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SUBMISSION TO THE U.S. TRADE REPRESENTATIVE REGARDING THE 2012 SPECIAL 301 REVIEW PROCESS

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Doctors Without Borders/Médecins Sans Frontières (MSF) would like to submit the following written comments to the 2012 Special 301 Process.

MSF also request to testify at the hearing that the United States Trade Representative (USTR) has announced for February 23, 2012. MSF would like to request that USTR facilitates the participation by other civil society and interested stakeholders from around the world, especially from developing countries where USTR policies have greater effect and the presence and substantive involvement of public health U.S. government agencies like DHHS, PEPFAR and the Global Health Initiative.

MSF is an independent, international medical humanitarian organization that delivers medical care to patients in nearly 70 countries, our work focuses on the medical needs of poor people living in developing countries whose needs are often neglected. We provide medical 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. 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.

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 one more year participating in the Special 301 Process because we are concerned about the effects that heightened intellectual property regimes and high prices being imposed on developing countries by the 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 countries due in part to intellectual property barriers and high costs.

The higher and inadequate standards of intellectual property that USTR is pursuing through the Special 301 Process 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.

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 through the use of flexibilities allowed under international law (e.g., compulsory licenses, 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 Special 301 mechanism is only one tool that the U.S. government has used to this end. The United States is aggressively advancing a TRIPS-Plus agenda, seeking intellectual property protections more extensive than those under international law and the WTO TRIPS agreement, through ACTA and TPP negotiations. Our recent press release and statements on the Transpacific Partnership Agreement¹ negotiation should therefore also inform this process.

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 increasingly on the low- and middle-income countries. As the UN HLM on NCDs recognized last year is essential to increased access to affordable, safe, effective and quality medicines and diagnostics and other technologies, including through the full use of trade-related aspects of intellectual property rights (TRIPS) flexibilities. 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.

¹ Access to Lifesaving Generic Medicines Threatened by US Trade Pact. Public Health Safeguards Could Erode Under Trans-Pacific Partnership Agreement. September 2011. Available at: <http://www.doctorswithoutborders.org/press/release.cfm?id=5519>

More than six 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%, from over \$10,000 in 2000 to under \$150 today.

While this represents important progress, approximately ten million more people are in immediate need of treatment according to current WHO treatment guidelines, a testament to the emergency that is the HIV/AIDS pandemic. Furthermore, 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 ARVs 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 3 times more expensive than the most affordable first-line regimens, and possible third-line regimens are estimated to cost over 20 times more than the most affordable WHO recommended first-line².

2011 was a historical year for the scale up of the HIV/AIDS response. In June at the UN High Level Meeting on HIV/AIDS in New York the U.S. with other UN Member States, committed to '15 by 15': scaling up to a total of 15 million people on HIV treatment by 2015. A few months later, NIH released new data that has proved that treatment of HIV can reduce the transmission of the disease by 96%, so that treatment is also prevention, making the scale-up of treatment all the more urgent. During the World AIDS Day, the Obama Administration responded to this new science and called for an AIDS-free generation and announced an increase in the U.S. government global commitments to support the HIV/AIDS.

Funding for AIDS has declined, leaving the Global Fund to Fight AIDS, TB and Malaria, the US government's PEPFAR and national programs short of resources The U.S government argues that these expanded targets are possible in a constrained budget environment due to "relentless work to bring down costs and find efficiencies. The per-patient cost to the U.S. of providing anti-retroviral treatment has fallen by over 50 percent since 2008 because PEPFAR has invested carefully, tailoring prevention to countries' urgent needs, using generic drugs..."³.

However, USTR pursued strategies in the Special 301 List and other strategies, like the Transpacific Partnership Agreement, are in contradiction, and will in fact directly threaten the U.S. government global health priorities and commitments by making it more difficult to rely on cost-saving generics. 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.

² Untangling the Web of Antiretroviral Price Reductions. 15th edition. Available at: <http://utw.msfacecess.org/>

³ Fighting the HIV/AIDS Epidemic and Supporting People Living with HIV/AIDS. White House release with the FY2013 Federal Budget request.

The importance of generic competition

MSF provides HIV treatment to 170,000 people in more than 19 countries and sources more than 80% of its anti-retrovirals (ARVs) from India.

U.S. Government-funded schemes, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and PEPFAR⁴ are also heavily reliant on the cost savings realized through competition between quality generic medicines. PEPFAR reports that generic formulations accounts for almost 98% of the ARV packs purchased with PEPFAR funds, up from 14.8% in 2005 and that this saved over \$380 million dollars in 2010 alone⁵. 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% reduction in cost, which allows South Africa to treat twice as many people on ARVs.⁶ The cost for a generic pediatric version of one ARV was cut in half from the price previously paid to the brand-name manufacturer.⁷

With ARV prices accounting for approximately one-third of the total costs of ART, PEPFAR and the U.S. Government should continue to address the regulatory environment to further reduce costs. Yet the USTR continues to undermine both PEPFAR and the Global Fund, as well as 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 demands create a fundamental contradiction between U.S. trade policy and the U.S. government's commitments and priorities on global health and development.

The full implementation of the WTO TRIPS Agreement since 2005 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. However, as re-affirmed by all WTO Members States (including the United States) in the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health, 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 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)

⁵ <http://www.pepfar.gov/press/remarks/2011/160817.htm#>

⁶ *Massive reduction in ARV prices*. South Africa Department of Health. 14 Dec 2010. Available at: <http://www.info.gov.za/speech/DynamicAction?pageid=461&sid=15423&tid=26211>

⁷ 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 Nov. 2010.

- the right to define data protection provisions;
- the right to not have to use public money or public authorities to enforce patents (including prohibiting linkage of drug registration with patent status);
- 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.

The U.S. government has the capacity and the obligation to incorporate concerns regarding access to medicines 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.

On May 10, 2007 the U.S. government under the Bush Administration announced a New Trade Policy for Peru, Panama, and Colombia and a bipartisan Congressional 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 some flexibility was included in the data exclusivity language. Peru has already incorporated some of these flexibilities in its national law.

However, instead of ensuring affordable access to medicines USTR is requiring stronger intellectual property protection and enforcement mechanisms. USTR is ignoring the broader U.S. government and the international community, both of which are emphasizing the need for sustainable, cost-effective, and innovative strategies to solve global health demands. International organizations and experts have also raised their concerns on the important threat that TRIPS-plus provisions pose to access to medicines. On 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 of lifesaving medicines—so-called ‘TRIPS plus’ measures such as ‘data exclusivity—and incorrect interpretations of the term ‘counterfeit’ should be avoided.” And just a few days ago, the Chair and

Executive Director of UNITAID published an op-ed⁸ asking the European Union to withdraw similar demands being pursued in the EU/India trade agreement and claiming that “If stringent patent and border measures are agreed at the EU-India free trade summit, patients in poor countries will no longer have access to cheap essential medicines” and that “the result could see patients in poor countries facing stock-outs, price increases and even having to pay the full cost of their treatment – meaning that only the richest among them will get treated.”

MSF COMMENTS TO USTR ON THE SPECIAL 301 PROCESS

The 2011 Special 301 List was the second review done under the Obama Administration. We remain disappointed that most of the issues that we raised in our 2010 and 2011 submissions remain unaddressed and that the process was once again used to pressure developing countries to adopt heightened intellectual property regimes and limit their use of public health flexibilities.

One more year 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, each of which is plainly permissible under TRIPS.

In our 2011 we highlighted 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:

- **The right to define data protection provisions**
- **The right to issue compulsory licenses for medicines**
- **The right to define enforcement within the confines of the TRIPS Agreement**
- **The right to define patentability criteria**

In our 2012 submission, we would like to focus in one of this measures that we believe has been negatively targeted by the US government trade policies: **the right to define patentability criteria with a public health perspective.**

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

⁸ Health of millions of poor people threatened by EU-India free trade deal by Philippe Douste-Blazy and Denis Broun. Available at: <http://www.guardian.co.uk/global-development/poverty-matters/2012/feb/10/health-threatened-by-india-trade-deal?newsfeed=true>

TRIPS only truly novel, inventive and innovations with industrial application are allowed to receive a patent monopoly under national law.

Several countries do not allow patents on new uses or new forms of existing medicines. For example, laws in India and the Philippines limit patents on new forms of existing medicines.

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 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.

'Section 3d' of Indian patent law provides a strict patentability standard in an effort to prevent companies from continually extending their 20-year drug patents by patenting minor changes to existing drugs. As such, Section 3d aims to prevent so-called "ever-greening" by prohibiting the patenting of new forms of existing pharmaceutical substances that do not demonstrate significantly enhanced "efficacy." India's strict patentability criteria, promotes access to medicines by protecting price-lowering generic competition.

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% of the AIDS medicines it uses from producers in India. We are not alone in our reliance on generics - a recent study found that more than 80% of donor-funded purchases of HIV medicines from 2003-2008 were sourced from producers of affordable generics in India.⁹ This source of affordable medicines is under threat if USTR success in eliminating flexibility in the way Indian law is allowed to define its patentability criteria.

There are several examples of patent applications that have been rejected based on Section 3d and that have already considerably reduce its cost for developing countries, for example:

In 1990, Boehringer Ingelheim (BI) was granted the basic patents for the widely-used ARV nevirapine (NVP) in several developing countries. BI was not able to patent the drug in countries such as India, Brazil, China or Thailand, which were not granting medicines for patents at the time, and therefore generic versions have been available for many years. However, after India introduced product patent protection for pharmaceuticals in 2005, BI applied for a patent on the hemihydrate form of NVP, which relates to the pediatric suspension. In 2006, civil society groups filed a pre-grant opposition to BI's application on various grounds including that the syrup formulation was a variation of a known drug and therefore ineligible for patenting under India's Section 3d patentability criteria. In June 2008, BI's application was

⁹ Waning B, Diedrichsen E, & Moon S. *A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries*. J. Int'l AIDS Society, 2010;13:35.

rejected by the Indian patent office, allowing for unrestricted generic competition for the manufacture and supply of the pediatric formulation. The generic price has dropped by almost 80% since 2001, and today is approximately 14% of the originator price.

Zidovudine/lamivudine (AZT/3TC), a fixed-dose combination (FDC) used for first- and second-line treatment for HIV/AIDS, was produced by Indian generic companies because none of the individual components was patented in India. However, these generic versions came under threat when India began granting patents on pharmaceuticals in 2005, and GSK applied for a patent on the combination. However, civil society groups filed a pre-grant opposition in March 2006, on the basis that the new form of the drug does not meet eligibility criteria for patenting under Section 3d. This resulted in GSK communicating in August 2006 that patents specifically related to the FDC were being withdrawn in many countries. Since 2001, generic prices have dropped by 63%. Yet in some countries, generic versions of the FDC are not available because of GSK's patent rights.

In India, Abbott has applied for several patents related to lopinavir (LPV), ritonavir (RTV) and the combination of lopinavir/ritonavir (LPV/r). A number of these applications were opposed by civil society organizations and generic companies. Following a pre-grant opposition to the application related to the tablet formulation of LPV/r, the application was rejected by the Indian patent office on the grounds that it was un-patentable under Section 3d. An appeal is pending, and several other patent applications related to LPV/r are still pending; however, in the meantime, Abbott has abandoned a number of other patent applications related to LPV/r. However, if any of the pending applications are granted, current generic competition, which has brought down prices by more than 60%, will be under threat.

In 2006, the Indian patent examiner rejected the patent that Swiss pharmaceutical company Novartis sought for the leukemia drug imatinib mesylate (marketed as Glivec), because it was based on a compound that already existed. In response to its drug patent being rejected, Novartis took the Indian government to court in 2006, not only challenging the rejection of its patent, but also the part of India's law, Section 3d, that formed the basis of the decision. If Section 3d were overturned, it would mean patenting would become much more widespread in India, severely limiting the production of more affordable generics. In August 2007, the Madras High Court ruled against Novartis. The company continues to appeal its case in India and has now challenged the previous courts' rulings at the Supreme Court, which will hear the Novartis case in February 2012.¹⁰

Despite the undisputed evidence on the positive impact that this kind of provisions have on public health, disappointingly, the 2011 USTR report once again cited India, among others, for defining the scope of patentability as allowed under TRIPS. USTR is asking India and other countries to broaden its patentability criteria and to make it more easy to grant patents on new forms or uses of old medicines, even after the original patents have

¹⁰ <http://msfaccess.org/novartis-drop-the-case>

expired. For example, the 2011 Report states: “Particular concerns have been raised regarding provisions of India’s Patent Law that prohibit patents on certain chemical forms absent a showing of increased efficacy, thereby possibly limiting the patentability of potentially beneficial innovations, such as temperature-stable forms of a drug or new means of drug delivery.” The Philippines was similarly placed on the “watch list” with the same objection noted.

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 a drug or new means of drug delivery.” USTR is requesting that India recognize the patentability of established industry practices, such as heat stabilization and fixed dose combinations, that have benefits for use and adherences. We acknowledge the importance and usefulness of these product adaptations, especially in resource-poor setting where we work, but we rejected USTR claims that only with stronger and longer monopolies and at the expense of access to medicines for millions can researchers be encouraged to bring these products into the market.

In our 2012 submission, we would like to reiterate that developing countries using 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 that go beyond these standards and reduce access to medicines. 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.

A better 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 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 protect commercial interest in monopolizing richer segments in developing countries, rather than the health of the poorest. As currently applied intellectual property has failed to serve the health needs of millions of people in the developing world.

There are better ways for the U.S. government to protect and promote innovation, which are currently discussion at the WHO. These would combine the goals of innovation and access, instead of denying access to affordable medical technologies and delaying the adaptation of better products to serve the needs in the resource-poor environments.

In 2006, the WHO released a report by the Commission on Intellectual Property, Innovation, and Public Health (CIPIH).¹¹ One of the most important 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 disproportionately 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 notes that even in regions with strong intellectual property rules, 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, MSF is well placed to see how the shortcomings of the current incentive mechanisms affect people in developing countries, 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 other WHO Member States 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 establishing how governments can promote innovation for diseases that disproportionately 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 (e.g., 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."

¹¹ Commission on Intellectual Property Rights, Innovation, and Public Health. *Public health, innovation, and intellectual property rights*. World Health Organization, 2006. Available at: <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>

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, including supporting trade policies that allow for the implementation of the recommendations that the WHO Consultative expert working group on research and development: financing and coordination (CEWG) will be presenting at the 65th WHA in May 2012.

RECOMMENDATIONS

For all the reasons stated in this submission, MSF urges USTR in its 2012 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 (e.g., compulsory license, patent oppositions or public health 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 and TPP.

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 advances an agenda supportive of both innovation and access to affordable medicines in developing countries, and ensures 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 countries but also in U.S. supported donor efforts like the Global Health Initiative, PEPFAR and the Global Fund; and
- that the U.S. government supports a system capable of delivering adapted and affordable drugs that respond to patients' needs. This should include continued promotion of open licensing of all publicly funded biomedical research and development for use in all developing countries, such as the NIH license on AIDS medicines to the Medicines Patent Pool.