MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

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

February 28, 2003

Ambassador Robert Zoellick
U.S. Trade Representative
Office of the U.S. Trade Representative
Washington, DC 20508

Sent Via E-mail at FR0060@ustr.gov

Dear Ambassador Zoellick,

I am pleased to submit these comments to the Office of the United States Trade Representative (USTR) on behalf of Doctors Without Borders/Médecins Sans Frontierès (MSF) in response to USTR's Request for Public Comments on the Second Draft Consolidated Texts of the Free Trade Area of the Americas (FTAA) Agreement. These comments focus entirely on the potential negative consequences of FTAA on access to essential medicines in developing countries in the Americas. MSF is deeply concerned that provisions in the FTAA Agreement related to intellectual property rights (IPRs) threaten to undermine the historic World Trade Organization (WTO) Ministerial Declaration on the TRIPS Agreement and Public Health, resulting in 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.

We wish to reiterate our demand that USTR abandon "TRIPS-plus" negotiating objectives and negotiate FTAA in keeping with the spirit and letter of the Doha Declaration, which the U.S. committed to uphold in November 2001. In order to ensure that countries, including the U.S., uphold that commitment in good faith, we must recommend that intellectual property provisions be excluded from the final FTAA Agreement altogether.

BACKGROUND: MSF

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. We operate over 400 medical relief projects in over 80 countries throughout the world. The organization was awarded the 1999 Nobel Peace Prize. 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.

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

According to the World Health Organization, there are currently 1.9 million people living with HIV/AIDS in Latin America and Caribbean. 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.

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 absence 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 World Trade Organization (WTO) Ministerial Declaration on the TRIPS Agreement and Public Health, 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. If FTAA creates a system that blocks use of equivalent but cheaper drugs, it will be a catastrophe for our patients and for all people in the Americas, because the difference in price can be the difference between life and death.

PREVIOUS MSF COMMENTS ON FTAA

MSF has raised concerns publicly about the First Draft Consolidated Texts of the FTAA Agreement and the U.S. negotiating objectives in particular, calling repeatedly on USTR to ensure that the Doha Declaration remains a ceiling for FTAA negotiations on IPRs as they relate to public health technologies.[5] The U.S. negotiating objectives would impose standards on pharmaceuticals that far exceed requirements set forth in the TRIPS Agreement, and 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] MSF submitted official comments regarding the First Draft Consolidated Texts (Chapter on Intellectual Property Rights[7]) to the

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[2] http://www.unaids.org/worldaidsday/2002/press/update/epiupdate2002_en.doc - Accessed February 27, 2003

[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.

[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] Available at http://www.ustr.gov/regions/whemisphere/intel.pdf - Accessed February 27, 2003

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

[7] Available at http://www.ftaa-alca.org/ftaadraft/eng/ngip_e.doc

Committee of Government Representatives on the Participation of Civil Society on May 1, 2002, in accordance with the official procedures.[8] We also delivered testimony summarizing our comments on September 9, 2002, at USTR's Public Hearing Concerning Market Access in the FTAA Negotiations. Specifically, we have raised concerns about U.S. proposals that would:

1. Dramatically limit the circumstances under which compulsory licenses on pharmaceuticals may be issued;
2. Extend patent terms on pharmaceuticals beyond the 20-year minimum in TRIPS;
3. Confer abusive powers to regulatory authorities to enforce patents; and
4. Grant exclusive rights over pharmaceutical data.

At the VII FTAA Ministerial Meeting in Quito in October 2002, the negotiating position of the U.S. was unchanged, and all of the provisions that MSF has raised concerns about in previous communications remain in the second draft text. We therefore wish to reiterate our demand that USTR abandon "TRIPS-plus" negotiating objectives and negotiate FTAA in keeping with the spirit and letter of the Doha Declaration. Toward that end, we have elaborated below upon proposals in the Chapter on IPRs of the second draft text that will be harmful to public health.

The promise of Doha—to which the U.S. and all other WTO members committed themselves in November 2001—is that 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."[9] But it is clear that the FTAA Agreement threatens to make it impossible for countries in the Americas to exercise the rights reaffirmed in Doha. In order to ensure the protection of public health and the promotion of access to medicines, we therefore must recommend that intellectual property provisions be excluded from the final FTAA Agreement altogether.

TRANSPARENCY OF FTAA NEGOTIATIONS

Despite numerous statements by FTAA negotiators indicating the importance of carrying out negotiations in a transparent manner, the text of the second draft is almost entirely in brackets, and all footnotes have been omitted from the draft text, making it impossible to know which proposals are attributed to which governments. We therefore urge USTR to insist on the inclusion of footnotes that would clearly indicate the various negotiating positions advanced by the 34 countries that are parties to the Agreement. The inclusion of footnotes would increase the level of transparency in the negotiations and greatly enhance efforts to engage in an informed public debate about crucial issues in the FTAA Agreement.

COMMENTS ON INTELLECTUAL PROPERTY PROVISIONS IN THE SECOND DRAFT CONSOLIDATED TEXTS OF THE FTAA

Part I of the Chapter on Intellectual Property Rights of the Second Draft Consolidated Texts of the FTAA sets forth general provisions and principles and Part II sets forth specific provisions for various types of intellectual property. There are several important references in Part I to the Doha Declaration on the TRIPS Agreement and Public Health. These references are extremely important to ensure that the Chapter on IPRs of the FTAA Agreement does not eliminate the gains achieved in Doha, namely the acknowledgment of the primacy of public health over private commercial interests. Should the final text of FTAA provide for stronger protection to patent owners than is required by the TRIPS Agreement, this agreement will be binding on all 34 FTAA countries and have primacy over the TRIPS Agreement and

[8] Available at http://www.accessmed-msf.org/prod/publications.asp?scntid=6520021213325&contenttype=PARA&
[9] To view the full Declaration, see http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

the Doha Declaration. Once the final agreement is signed, FTAA Member States will not be able to invoke the Doha Declaration to remedy patent abuses and take measures contrary to FTAA to protect the public health of their populations.

One of the most important paragraphs of the Declaration, paragraph 4, is quoted in Article 1.4 of Part I of the second draft FTAA Agreement:

[No provision of this Chapter prevents, and should not prevent, any Party from adopting measures to protect public health, and it should be interpreted and implemented in a manner that takes into account each Party's right to protect public health and, in particular, to promote access to existing medicines and to the research and development of new medicines.]

The spirit of this proposal should be wholeheartedly supported by USTR. Nothing more is required in reference to intellectual property rights as they relate to public health technologies.

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), proposals in the second draft of the FTAA Agreement would dramatically limit the circumstances under which compulsory licenses on pharmaceuticals may be issued. MSF urges USTR to reject the inclusion of any clause in Section 5, Article 5 (Part II) that would impose more stringent conditions than the TRIPS Agreement requires for the granting of compulsory licenses. In particular, MSF brings to your attention, Section 5, Article 5.1. (a) (Part II):

[The authorization shall be granted only for public non-commercial purposes or in situations of a declared national emergency or other situations of extreme urgency].

Should this proposal be adopted, it would eliminate 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. Furthermore, limiting the granting of compulsory licenses to emergency situations in FTAA may lead parties to the FTAA Agreement to draw the conclusion that compulsory licensing under TRIPS is only designed to address national emergencies or other circumstances of extreme urgency. This is clearly not the case and was a battle fought time and time again before Doha. Recent negotiations at the WTO TRIPS Council meeting on Paragraph 6 of the Doha Declaration again illustrate that the inclusion of a national emergency clause would limit when countries could issue a compulsory license and is therefore not in the best interest of all countries. It was soundly rejected by Member States and should be similarly rejected in FTAA negotiations.

2. Extensions of patent terms on pharmaceuticals beyond the 20-year minimum in TRIPS

The TRIPS Agreement obligates WTO members to provide patent protection on medicines for 20 years. Proposals in the second draft text provide for an unjustifiable extension of patent terms. Twenty-year patents are more than enough—indeed they may be considered excessive—to allow the pharmaceutical industry to recoup investments made in research and development, if such investments were made.

Section 5, Article 8.2 (Part II) states:

[8.2. Each Party, at the request of the patent owner, shall extend the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than four years from the date of filing of the application in the Party, or two years after a request for examination of the application has been made, whichever is later, provided that periods of time attributable to actions of the patent applicant need not be included in the determination of such delays.]

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] It is critically important that the terms of pharmaceutical patents not exceed what is required in TRIPS and not allow for possible extensions. To extend patent terms on pharmaceuticals beyond the 20-year minimum required in TRIPS would be detrimental to countries as it would limit or delay generic competition. In addition, it is well known that patent offices worldwide, especially small ones with limited resources, are overwhelmed with an increasing number of patent applications. Article 8.2 will penalize small patent offices, and may result in the granting of "bad quality" patents for lack of necessary time of examination. We therefore urge USTR to reject this language.

Section 5, Article 8.3 would impose patent term standards of rich countries (which are often longer than 20 years) on poor countries, which very often rely on rich countries' patent examination for lack of technical resources.

[8.3. Where a Party provides for the grant of a patent on the basis of an examination of the invention conducted in another country, that Party, at the request of the patent owner, shall extend the term of a patent granted under such procedure by a period equal to the period of the extension, if any, provided in respect of the patent granted by such other country.]

This proposal must also be rejected.

3. Abusive powers to regulatory authorities to enforce patents

Proposals in the second draft text include provisions that would require drug regulatory authorities to 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.

Section 10, Article 1.5(a) (Part II) states:

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

[1.5. Where a product is subject to a system of marketing approval pursuant to paragraphs 1.2 or 1.4 and is also subject to a patent in the Party:
a) the Party shall not approve an application to market a product on the basis of information in an earlier marketing approval for the same product where that application has been filed by a party other than the recipient of the original marketing approval or with his consent, and shall not otherwise authorize a third party to market the same product, prior to the expiration of the patent….]

We urge USTR to reject this proposal, as it 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

Although the TRIPS Agreement only requires WTO Members to protect clinical information that is generally required by drug regulatory authorities to approve the marketing of a new medicine ("undisclosed test or data") against "unfair commercial use" and "disclosure" in the framework of unfair competition law, proposals in the second draft text would grant exclusive rights on these data for at least five years.

Section 10, Article 1.2 and 1.4 states:

[1.2. If a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product prior to permitting the marketing of such product, such Party shall not permit third parties not having the consent of the party providing the information to market the same or a similar product on the basis of the approval granted to the party submitting such information for a period of at least five years from the date of approval.[12]] …

[1.4. If a Party provides a means of granting approval to market products specified in paragraph 1.2 on the basis of the grant of an approval for marketing of the same or similar product in another Party, the Party shall defer the date of any such approval to third parties not having the consent of the party providing the information in the other Party for a period of at least five years from the date of approval in the Party or the date of approval in the other Party, whichever is later.]

Such proposals will result in delaying and limiting generic competition in cases where a patent does not exist or a compulsory license has been granted. We urge USTR to reject these proposals.

CONCLUSION

The U.S. negotiating objectives for FTAA and the proposals outlined above in the second draft text of the FTAA Agreement aim to strengthen patent rights beyond what is required in TRIPS, and reduce the extent of TRIPS safeguards to the detriment of public health. If the FTAA creates a system that undermines and contradicts the Doha Declaration, blocking use of affordable generic medicines, it will be a catastrophe for our patients and millions of others in the Americas with HIV/AIDS and other diseases.

[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

[12] [Where a Party, on the date of its implementation of the TRIPS Agreement, had in place a system for protecting pharmaceutical or agricultural products not involving new chemical entities from unfair commercial use which conferred a period of protection shorter than that specified in paragraph 1.2 that Party may retain such system notwithstanding the obligations of said paragraph.]

One hundred and forty two countries, including the U.S., negotiated and adopted the Doha Declaration, firmly placing public health needs above commercial interests and offering much needed clarifications about key flexibilities in the TRIPS Agreement related to public health. We have repeatedly stated that the Doha Declaration must remain a ceiling for international trade negotiations on intellectual property rights as they relate to public health technologies and called upon the U.S. government to work with other FTAA negotiators to ensure that the final draft of the FTAA Agreement does not renege on the historic agreement reached in Doha.

The TRIPS Agreement already establishes comprehensive standards for IP protection in WTO members, which protect sufficiently the interests of IP holders. The promise of Doha is that 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."[13] The FTAA Agreement threatens to make it impossible for countries in the Americas to exercise the rights re-confirmed in Doha. As a medical humanitarian organization, we cannot accept the subordination of the health needs of our patients and millions of others to U.S. trade interests. In order to ensure the protection of public health and the promotion of access to medicines, we therefore must recommend that intellectual property provisions be excluded from the final FTAA Agreement altogether.

Sincerely,

Nicolas de Torrente
Executive Director

cc: Ambassador Peter F. Allgeier, Deputy U.S. Trade Representative and Co-Chair of the FTAA Trade Negotiations Committee
Regina Vargo, Assistant USTR and Vice-Ministerial Representative to the FTAA
Karen M. Lezny, Deputy Assistant USTR for the FTAA
Andrea C. Malito, Director for the FTAA Co-Chairship
Russell F. Smith, Acting Director, FTAA
Kira Alvarez, Director for Intellectual Property Rights and Head of U.S. Delegation, FTAA Negotiating Group on Intellectual Property
Cristina Sevilla, Director for Intergovernmental Affairs and Head of U.S. Delegation, FTAA Committee of Government Representatives on the Participation of Civil Society

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