MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

333 Seventh Avenue, 2nd Floor
New York, NY 10001-5004

Tel: 212.679.6800
Fax: 212.679.7016
doctors@newyork.msf.org
www.doctorswithoutborders.org

Contact: **Judit Rius**
Campaign For Access to Essential Medicines
Judit.Rius@newyork.msf.org

SUBMISSION TO THE U.S. TRADE REPRESENTATIVE REGARDING THE 2011 SPECIAL 301 REVIEW PROCESS

15 FEBRUARY 2011

Executive Summary

Doctors Without Borders/Médecins Sans Frontières (MSF) would like to submit the following comments to the 2011 Special 301 Review Process and request to testify at the hearing that USTR has announced for March 2, 2011.

MSF is an independent, international medical humanitarian organization that delivers medical care to patients in over 60 countries, our projects focus on the medical needs of poor people living in developing countries whose medical needs are often the most neglected.

MSF is concerned about the effects that heightened intellectual property regimes and high prices being imposed on developing countries by the United States Trade Representative (USTR) will have on access to affordable generic medicines for our patients and medical operations, as well as on the lack of innovation adapted to the needs of the resource-poor settings where we work. Populations in developing countries are denied access to medicines, vaccines, and diagnostic tools either because they do not exist due to inadequate incentives for the development of appropriate and effective tools; or because they exist but are not available in their countries due in part to intellectual property barriers and high costs.

MSF is concerned by the U.S. Government's continued use of trade pressures to challenge efforts by developing countries to ensure access to medicines for their populations, and to drive countries to implement intellectual property measures into their domestic laws above those required by international trade law. The Special 301 mechanism is only one tool that the U.S. government has used to this end.

We urge the U.S. Government to abstain from threatening with trade sanctions developing countries that are trying to respond to public health needs using policies and flexibilities allowed under international trade law.

The United States Trade Representative (USTR) demands not only directly undermine the commitments made by the U.S. government under the WTO Doha Declaration on the TRIPS agreement and public health and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, but also create a fundamental contradiction between U.S. trade policy and the U.S. government commitments and priorities on global health and development.

We further urge USTR to align itself with the access to medicines policies pursued by the U.S. government. During the January 2011 128th Executive Board of the World Health Organization the U.S. government made a very powerful intervention in support of generic competition to lower the price of HIV/AIDS treatment in developing countries. Recognizing that pharmaceutical price discounts do not always have as much impact on bring down prices as robust generic competition does, it urged companies to join the recently created Medicines Patent Pool in order to increase generic competition for newer HIV/AIDS drugs, as the U.S. National Institute of Health (NIH) has recently done. We welcome these statements and the NIH leadership.

PEPFAR itself has reported cost savings of up to 80 percent through the purchase of Indian generic medicines. Other U.S. Government-funded schemes, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, are heavily reliant on the cost savings realized through competition between quality generic medicines. Yet the USTR continues to undermine both PEPFAR and the Global Fund and treatment providers such as MSF by threatening trade repercussions against countries who use the flexibilities in international trade law that allow for generic competition to continue.

The USTR presents the Special 301 process and its efforts to demand stronger regimes of intellectual property protection to developing countries as a tool to protect innovation. MSF recognizes the importance of innovation and the need to finance research and development processes. We are a humanitarian medical organization that needs and welcomes biomedical innovation to better treat our patients. However the reality is that intellectual property protection in the medical field creates access problems due to high prices and does not stimulate innovation for many of the diseases affecting people in developing countries, where patients have limited purchasing power. By seeking greater and higher intellectual property norms in developing countries, the U.S. government through USTR is perpetuating a failed business model that links innovation costs to high prices and does not address the innovation needs of developing countries. Higher intellectual property norms are a sledgehammer designed to protect commercial interests in the possibility of monopolizing richer segments in developing countries, not public health, and its weight falls on the poorest. It is too blunt an instrument as currently applied to serve the health needs of millions of people in the developing world.

There are better and newer ways for the U.S. government to protect and promote innovation currently being piloted and under discussion at the WHO. Ways that would combine innovation and access, instead of denying access to affordable medical technologies and delaying the

adaptation and innovation of better products to allow our medical teams to better serve the needs in the poor-resource environments where we work.

For all the reasons stated in this submission, MSF urges USTR in its 2011 Special 301 Review Process to refrain from:

- using the Special 301 process to increase pressure on developing countries to implement intellectual property measures into their domestic laws beyond the requirements contained in international law, including TRIPS Plus provisions like data exclusivity;

- using the Special 301 process against developing countries acting within their legal rights to overcome intellectual property barriers in response to the health needs of their populations, or against countries embracing TRIPS flexibilities to ensure access to medicines such as compulsory licenses or patentability criteria's; and

- using the Special 301 process to impose new intellectual property enforcement norms that would hurt access to medicines, such as those included in the ACTA agreement.

Rather than using the Special 301 Review Process as a unilateral tool to impose a heightened intellectual property regime on developing countries, the U.S. government should use its laws, policies, and financial resources to ensure that developing countries exercise the full flexibilities available to them to ensure access to medicines for all.

This will mean:

- that the Doha Declaration play a prominent role in shaping U.S. policy on access to medicines in developing countries;

- that the U.S. government encourages countries to fully implement the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, including the use of incentive mechanisms that separate research and development incentives from high prices, for example through the use of innovation inducement prizes that reward innovations that improve health outcomes and permit open competition for products; and the creation of new global norms on research and development, including a possible biomedical R&D treaty.

- that the U.S. government advance an agenda supportive of both innovation and access to affordable medicines in developing countries, and ensure that U.S. trade policy is aligned with the U.S. global health and development agenda;

- that the U.S. government conducts impact assessments of the effects that USTR demands would have not only on access to medicines and innovation by patients living in developing counties but also in U.S. supported donor efforts like PEPFAR and the Global Fund.

- that the U.S. government supports a system capable of delivering adapted and affordable drugs that respond to patients' needs. This should include continue with the promotion of open licensing of all publically funded biomedical research and development for use in the developing world, following up with NIH recent announcement of its license on a AIDS medicines to the Medicines Patent Pool.

Finally, MSF would like to also request that the USTR facilitate that other civil society and interested stakeholders from around the world, especially from developing countries where USTR policies have greater effect, are allowed to express their views in the public hearing.

I - BACKGROUND

Médecins Sans Frontières

Doctors Without Borders/Médecins Sans Frontières (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 medical relief projects in over 60 countries throughout the world. Our teams provide medical care for people with HIV/AIDS, malaria, malnutrition, tuberculosis, Chagas, leishmaniasis, and other diseases, as well as primary care, maternal and child health care, and other services for displaced, homeless populations and for indigenous people.

We seek increasing access to and affordability of lifesaving medicines and diagnostic tools in developing countries and to stimulate the development of urgently needed better tools for people in countries where MSF works.

MSF is concerned about the barriers posed by intellectual property protections in ensuring access to medicines. Populations in developing countries are denied access to medicines, vaccines, and diagnostic tools either because they do not exist due to inadequate incentives for the development of appropriate and effective tools; or because they exist but are not available in the global South due in part to patent barriers and high costs.

The magnitude of the access to medicines crisis

The problem of access to medicines extends to any new drug, diagnostic test or vaccine needed to treat, detect or prevent a range of diseases affecting the people we treat in developing countries.

It is important to note that the problem of access to medicines is not limited to HIV/AIDS and other communicable diseases. The global burden of non-communicable diseases is increasing worldwide, with the heaviest burden falling on the low- and middle-income countries. However the magnitude of the HIV/AIDS pandemic has not only highlighted the fact that millions in the developing world do not have access to medicines needed to treat disease or alleviate suffering

because they or their governments cannot afford them, but also the benefits that generic competition has had in reducing the cost of treatment.

More than five million people across the developing world are on antiretroviral treatment (ART). This success would not have been possible without generic competition bringing the price of first line ART down by 99 percent, from over $10,000 in 2000 to under $80 today.

MSF provides treatment to 160,000 people in more than 30 countries and sources more than 80 percent of its anti-retrovirals from India. PEPFAR itself has reported generics representing 88 percent of PEPFAR-funded ARVs in 2009 and a cost savings of $300 million over four years. Such cost savings has enabled PEPFAR to expand service delivery to reach more new people in 2010 than in any previous year[1].

The success of PEPFAR also lies, in part, in the ability of partner governments to scale-up services using national resources. In South Africa, an improved tender allowing more generic competition for the largest national ARV program availed the government of the best world-wide price of generics resulted in a 53.1 percent reduction in cost, which allows South Africa to treat twice as many people on ARVs."[2] The cost for a generic pediatric version of one ARV was cut in half from the price previously paid to the brand-name manufacturer[3].

Other U.S. Government-funded schemes, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, are heavily reliant on the cost savings realized through competition between quality generic medicines.

While this represents important progress, approximately ten million more people are in immediate need of treatment according to new 2010 WHO treatment guidelines, a testament to the emergency that is the HIV-AIDS pandemic.

The new WHO HIV-AIDS treatment guidelines revisions support recent evidence showing that starting treatment earlier (when people's CD4 cell count drops to 350 instead of 200 cells/mm3) improves survival and reduces illness, in particular tuberculosis (TB) – the number one killer of people living with HIV/AIDS. Data published from MSF's project in Lesotho shows that providing people with treatment earlier (at a CD4 cell count above 200) led to reductions in

---

[1] Holmes C, Coggin W, Jamieson D, et al. Use of Generic Antiretroviral Agents and Cost Savings in PEPFAR Treatment Programs. JAMA. 2010; 304(3):313-320 (doi:10.1001/jama.2010.993)

[2] Department of Health. Massive reduction in ARV prices. South Africa Department of Health, 14 Dec 2010. Available: http://www.info.gov.za/speech/DynamicAction?pageid=461&sid=15423&tid=26211

[3] Section27 and Treatment Action Campaign. SECTION27 and TAC Applaud Successful ARV Medicine Tender – But Call for Continued Actions to Drive Prices of Essential Medicines Down Further. 15 November 2010.

deaths (by 68%), reductions in new diseases (by 27%), reductions in hospitalization (by 63%), and reductions in defaulting from care (by 39%)4. With growing numbers of patients in developing countries having been on treatment for five years or longer, new challenges are emerging to ensure their long-term survival. As resistance to medicines inevitably develops, people on antiretroviral treatment will need to be switched to newer, more expensive drugs. MSF data shows how this will impact the cost of treatment programs – the WHO-recommended second-line treatment is around 4.4 times more expensive than the most affordable first-line regimens, and expected third-line regimens are estimated to cost over $2,200 for one year's treatment. Further, the WHO guidelines reinforce the importance of moving towards the use of better-tolerated medicines such as tenofovir, and away from older, more toxic medicines such as stavudine.

The importance of TRIPS flexibilities

India became a key source of affordable medicines because the country did not grant patents on medicines. This meant that affordable generic versions could be produced freely by multiple producers, bringing prices for the most-commonly-used AIDS treatment combination down.

However since 2005, all member countries of the World Trade Organization (WTO), except the least developed ones, have the obligation to fully implement the WTO Agreement on Trade-Related Aspects of Intellectual Property Right (TRIPS Agreement) and to grant patents for pharmaceutical products and processes.

The full implementation of the TRIPS Agreement has created an important threat to generic competition and has made crucial that countries are not only allowed but also encouraged to implement legal intellectual property regimes in a way that ensures continued access to lifesaving medicines.

As re-affirmed by all WTO Members States, including the United States, in the 2001 WTO Doha Declaration TRIPS Agreement and Public Health, under international law countries have the right and the obligation to interpret and implement the TRIPS Agreement, "in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".

Implementing the TRIPS Agreement with a pro-public health perspective, includes allowing the use of flexibilities and safeguards such as:

- the rights to define patentability criteria,

---

[4] Ford N, Kranzer K, Hildebrand K et al. Early initiation of antiretroviral therapy and associated reduction in mortality, morbidity and defaulting in a nurse-managed, community cohort in Lesotho. AIDS 2010, 24: 2645-2650

- the right to define data protection provisions,
- the right to not have to use public money or public authorities to enforce patents including to not link drug registration with patent status, and
- the right to issue compulsory licenses,
- the right to define enforcement appropriately within the confines of the TRIPS Agreement, and
- the right to parallel importation.

Such flexibilities will be critical in ensuring that newer drugs, including those that the WHO expects to form the cornerstone of future preferred first, second, and third-line AIDS treatments, can be brought within the reach of people in developing countries.

II - MSF COMMENTS TO USTR ON THE SPECIAL 301 REVIEW PROCESS

MSF would like to submit the following written comments to the 2011 Special 301 Review Process. MSF would also like to testify in the public hearing that USTR has announced for March 2, 2011 and provides this document as a request to testify and a summary of MSF's hearing statement.

MSF would like to also request that the USTR facilitate that other civil society and interested stakeholders from around the world, especially from developing countries where USTR policies have greater effect, are allowed to express their views in the public hearing.

Higher and inadequate standards of intellectual property are a direct threat to generic competition and to the treatment that we provide to our patients. In submitting these comments, MSF is concerned about the difficulties in both ensuring access to medicines and exploring new incentive mechanisms for research and development relevant to our patients and our medical operations in developing countries. Populations in developing countries are denied access to medicines, vaccines, and diagnostic tools either because they do not exist due to inadequate incentives for the development of appropriate and effective tools; or because they exist but are not available due in part to intellectual property barriers and high costs.

Specifically, MSF is concerned by the U.S. government's use of unilateral trade pressures such as the Special 301 review process to challenge efforts by developing countries to ensure access to medicines for their populations when trying to use flexibilities allowed under international law, like compulsory license, data protection or patentability criteria. The future of generic competition, the sustainability of treatment and the possibility of new incentive mechanisms and business models relevant to our patients in developing countries is further threatened by the increased intellectual property protection that the U.S. government is asking developing countries to adopt. The United States is aggressively advancing a TRIPS-Plus agenda, seeking for intellectual property protections more extensive than those under international law and the WTO TRIPS agreement.

The U.S. Trade Representative demands not only directly undermine the WTO Doha Declaration and the WHO Global Strategy and Plan of Action, but also **create a fundamental contradiction between U.S. trade policy that pushes developing countries to introduce high IP standards and the U.S. government's commitments and priorities on global health and development which rely on generic products to fund its programs.**

In times of economic crisis, the USTR is not only perpetuating a failed incentive model to protect big pharmaceutical corporate interests but also threatening the possibility of more affordable competition in the treatment of diseases relevant to patients living in developing countries. USTR is ignoring the broader U.S. Government and the international community that are not only recognizing but urging on the need for sustainable, cost-effective and innovative strategies to solve global health needs.

As mentioned, the United States government has on several occasions recognized the importance of generic competition in ensuring access to treatment for patients living in developing countries. In September 2010, the White House announced that the National Institute of Health (NIH), supported by the US Government, would be the first to license patents on an anti-retrovirals used to treat people with HIV/AIDS to the recently created Medicines Patent Pool to help bring prices down by encouraging competition among multiple producers; and facilitate new medicine formulations, including versions for children and versions in which several drugs are combined into a single pill.

Most recently, during the January 2011 128th Executive Board of the World Health Organization the U.S. Government made a very powerful intervention in support of generic competition to lower the price of HIV-AIDS treatment in developing countries, recognizing that pharmaceutical companies strategies of differential pricing do not always have the impact on the pricing that robust generic competition does.

International organizations and experts have also raised their concerns on the important threat that TRIPS Plus provisions pose to access to medicines. In December 9 2010, UNAIDS issued a request for trade agreements not to "hinder efforts towards universal access to HIV prevention, treatment, care and support". "The flexibilities set out in the Doha Declaration and the TRIPS Agreement to protect public health and provide access to medicines for all must not be undermined by other trade agreements," said UNAIDS Executive Director Michel Sidibé. The statement further added that "In this current economic climate, resources for AIDS have already flattened and need for treatment continues to outstrip supply. Trade agreements that place additional burdens on the manufacture, import or export lifesaving medicines—so-called 'TRIPS plus' measures such as 'data exclusivity—and incorrect interpretations of the term 'counterfeit' should be avoided."

The U.S. government has the capacity and the obligation to incorporate concerns regarding access to medicines centrally into U.S. trade policy. Indeed, the United States did this in part with the Clinton Administration Executive Order 13155 on HIV/AIDS Pharmaceuticals and Medical Technologies, prohibiting the U.S. government from seeking TRIPS-plus measures regulating HIV/AIDS-related medicines and technologies in sub- Saharan Africa.

More recently, in May 10, 2007 the U.S. government under the Bush Administration announced a New Trade Policy for Peru, Panama and Colombia and a bipartisan House and Senate agreement to include important public health flexibilities in the Free Trade Agreements negotiated with these three countries. Patent-registration linkage and patent extensions were made optional for developing countries and although the data exclusivity demand remained TRIPS plus, some flexibility was included in the data exclusivity language. Peru has already incorporated some of these flexibilities in its national law.

The 2010 Special 301 List was the first review done under the new Administration and we were disappointed that most of the issues that we raised in our 2010 submission were unaddressed and the process was one more year used to pressure developing countries to adopt heightened intellectual property regimes and limit their use of public health flexibilities. However, it is fair to acknowledge that in 2010 the USTR created a process for public hearing, which we welcome although it still has many challenges, for example, because civil society from developing countries were not provided with the opportunity to participate. Furthermore, the 2010 Special 301 report included a more robust recognition of the Doha Declaration and a partial endorsement the New Trade Policy by considerably improving the language on patent-registration linkage for some countries.

In our 2011 submission, MSF would like to urge USTR to go one step further and give content to expressions included in past Special 301 report like "the United States reiterates its support for the 2001 Doha Declaration on the TRIPS Agreement and Public Health." We urge the US government to fully honor and implement paragraph 4 of the Doha Declaration that reads as follows: "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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."

The Doha Declaration requires that the TRIPS Agreement is implemented in such a manner that it allows for measures to ensure access to medicines for all. In order to do so USTR must refrain from pressuring countries to amend their laws or undermine implementations of their international obligations that promote access to medicines.

In our 2011 submission, we would like to highlight different public health policy measures that we believe are essential for developing countries to be able to use and USTR to respect in order to ensure access to medicines. MSF would like to request that USTR not list any country in the Special 301 List process or threaten trade sanctions for the use or consideration to use any of the following public health policy safeguards or flexibilities:

(1) The right to define data protection provisions

The United States government has been using the Special 301 Review Process and other trade tools to force developing countries to implement data protection provisions with a data exclusivity regime.

Data exclusivity is a TRIPS Plus demand because it is not required by TRIPS which obligates countries only to protect from *unfair commercial use* of *undisclosed* data, the origination of which involves a *considerable effort* and that is used to register *new chemical entities*.

Data exclusivity has important negative effects on access to medicines because it creates a new monopoly for the originator of the data and allows pharmaceutical companies to block the registration of generic medicines until the period of exclusivity expires, whether or not patent protection is in place. Data exclusivity has been shown to raise the price of medicines wherever it has been adopted, including studies in Jordan[5] and Guatemala[6].

When data exclusivity laws are in force, a generic manufacturer and the national regulatory authorities are prohibited from relying on the pharmaceutical or biological test data submitted by the originator company. Generic companies are forced to delay generic entry or to duplicate clinical trials and generate their own clinical data. The requirement to re-test a drug already proven to be safe and effective is medically unethical, because it forces the unnecessary duplication of clinical trials in patients and animals, and requires some patients to take placebos in order to compare outcomes with the actual drug and therefore forego a proven treatment.

Further, data exclusivity regimes could make important patent flexibilities like patent compulsory licenses ineffective. Even if a company is given authority to produce a generic drug under a compulsory license, it still needs to register the drug with the national drug regulatory authority. Data exclusivity would prevent such registration for the period of exclusivity, and thereby prevent the effective use of a compulsory license during that time[7].

In our 2010 submission, MSF requested that USTR not list countries for not adopting data exclusivity regimes. However, in the 2010 Special 301 report a number of developing countries were listed including key generic producing countries. Countries listed included Algeria, Argentina, Brazil, Chile, China, Dominican Republic, Ecuador, Egypt, India, Indonesia, Lebanon, Malaysia, Mexico, Paraguay, Pakistan, Venezuela and Vietnam.

---

[5] Oxfam briefing paper – All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines.

[6] Ellen R. Shaffer and Joseph E. Brenner, A Trade Agreement's Impact On Access To Generic Drugs, Health Affairs, 28, 5 (2009): w957-w968 (Aug. 2009)

[7] WHO SEARO Briefing Note: Data Exclusivity and Other TRIPS Plus". March 2006. Available at: http://www.searo.who.int/en/Section1243/Section2599_15088.htm

In our 2011 submission we would like to reiterate the importance of USTR respecting the right of member states to implement their data protection obligations without a TRIPS Plus data exclusivity regime.

The Case of India: the Pharmacy of the Developing World

India plays a critical role in supplying the developing world with affordable quality generic medicines, and has been called the 'pharmacy of the developing world.' MSF purchases more than 80 percent of the AIDS medicines it uses to treat 160,000 people with HIV/AIDS from producers in India. We're not the only ones - a recent study found that more than 80 percent of donor-funded purchases of HIV medicines from 2003-2008 were sourced from producers of affordable generics in India[8].

But this source of affordable medicines is under threat if USTR and other developed countries push for stronger levels of intellectual property protection. Data exclusivity is particularly dangerous in India because it could even apply to drugs that do not merit a patent under the strict patentability criteria in Indian's law or that are subject to a compulsory license. If India accepts data exclusivity, even if a drug was not found to merit a patent, only the originator company would be allowed to produce for a period of up to ten years, thereby completely undermining the public-health flexibilities in India's patent law.

(2) The right to define patentability criteria

According to the WTO TRIPS Agreement, countries have an obligation to grant patents on pharmaceutical products and processes, but the question of what criteria to use to define what is patentable is left for countries to determine. Countries have the right to determine patentability criteria in the area of pharmaceuticals in light of their own social and economic conditions. Some governments have done precisely that and have chosen strict national patentability criteria to make sure that in compliance with article 27 of TRIPS only truly novel, inventive and innovations with industrial application are allowed to receive a patent monopoly under national law.

In our 2010 submission we shared with USTR the case of Brazil and India, explaining why their use of this important public health flexibility is important for public health. India and Brazil have balanced the importance of ensuring access to safe, effective and affordable medicines with its international obligations by making full use of the flexibilities under TRIPS.

When India became fully compliant with the TRIPS Agreement and introduced a product patent regime in 2005, it coupled its law with a critical safeguard of refusing patents on routine

[8] Waning B, Diedrichsen E, Moon S. A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. Journal of the International AIDS Society 2010, 13: 35

improvements and discoveries of new forms, combinations or new uses of known substances. The Indian patent law does not consider such routine improvements to be patentable, unless an enhancement in efficacy is proven, and therefore patents should not be granted. This is in accordance with the TRIPS Agreement which does not define what an invention is and allows WTO countries to freely "determine the appropriate method of implementing the provisions" of TRIPS.

Section 3(d) of the Indian Patent Law is an important public health safeguard which aims at preventing pharmaceutical companies from obtaining patents on trivial improvements or new medical uses of known molecules. This is to prevent a common practice in wealthy countries called 'evergreening,' whereby pharmaceutical companies are able to receive consecutive patent terms of 20 years on small changes to an existing drug. Equally important are the provisions in India's patent law allowing pre- and post-grant oppositions in assisting the Indian Patent office with crucial information on the patentability of key medicines. Public interest groups are using these provisions in select cases where generic competition is essential in ensuring the availability and affordability of medicines. When Roche, for example, attempted to patent valganciclovir, a new form of ganciclovir, a drug that was invented in the 1980s to treat cytomegalovirus (an opportunistic infection that causes blindness in HIV patients), its application for a patent was rejected in India.

Disappointingly the 2010 USTR report cited both countries and others for the use of this type of flexibility. For example, the 2010 special 301 report mentions Brazil in these terms: "Patent concerns remain, including about the scope of patentability and the uncertain role of ANVISA, Brazil's sanitary regulatory agency, in examination of certain patent applications." The 2010 Special 301 Report mentions India in these terms: "The United States continues to urge India to improve its IPR regime by providing stronger protection for patents. One concern in this regard is a provision in India's Patent Law that prohibits patents on certain chemical forms absent a showing of increased efficacy. While the full import of this provision remains unclear, it appears to limit the patentability of potentially beneficial innovations, such as temperature-stable forms of a drug or new means of drug delivery."

We strongly object to this kind of pressure on developing countries for using legal flexibilities to protect public health. We are especially concerned with the reference to "temperature-stable forms of drugs or new means of drug delivery". USTR is requesting the patentability in India of industry known practices that have undoubtedly benefits for use and adherence such as heat stabilization and fix dose combinations, but that are not genuine innovation with therapeutic benefits. Public health implications and access costs demands that monopoly protection in developing countries be reserved to only truly innovative products.

In our 2011 submission, we would like to reiterate to USTR that developing countries that use strict patentability criteria are acting entirely within their international legal obligations and in consistency with the TRIPS agreement and the Doha Declaration. The USTR is attempting to impose TRIPS-plus patentability requirements.

The Case of Brazil: a government providing universal access to medicines

Brazil recognizes universal access to medicines in its national public health system. Yet rising medicines costs are creating tremendous burdens for the system. Brazil's medicines costs increased dramatically following the early implementation of the TRIPS agreement: between 2002 and 2006 national healthcare spending increased 9.6 percent while spending on medicines increased 123.9 percent. Between 2003 and 2006, the cost of ARVs increased 51.1 percent despite only a 28.7 percent increase in the number of patients treated. The increased ARV burden has been considered a threat to the sustainability of the policy of universal access to AIDS treatment.

In response, Brazil has embraced flexibilities regarding strict patentability consistent with Article 27 of the TRIPS agreement. These include Brazil's incorporation of the National Health Surveillance Agency (ANVISA) in the review of pharmaceutical patent applications, and decisions regarding the non-patentability of second uses and polymorphs. These flexibilities are TRIPS-compliant and yet Brazil is cited in past Special 301 report.

Brazil incorporated ANVISA in the review of pharmaceutical patent applications as part of a 2001 amendment to Brazilian patent law. The ANVISA prior consent mechanism incorporated the national health authority in the patent examination process, supporting a strict interpretation of the patentability requirements of novelty, inventiveness, and industrial application. ANVISA works in partnership with INPI – National Institute of Industrial Property (Brazilian patent office) when reviewing patentability requirements of patent applications.

The involvement of the Ministry of Health and ANVISA is an important way to ensure that countries implement patent laws in a way that also allows them to protect public health and promote access to medicines as allowed under international law. The WHO CIPIH Report noted that "there is a case for patent authorities to consult health authorities in the examination process to help determine whether patentability criteria are met" to prevent evergreening and patents being used as barriers to legitimate competition.

A study developed by ANVISA analyzes qualitatively the decisions taken in the scope of prior consent from 2001 to 2009[9]. The study demonstrates the importance of ANVISA's prior consent in the process of granting patents in the pharmaceutical area as a tool to avoid improper granting of patents. In that period, ANVISA reviewed 1,346 patent applications, out of which 988 were given prior consent, 119 were not given prior consent, 90 were denied by INPI after ANVISA's participation in the process and 149 are in other situations (such as waiting for ANVISA's review or waiting for the applicant to

[9] Coordenação de Propriedade Intelectual – COOPI/GGMED/ANVISA. NOTA TÉCNICA PROBLEMAS EM PEDIDOS DE PATENTE FARMACÊUTICOS. Annex 1 (in Portuguese).

answer requirements made by the agency). Some examples of ANVISA's denial of prior consent are for lack of novelty (total or partial) (47,9%), lack of inventive step (22,7%) and lack of sufficient description (16%).

Decisions regarding patentability are ultimately decisions for each country and a question of national sovereignty within the framework set by TRIPS. Countries must be able to use the flexibilities consistent with their national health systems' commitment to universal access to medicines and the Doha Declaration.

(3) The right to issue compulsory licenses for medicines

A compulsory license is a legal mechanism to foster competition and increase access to generic versions of patented medicines. Under the WTO TRIPS agreement, compulsory licenses have a clearly regulated set of conditions and procedures. Although the 2001 Doha Declaration reiterated that countries are free to determine the grounds for granting compulsory licenses and the right to use compulsory license is not limited to national emergencies, the TRIPS agreement allows countries to create a privileged and fast-track process in three sub-types of compulsory licenses: for national emergencies or circumstances of extreme urgency, for government use or public non-commercial use, or when the license is issued to remedy an anti-competitive practices. In these cases prior consent or negotiation with the patent holder is not necessary.

Compulsory licenses are considered a standard feature of effective intellectual property regimes. The United States government and companies have frequently benefited from the use and threat to use compulsory licenses for a broad variety of technologies, including for health products. Yet the United States has also consistently challenged developing countries who aim to use compulsory licenses for health priorities.

In the 2010 Special 301 List both Ecuador and China were listed for considering using or using compulsory licenses of pharmaceutical products. Although USTR claimed that "the United States respects our trading partners' rights to grant compulsory licenses, in a manner consistent with the provisions of the TRIPS Agreement...." the references to compulsory seems to mainly refer to the 2003 WTO Paragraph 6 mechanism for countries with insufficient or no manufacturing capacity that has clearly proven to be ineffective.

In last year's submission we highlighted the importance of Thailand compulsory licenses for several essential HIV-AIDS, anti-hypertension and cancer drugs.

The Case of Thailand: a model use of compulsory licenses for public health needs

Thailand's national AIDS program today offers universal access to treatment, care and prevention. The local production of low-cost generic AIDS medicines and the use of TRIPS flexibilities have been central to this success.

In 1999, Thai AIDS activists asked the government to issue a compulsory license for the AIDS drug didanosine (ddI) to enable local production of the drug in its tablet form. The USTR warned Thailand against the use of compulsory licensing but later withdrew its protest after a global outcry. Yet the Thai government nevertheless did not infringe the patent out of concern for trade sanctions.

Thailand subsequently started to provide ARV triple-therapy in 2000. Because of the high costs, initial coverage was limited. Scale-up did not occur until 2003 when the Government Pharmaceutical Organisation (GPO) began producing a first-line fixed dose combination.

In 2005, acknowledging rising drug costs, the World Bank recommended that Thailand issue compulsory licenses to allow for the local production of second-line ARVs. There were particular needs for compulsory licensing in Thailand, including concerns regarding the price, appropriateness and reliability of supply of second-line ARVs. There was urgency in resolving problems around the availability of Merck's efavirenz which was expensive and experienced regular stock-outs. In addition, Abbott sold lopinavir/ritonavir to the Thai government for $2,967 per patient per year and, after pressure, $2,200. The price prevented the Thai government from providing the drug to all those in need. Further, Abbott did not make the existing heat-stable version available in developing countries where it was most needed.

The TRIPS Agreement does not require prior negotiation with the patent holder for government use licenses. Nevertheless, Thailand tried to negotiate better prices with the patent-holders without significant results. Therefore Thailand issued a government use compulsory license for these two drugs, authorizing the GPO to import or produce generic versions for non-commercial use in the public health sector. This resulted in an immediate 50 percent price reduction of efavirenz, allowing Thailand to increase coverage by 20,000 people.

The issuing of the government use compulsory licenses was done in a legal manner, fulfilling all national and international procedural requirements. Yet there was a vicious outcry from the media, politicians, pharmaceutical companies and their lobby groups. Abbott retaliated by withdrawing all new drug applications from the Thai Food and Drug Administration, including the much needed heat-stable lopinavir/ritonavir, and specifically excluded Thailand from discounted drug offers.

In recent years the government of Thailand has issued other similar compulsory licenses for other important public health needs including for the treatment of HIV-AIDS, heart disease and cancer.

In 2010 the Thailand government rightly decided to modify its compulsory licenses for anti-retroviral drugs by both extending the terms of the licenses until the end of the patents and allowing the generics imported or produced under the compulsory licenses to be made available to many non-Thai citizens living and working in Thailand, whom were previously excluded.

Because of concerns, members of the US Congress urged the USTR to respect the right of Thailand and other nations to implement the Doha safeguards, and expressed concern about a possible US government intervention. In her response, USTR Susan Schwab was forced to acknowledge that Thailand had acted within its legal rights: “We have not suggested that Thailand has failed to comply with particular national or international law.”

Although the term compulsory license was not mentioned in the listing of Thailand as a “priority watch list” country in the 2010 report, the 2010 Out-of Cycle Review and the following paragraph was unequivocally understood to be a threat concerning the Thailand government recent use of compulsory licenses: “The United States encourages Thailand to engage in a meaningful and transparent manner with all relevant stakeholders, including owners of intellectual property rights, as it considers ways to address Thailand’s public health challenges while maintaining a patent system that promotes investment, research, and innovation”.

The inclusion of Thailand in the Special 301 List puts pressure on Thailand but also sends a signal to other developing countries to be wary of using all legal means to ensure their population has a sustainable and continued supply of lifesaving medicines as they are then likely to be subjected to trade pressure from the United States.

MSF demands that USTR not pressure the Thailand government for their use of this important public health flexibility, including demands that the pharmaceutical industry be given a privileged voice in governmental public health policy. The Thailand government has been extremely transparent in their consideration of compulsory licenses and has fulfilled all the requirements under national and international law. The use of compulsory licenses by the Thailand government have not only increased the number of patients that are now receiving treatment but has also benefited US supported donor agencies like the Global Fund enabling them to use their limited resources more efficiently.

(4) The right to define enforcement within the confines of the TRIPS Agreement

The TRIPS Agreement contains some intellectual property enforcement obligations for WTO member states but leaves important leverage to Member States in the definition and implementation of these obligations. Developing countries must have the flexibility to implement TRIPS-compliant enforcement mechanisms that are responsive to their particular contexts and needs and not on any primary obligation to protect foreign business interests. In the access to medicines context, great caution must be taken to not unduly deter generic competition by increasing the financial or legal risks of bringing affordable and legal pharmaceutical competitors to market.

USTR has repeatedly used pressure to increase enforcement measures for intellectual property violations beyond what TRIPS requires. In 2010, USTR listed several countries for enforcement concerns and often linked intellectual property enforcement with counterfeiting concerns. However, USTR was unclear about what changes in developing countries national law were needed to satisfy US government demands.

For example, in 2010 India was listed with the following terms: ”concerns remain over India’s inadequate legal framework and ineffective enforcement. Piracy and counterfeiting, including the counterfeiting of medicines, remains widespread and India’s enforcement regime remains ineffective at addressing this problem” and “The United States encourages India to improve its criminal enforcement regime by providing for expeditious judicial disposition of IPR infringement cases as well as deterrent sentences, and to change the perception that IPR offenses are low priority crimes”. Bolivia was mentioned in these terms: “Piracy and counterfeiting, including counterfeiting of medicines, continue to be widespread in Bolivia” and “Despite a notable enforcement action resulting in the seizure of more than 30 tons of counterfeit pharmaceutical products and corresponding prosecutions, substantial additional resources and a commitment by enforcement and judicial authorities are needed to improve enforcement actions against piracy and counterfeiting.”

MSF is committed to ensuring that our medical operations and patients have access to high quality and affordable medicines. Fake medicines can be a problem in all countries although our experience shows a greater problem of substandard medicines, those produced by legitimate manufactures but that are harmful because of failures in production or storage.

MSF is concerned that the public health concerns about fake or substandard medicines are being used to create barriers to generic production, transit and supply and future innovation due to inappropriate levels of enforcement of intellectual property regimes. Such an approach harms access, undermines the necessary strengthening of drug regulatory systems and fails to properly tackle the public heath problems. Our experience indicates that measures should be focused on addressing public health problems like weak or non-existent regulatory regimes and not intellectual property enforcement.

The term “counterfeiting” is defined under the WTO TRIPS agreement in the context of trademark, which are a form of intellectual property concerning the use of brand names, logos, packaging, etc. Under TRIPS, countries are obliged to criminalize wilful cases of trademark counterfeiting on a commercial scale. But the WTO notes that “trademark counterfeiting” is different from “trademark infringement” and that this difference needs to be acknowledged in measures to fight against counterfeiting - this means that trademark infringement disputes when companies may contest that competitors are using over-similar names or packaging cannot be considered as trademark counterfeiting[10].

The tendency to conflate the term counterfeit with all fake drugs and to link measures against fake drugs only to intellectual property enforcement has led to inappropriate definitions in anti-counterfeit legislation that go beyond trademark counterfeiting to cover pure commercial trademark disputes which do not represent a threat to public health or to patent rights.

---

[10] Patients first: access to safe, quality and effective drugs. April 2010. Available at**:** **http://www.msfaccess.org/resources/key-publications/key-publication-detail/index.html%3ftx_ttnews%5Btt_news%5D=1647&cHash=d2bcf93e4c**

Overbroad definitions have already had negative consequences like the seizure of generics in Europe in transit to and from developing countries, and the anti-counterfeiting Act in Kenya.

Because of the risks of this fatal confusion the World Health Organization has recently suggested that the term "counterfeiting" should not be used to refer to fake medicines but rather to start using the term "falsified" [11]. We encourage the U.S. government to also consider clearly defining the terms it uses in the Special 301 Report in order to a) not require TRIPS plus enforcement measures, and to b) avoid irresponsibly conflating the issues of trademark counterfeiting and legitimate generic competition.

One of the most effective ways to stop the demand for false medicines is to ensure that there are low cost quality generic medicines available. If the U.S government genuinely wishes to stop harmful medicines it must ensure that its trade policies not seek to undermine the ability for the production and trade of generic medicines.

One of most important efforts by USTR to increase intellectual property enforcement measures, grounded in a misleading challenge to "counterfeiting," has been the recently concluded negotiation of the Anti-Counterfeiting Trade Agreement (ACTA) with the European Union and other mostly developed trading partners. MSF has on several occasions raised concerns with both the process and the content of this intellectual property negotiation[12].

Although the final ACTA text excludes patents from the scope of the border measures section, important concerns remain regarding the text. For example, trademarks are not excluded from the scope of the border section and both patents and data protection regimes are made only optional in the civil enforcement section. Importantly, ACTA has the potential to impose limits on generic competition and jeopardize the free flow of legitimate medicines across borders. ACTA greatly extends the ability of customs officials to detain and destroy medicines based on suspected trademark infringements – even before a judicial review is performed or the producer is notified. This agreement also greatly increases punishment for alleged intellectual property infringement, including making it possible to bring criminal charges against all parties, from the producer to recipients and third parties, such as suppliers of active pharmaceutical ingredients, donors, or even healthcare providers like MSF that use medicines to treat people.

ACTA has been negotiated mostly by developed countries completely outside of multilateral norm-setting institutions to advance the interest of pharmaceutical companies. MSF is worried

---

[11] WHO's role in the prevention and control of medicalproducts of compromised quality, safety and efficacy such as substandard/spurious/falselylabelled/ falsified/counterf eit medical products. February 2011. Available at: http://apps.who.int/gb/SSFFC/

[12] THE SECRET TREATY: Anti-Counterfeiting Trade Agreement (ACTA) and Its Impact on Access to Medicines. November 2010. Available at: http://www.msfaccess.org/resources/key-publications/key-publication-detail/index.html%3ftx_ttnews%5Btt_news%5D=1654&cHash=77bc8bb088

about recent reports that developing countries will be forced to join ACTA or implements its content through tools like the Special 301 List.

Developing countries must have the flexibility to implement TRIPS-compliant enforcement mechanisms that are responsive to their particular contexts and needs and not on any primary obligation to protect foreign business interests. In the access to medicines context, great caution must be taken to not unduly deter generic competition by increasing the financial or legal risks of bringing affordable and legal pharmaceutical competitors to market.

We urge the US government not to impose new enforcement intellectual property norms to developing countries that would hurt access to medicines, such as those included in the ACTA agreement.

III. A better US government approach to public health, innovation and intellectual property: incentive mechanisms for needs-driven, adapted and affordable innovation.

The USTR presents the Special 301 process and its efforts to demand stronger regimes of intellectual property protection to developing countries as a tool to protect innovation. MSF recognizes the importance of innovation and the need to finance research and development processes. We are a humanitarian medical organization that needs and welcomes biomedical innovation to improve treatment for our patients.

However the reality is that intellectual property protection in the medical field creates both access problems due to high prices and does not stimulate innovation for many of the diseases affecting people in developing countries, where patients have limited purchasing power. By seeking greater and higher intellectual property norms in developing countries, USTR is perpetuating a failed business model that links innovation costs to high prices and does not address the innovation needs of developing countries. Higher intellectual property norms are a sledgehammer designed to protect commercial interests in the possibility of monopolizing richer segments in developing countries, not public health, and its weight falls on the poorest. It is too blunt an instrument as currently applied to serve the health needs of millions of people in the developing world.

There are better and newer ways for the U.S. government to protect and promote innovation currently being piloted and under discussion at the WHO. Ways that would combine innovation and access, instead of denying access to affordable medical technologies and delaying the adaptation and innovation of better products so that our medical teams can better serve the needs in the poor-resource environments where we work.

In 2006 the World Health Organization (WHO) released a report by the Commission on Intellectual Property, Innovation, and Public Health (CIPIH)[13]. One of the most important

[13] WHO 2006 Report on Intellectual Property, Innovation and Public Health (CIPIH Report). Available at:

findings of the CIPIH report is that the current system of drug development is fundamentally flawed because of its reliance on patents and monopolies as incentives for the priority setting and financing of medical research and development. The report concluded that the system leaves huge health needs unmet, especially for diseases that disproportionally affect developing countries and that intellectual property is irrelevant in stimulating innovation for many of the diseases affecting people in developing countries, where patients have limited purchasing power. Further, the report called attention to the fact that patents can actually hamper innovation, by blocking follow-on research or access to research tools. It also pointed out that even in regions with strong intellectual property, innovation results are declining. In the United States for example, medical R&D spending doubled between 1995 and 2002, while the registration of new products declined, as well as the therapeutic significance of products reaching the market.

As an international humanitarian medical organization, Médecins Sans Frontières is well placed to see how the shortcomings of the current incentive mechanisms hit people in developing countries hardest, particularly those patients suffering from neglected diseases for which diagnostic, treatment, or prevention tools are lacking, or those patients that need medicines that are priced out of reach from them or the governments and donors that are paying for treatment.

Following on these important findings, in May 2008, the United States joined the rest of the Member States of the WHO in agreeing to a historical Global Strategy and Plan of Action on Intellectual Property, Innovation and Public Health. The WHO Global Strategy and Plan of Action created a historical normative pathway on how governments can promote innovation for diseases that disproportionally affect developing countries as well as re-affirming the importance of ensuring access to the resulting medicines and technologies. The United States committed to "explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, **the de-linkage of the costs of research and development and the price of health products**, for example, through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries" and to “encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an **essential health and biomedical R&D treaty**”.

The U.S. government should discuss with countries ways in which they can support innovation that also promotes access. The U.S. government should also invest the resources wisely with incentive mechanisms that do not create access problems and ensure sustainability of treatment like incentives that de-link the cost of research and development from the price of products.

---

http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf

IV. RECOMMENDATIONS

For all the reasons stated in this submission, MSF urges USTR in its 2011 Special 301 Review Process to refrain from:

- using the Special 301 process to increase pressure on developing countries to implement intellectual property measures into their domestic laws beyond the requirements contained in international law, including TRIPS Plus provisions such as data exclusivity;

- using the Special 301 process against developing countries that are acting within their legal rights to overcome intellectual property barriers in response to the health needs of their populations, or against countries embracing TRIPS flexibilities to ensure access to medicines such as compulsory license or patentability criteria; and

- using the Special 301 process to impose new intellectual property enforcement norms that would hurt access to medicines, such as those included in the ACTA agreement.

Rather than using the Special 301 Review Process as a unilateral tool to impose a heightened intellectual property regime on developing countries, the U.S. government should use its laws, policies and financial resources to ensure that developing countries exercise the full flexibilities available to them to ensure access to medicines for all.

This will mean:

- that the Doha Declaration play a prominent role in shaping U.S. policy on access to medicines in developing countries;

- that the U.S. government encourages countries to fully implement the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, including the use of incentive mechanisms that separate research and development incentives from high prices, for example through the use of innovation inducement prizes that reward innovations that improve health outcomes and permit open competition for products; and the creation of new global norms on research and development, including a possible biomedical R&D treaty.

- that the U.S. government advance an agenda supportive of both innovation and access to affordable medicines in developing countries, and ensure that U.S. trade policy is aligned with the U.S. global health and development agenda;

- that the U.S. government conducts impact assessments of the effects that USTR demands would have not only on access to medicines and innovation by patients living in developing counties but also in US supported donor efforts like PEPFAR and the Global Fund.

- that the U.S. government supports a system capable of delivering adapted and affordable drugs that respond to patients' needs. This should include continue with the promotion of open licensing of all publically funded biomedical research and development for use in the

developing world, following up with NIH recent announcement of its license on a AIDS medicines to the Medicines Patent Pool.