we have witnessed in countless instances in the field, particularly with antiretrovirals for the treatment of HIV/AIDS.

² http://www.unaids.org/worldaidsday/2001/Epiupdate2001/EPIupdate2001_en.doc - Accessed April 20, 2002.

³ According to the U.S. National Institute of Allergies and Infectious Diseases (at the National Institutes of Health) and the Centers for Disease Control and Prevention, the estimated annual number of AIDS-related deaths in the United States fell approximately 70 percent from 1995 to 1999, from 51,117 deaths in 1995 to 15,245 deaths in 2000. This drop is attributed primarily to the introduction of highly active antiretroviral therapy (HAART). Centers for Disease Control and Prevention (CDC). *HIV/AIDS Surveillance Report 2001*; 13 (no.1):1-41.

The Effects of Generic Competition
Sample AIDS Triple-Combination: Lowest World Prices
(stavudine (d4T) + lamivudine (3TC) + nevirapine)



Just two years ago, the average cost of a triple combination of antiretrovirals was between \$10,000-\$15,000 per patient per year, and today it is available for as little as \$300 per patient per year. These price reductions were the direct result of international public pressure and generic competition, particularly from Indian and Brazilian manufacturers. Generic competition was possible because of the lack of patent protection in those countries. In the coming years, such competition will not be possible due to the filing of patents on pharmaceuticals in key developing countries with manufacturing capacity, unless flexible conditions for granting compulsory licenses are available, as per the Doha Declaration, and compulsory licenses are routinely issued to address public health concerns. Compulsory licensing of pharmaceuticals is one of the most important policy tools for ensuring generic competition.

The case of AIDS drug prices helps illustrate what is to come when all new pharmaceutical products will be patent protected in 2006, after most WTO members have implemented the TRIPS Agreement.⁴ For all these new medicines, generic competition will be stamped out. As a consequence, prices of new medicines will inevitably shoot up, far beyond the means of patients in need. The lever that has brought the price of AIDS drugs down will be lost.

POTENTIAL IMPLICATIONS FOR ACCESS TO MEDICINES IN POOR COUNTRIES IN THE AMERICAS

It is clear in information about the FTAA negotiating objectives of the United States made public by the Office of the U.S. Trade Representative (USTR)⁵ that the U.S. is pushing to impose standards on pharmaceuticals that far exceed requirements set forth in the TRIPS Agreement, and that, in some cases, these standards directly contradict the spirit and letter of the Doha Declaration, which clearly recognized concerns about the effects of patents on prices and stated unambiguously that TRIPS 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.”⁶

⁴ Recently extended to 2016 for least-developed countries, as per the WTO Declaration on the TRIPS Agreement and Public Health, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

⁵ See <http://www.ustr.gov/regions/whemisphere/intel.pdf> - Accessed April 30, 2002.

⁶ To view the full Declaration, see http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

Field Code Changed

In contrast, the U.S. proposal includes several key points, which will have a direct and negative impact on access to essential medicines in the Americas, including, but not limited to:

1. DRAMATIC LIMITATIONS ON THE CIRCUMSTANCES UNDER WHICH COMPULSORY LICENSES ON PHARMACEUTICALS MAY BE ISSUED

Although the Doha Declaration has reaffirmed the right of WTO Member countries to issue a compulsory license for whatever reason (not only in cases of emergency), the U.S. proposal explicitly provides that compulsory licenses shall be granted *only* in four limited circumstances (public non-commercial purposes, situations of a declared national emergency, other situations of extreme urgency, or declared anti-competitive practices) and solely for purposes of government use. Should such a provision be adopted, it would cancel the possibility of granting compulsory licenses to remedy patents abuses, such as excessive pricing, and to foster competition in the private sector to increase access to patented essential medicines.⁷

2. EXTENSIONS OF PATENT TERMS ON PHARMACEUTICALS BEYOND THE 20-YEAR MINIMUM IN TRIPS

The U.S. proposes to extend the term of a patent in exchange for “early registration of generics”⁸ and to compensate for unreasonable administrative or regulatory delays that occurred while granting the patent⁹. This is not required by the TRIPS Agreement and a WTO panel expressly stated that such patent extensions do not constitute a “legitimate interest” of patent owners.¹⁰

3. ABUSIVE POWERS TO REGULATORY AUTHORITIES TO ENFORCE PATENTS

The U.S. proposes that drug regulatory authorities notify the patent owner of the identity of any company that is seeking approval to market a generic version of the patented invention while the patent is in effect. This effectively means that drug regulatory authorities will function as patent enforcement agencies and is likely to result in unjustified patent extensions. Such a proposal can only serve to protect invalid patent claims, as valid claims receive adequate protection through normal judicial processes.¹¹

4. EXCLUSIVE RIGHTS OVER PHARMACEUTICAL DATA

This refers to clinical information that is generally required by drug regulatory authorities to approve the marketing of a new medicine. Although the TRIPS Agreement only requires WTO Members to protect these “undisclosed test or data” against “unfair commercial use” and “disclosure” in the framework of unfair competition law, the U.S. is proposing to grant exclusive rights on these data for at least five years. Such a proposal will result in delaying and limiting

⁷ As shown in the graph on page 2.

⁸ Often referred to as “Bolar” exception.

⁹ Another proposal is based on the lack of human, technical and financial resources of developing and least-developed countries that very often do not undertake their own examination of patent applications and rely on examinations made in developed countries. Therefore, the U.S. proposed that, when a patent in country A has been granted on the basis of an examination made in country B, the patent term in Country A should be extended by a period equal to the period of protection in country B.

¹⁰ Canada - Patent protection of pharmaceutical products - Complaint by the European Communities and their member states (WT/DS114/R).

¹¹ See also Essential Action comments in response to USTR request for public comment on FTAA draft text, August 22, 2001, Rob Weissman – available at <http://lists.essential.org/pipermail/pharm-policy/2001-August/001422.html>

generic competition in cases where a patent does not exist or a compulsory license has been granted.

CONCLUSION

All the proposals outlined above have been described by Carlos Correa of the University of Buenos Aires, a leading expert on integrating public health concerns into patent legislation in developing countries, as “clearly TRIPS-plus.”¹² The U.S. negotiating objectives for FTAA aim to strengthen patent rights beyond what is required in TRIPS, and reduce the extent of the safeguards to the detriment of public health. If the U.S. achieves its negotiating objectives, FTAA will annul the achievements of the Doha Declaration on the TRIPS Agreement and Public Health and could have devastating consequences in terms of access to medicines for millions of people in middle- and low-income countries in the Americas with HIV/AIDS and other neglected diseases. For them, this is a matter of life and death.

Sincerely,

Nicolas de Torrente
Executive Director
MSF USA

Olaf Valverde, MD
Field Physician & Regional Coordinator,
Access to Essential Medicines Campaign
MSF Guatemala

cc: Ambassador Robert Zoellick, United States Trade Representative (USTR)
Ambassador Peter Allgeier, Deputy USTR
Joseph Papovich, Assistant USTR for Services, Investment, and Intellectual Property
Claude Burcky, Deputy Assistant USTR for Intellectual Property

¹² *Inter Press Service*, April 2, 2001. Note that “‘TRIPS-plus’ is a non-technical term which refers to efforts to: extend patent life beyond the 20-year TRIPS minimum; limit compulsory licensing in ways not required by TRIPS; and limit exceptions which facilitate prompt introduction of generics. Since the public health impact of TRIPS requirements have yet to be fully assessed, WHO recommends that developing countries be cautious about enacting legislation that is more stringent than the TRIPS requirements” (*WHO Policy Perspectives on Medicines*, No. 3, March 2001).