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SUBMISSION TO THE U.S. TRADE REPRESENTATIVE (USTR) REGARDING THE 2010 SPECIAL 301 REVIEW

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I - BACKGROUND

Médecins Sans Frontières

Médecins Sans Frontières (MSF, Doctors Without Borders) 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 70 countries throughout the world.

Teams provide medical care for people with HIV/AIDS, malaria, tuberculosis, Chagas' disease, leishmaniasis, and other diseases, as well as primary care, maternal/child health care, and other services for displaced and homeless populations and for indigenous people. The organization was awarded the 1999 Nobel Peace Prize.

MSF is concerned about the barriers posed by intellectual property (IP) 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.

MSF is similarly 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 law. The Special 301 mechanism is only one tool that the U.S. government has used to this end. As applied to medicines, this is a tool to strongarm countries that are acting within their legal rights in response to the health needs of their populations.

The magnitude of the AIDS crisis

It is important to note that the problem of access to medicines is not limited to HIV/AIDS. It extends to any new drug, diagnostic test or vaccine needed to treat, detect, or prevent a range of diseases affecting developing countries.

However, the magnitude of the AIDS crisis has 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.

Four million people across the developing world are on antiretroviral treatment (ART). This success would not have been possible without the 99% drop in price of the first-line ART witnessed since the advent of generic competition, from over $10,000 in 2000 to under $80 today.

MSF provides treatment to 140,000 people in more than 30 countries and sources more than 80% of its antiretrovirals from India. PEPFAR itself has reported cost savings of up to 90% 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.

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

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 programmes – 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.

Sustainable mechanisms to ensure these costs are contained are urgently needed. This has become even more urgent in light of impending financial restrictions on AIDS funding. The 2011 budget proposed by the White House would flatfund the US bilateral AIDS and TB funding through PEPFAR for the third year in a row, and decrease the US government funding directed towards the multilateral Global Fund.

Re-assessing the impact of intellectual property rights

In April 2006, the Commission on Intellectual Property, Innovation, and Public Health (CIPIH) established by the WHO released its report presenting a wealth of evidence in support of the view that the current system of drug development, because of its reliance on patents and commercial incentives for the priority setting and financing of medical research and development (R&D), is fundamentally flawed.

The system leaves huge health needs unmet. As an international humanitarian organization, Médecins Sans Frontières is well placed to see how these shortcomings hit people in developing countries hardest, particularly those patients suffering from neglected diseases for which diagnostic, treatment, or prevention tools are lacking.

The report concludes 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 draws attention to the fact that patents can actually hamper innovation, by blocking follow-on research or access to research tools. It also points out that even in regions with strong IP, innovation results are declining. In the United States,

for example, medical R&D spending has doubled between 1995 and 2002, while the registration of new products has declined, as well as the therapeutic significance of products reaching the market.

Crucially, the report also warns against trade agreements that include excessive IP protection –so-called "TRIPS plus" measures - "that may reduce access to medicines in developing countries", and analyzes the various tools at governments' disposal, such as compulsory licensing, to counter this crisis of access to medicines.

In May 2008, the United States joined the rest of the members of the World Health Assembly in agreeing to the Global Strategy and Plan of Action on Intellectual Property, Innovation and Public Health (GSPOA) based on the CIPIH report. The GSPOA outlines obligations of all members of the WHO in promoting R&D for neglected diseases as well as promoting the use of TRIPS flexibilities by developing and least developed countries in ensuring access to medicines.

Specifically Element 5 and Element 6.3 outline the responsibilities of governments regarding the management and application of intellectual property to contribute to innovation and to public health.

The United States, along with other governments, has committed to, among other things, "*encourage and support* the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS Agreement and other WTO instruments related to that agreement and meets the specific R&D needs of developing countries." [emphasis added]

Bound by the Doha Declaration, the United States must respect the right of all WTO member states 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." In agreeing to the GSPOA, the United States has re-iterated this commitment and additionally agreed to explore alternate mechanisms for research and development in diseases that predominantly affect the developing world.

TRIPS flexibilities

The full implementation of the TRIPS Agreement in generic producing countries has made all the more crucial the use of TRIPS flexibilities enshrined in the Doha Declaration to ensure competition can occur. Under international law, countries have the right to implement these flexibilities in intellectual property law and policy to protect public health. These include:

(1) the rights to define patentability criteria,
(2) the right to define data protection provisions,
(3) the right to parallel importation,
(4) the right to not to use public money or public authorities to enforce patents including to not link drug registration with patent status, and
(5) the right to define enforcement appropriately within the confines of the TRIPS Agreement.

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.

Yet in 2009, the U.S. government used the platform of the Special 301 to challenge developing countries attempting to realize many of these flexibilities with regard to medicines.

II - MSF COMMENTS TO USTR ON THE SPECIAL 301 REPORT

On numerous occasions, MSF has raised concerns publicly about the U.S. insistence on including TRIPS-plus IP provisions. These directly undermine the Doha Declaration which clearly recognized concerns about the effects of patents on prices and stated unambiguously that TRIPS should be interpreted and implemented in a manner "supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

Nevertheless, the United States has aggressively advanced a TRIPS-plus agenda, seeking from their trading partners intellectual property protections more extensive than those provided for by the TRIPS Agreement. The United States has advanced TRIPS-plus measures through, among other fora, free trade agreements (FTAs), multilateral treaties, bilateral negotiations, and through the Special 301 process.

Section 301 of the U.S. Trade Act of 1974 (PL 93-618) authorizes the U.S. Trade Representative (USTR) to identify trade barriers resulting from purportedly inadequate intellectual property protections. The "Special 301 Report," resulting from 1988 amendments to the law, is an annual review in which countries are challenged for their intellectual property laws and policies.

The U.S. government has the capacity and the obligation, as a signatory to the Doha Declaration, to incorporate concerns regarding access to medicines centrally into U.S. trade policy. Indeed, the United States did this in part with the Executive Order 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. In Executive Order 13155, the Clinton Administration expressed the principle of not using U.S. trade pressures to undermine access to medicines in developing countries; and the Government Accountability Office (GAO) similarly expressed the importance of ensuring that U.S. trade policies are consistent with U.S. obligations under the Doha Declaration.

This bully pulpit of the Special 301 report has been used to strengthen the negotiating position of the United States and threaten sanctions against non-cooperative partners. In 2009, the U.S. Government has repeatedly used the platform of the Special 301 to challenge developing countries attempting to realize many TRIPS flexibilities with regard to medicines.

(1) The right to define patentability criteria

Pursuant to the TRIPS Agreement, countries have an obligation to grant patents on pharmaceutical products and processes, but the question of what criteria to use 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, such as Brazil, Thailand or India, have done precisely that. They are acting entirely within their international legal obligations with their embrace of these TRIPS flexibilities. These are

not TRIPS violations. This interpretation of patentability is consistent with the Doha Declaration and should be encouraged by U.S. trade policy for these and other countries rather than challenged by placing such countries on the Special 301 watch list.

Challenges to TRIPS Patentability Flexibilities: The Case of Brazil

Brazil recognizes universal access to medicines in its national public health system. Yet rising medicines costs are creating tremendous burdens for the system.

Brazil has embraced flexibilities regarding strict patentability consistent with Article 27 of the TRIPS agreement and the Doha Declaration. These include the challenge to so-called "pipeline" patents issued during the transition period in which the Brazilian government did not need to recognize pharmaceutical patents, 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 the Special 301 listing, with particular concerns raised about Brazil's use of some of these flexibilities.

Legislation recognized "pipeline patents" filed between May 1996 and May 1997, allowing early patentability based on the date of first foreign filing for fields not previously recognized under Brazilian patent law, including pharmaceuticals. Hundreds of patent applications filed in the country during this time, including for five important ARVs (lopinavir/ritonavir, efavirenz, abacavir, nelfinavir and amprenavir) have been patented already in Brazil under this legislation.

Brazil's medicines costs increased dramatically following the early implementation of the TRIPS agreement: between 2002 and 2006 national healthcare spending increased 9.6% while spending on medicines increased 123.9%. Between 2003 and 2006, the cost of ARVs increased 51.1% despite only a 28.7% 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. Though not required to implement TRIPS until 2005, the Brazilian government spent an estimated $420 to $519 million more for the five aforementioned ARVs between 2001 and 2007 than they would have spent had they purchased them generically.

The pipeline legislation illustrates how the granting of improper patents can negatively affect public health. In 2009, the Brazilian Attorney General challenged the law that established the pipeline mechanism. Brazil should have access to the full transition period prior to 2005 before TRIPS implementation was required. It is in the interests of Brazilian access to medicines to ensure that there is not unnecessary and improper patenting of medicines that prices these medicines out of reach of populations in need.

Brazil also incorporates Anvisa, Brazil's drug regulatory authority, in the review of pharmaceutical patent applications as part of a 2001 amendment to Brazilian patent law. The Anvisa prior consent mechanism incorporates this national health authority in the patent examination process, supporting a restrictive interpretation of the patentability requirements of novelty, inventiveness, and industrial application consistent with TRIPS Article 27. The USTR Special 301 attempts to limit a country's right to adopt strict patentability requirements in order to protect public health in compliance with TRIPS.

Brazil's patent law does not allow patents for second uses and polymorphs following a December 2008 decision by Brazil's Interministerial Group of Intellectual Property (GIPI). Under TRIPS, patenting for second uses can be excluded from patentability as a therapeutic method and lacking novelty and industrial applicability. Polymorphs are considered an intrinsic characteristic of the molecule and, therefore, classified as a "discovery" not fulfilling the novelty requirement. The TRIPS Agreement does not require the grant of patents for new uses. The USTR is attempting to impose TRIPS-plus patentability requirements on Brazil.

Decisions regarding patentability are ultimately political decisions of each country within the framework set by TRIPS. Countries such as Brazil must be able to use the flexibilities consistent with their national health system's commitment to universal access to medicines and the Doha Declaration. The necessity of these flexibilities in the Brazilian context is apparent from a review of the rapidly increasing drug costs and the impact on access to medicines.

Challenges to TRIPS Patentability Flexibilities: The Case of India

India is a vital source of affordable medicines for people across the developing world. This is because until 2005 India did not grant pharmaceutical patents, and so affordable versions of medicines patented elsewhere could be freely produced in India.

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 discoveries of new forms or new uses of known substances. The Indian patent law does not consider such discoveries as inventions, 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.

Indeed 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. Section 3(d) is an example of such a provision. Section 3(d) of the Indian Patent Law is thus 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.

In fully complying with its obligations under the TRIPS Agreement, India has balanced the importance of ensuring access to safe, effective and affordable medicines with its international obligations making full use of the flexibilities under TRIPS. Yet the USTR has placed India on the Priority Watch List, citing its "weak IPR protection and enforcement."

India has fully used its right to shape a patent law according to its national sovereign interests. 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.

(2) The right to define data protection provisions
Where data exclusivity laws are in force, a generic manufacturer is prohibited from relying on the pharmaceutical test data submitted by the originator company to drug regulatory authorities when seeking to obtain market authorization. It creates a new patent-like monopoly by blocking the registration of generic medicines. It is not required by TRIPS which obligates countries only to "protect . . . against unfair commercial use" undisclosed test or other data concerning "new chemical entities."

With only vague language, the USTR has repeatedly criticized countries for failing to "protect[] . . . against unfair commercial use [] undisclosed test and other data" – the most commonly cited issue raised in the USTR 2009 Special 301 report. But this is clearly a TRIPS-plus demand.

Data exclusivity provisions are harmful for access to medicines in developing countries because they can delay generic competition, whether or not patent protection is in place.

These provisions will keep generic versions of drugs that have already been registered out of a country during the period of data exclusivity (i.e. five years). The requirement for a company to generate its own test data will likely discourage generic manufacturers from seeking registration for their drugs. It may even make generic competition impossible, especially for domestic firms in developing countries, given the costs of test data and low margins of generic production. The main effect of this provision will be on drugs which are not under patent, as the generic manufacturer will still be unable to use the originator's test data to obtain registration. I

In such an instance, data exclusivity acts as a de facto patent, preventing competition. This impact is heightened if the data exclusivity applies from the date of approval in the United States as it means that a brand-name originator drug does not even have to be registered (and thus available) in the country for generic competitors to be blocked from entry. This could lead to a complete lack of availability of essential medicines (either generic or originator versions) if originator companies decide for whatever reason not to market a drug in a given country.

The requirement to re-test a drug already proven to be safe and effective is medically unethical, because it forces a number of patients to take part in clinical trials which are not necessary, and requires some to take placebos in order to compare outcomes with the actual drug and therefore forego a proven treatment. It will also increase the cost of the generic medicine.

Further, data exclusivity could effectively block compulsory licenses. 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 (NDRA). Data exclusivity would prevent such registration for the period of exclusivity, and thereby prevent the use of a compulsory license during that time.

(3) The right not to use public money or public authorities to enforce patents including not to link drug registration with patent status

The USTR in the 301 listings has repeatedly criticized countries for failing to "implement an effective system to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products." Linking a drug's registration (also known as marketing approval) to its patent status seeks to prevent generic competition as it would prevent the registration of a generic version of a drug that is under patent in a country unless the patent owner gives consent even if the generic has been proven to be of quality, safe and effective.

A drug's patent status and its registration status are two separate things. Patent linkage seeks to create a new role for NDRAs as enforcers of drug patents, which they are not equipped to do as their job is to assess the quality safety and efficacy of a drug. It turns the NDRA into the enforcer of a company's private patent rights. The patent owner does not have to sue an alleged infringer in court—a practice which ensures the validity of a patent can be publicly questioned and held up to scrutiny before it is enforced.

This is of considerable advantage to the patent holder. Rather than the company having to sue through the courts to enforce its patent, the job is done behind the scenes and without publicity by the NDRA. It is also more likely that patents that have been awarded improperly will be wrongfully enforced. The NDRA will be obliged to enforce a patent monopoly, even though it does not have the power of a court to judge whether a patent has been properly awarded or not. Further, the linking of patent status and drug registration could undermine the possible use of compulsory licences. A company given authority to produce a generic drug under compulsory license (i.e. without the patent holder's consent) still needs to register that drug with the NDRA. But if the NDRA is not allowed to register generics until the patent expires, the compulsory license is effectively useless.

Nowhere in the TRIPS agreement is there any reference to an obligation to link patent protection and drug registration. On the contrary, the preamble recognises that intellectual property rights are 'private rights,' meaning that it is up to patent holders to enforce their rights, not NRDAs.

At the same time as seeking to put pressure on countries to introduce TRIPS-plus measures that would undermine the registration and access to medicines, the 301 watch list also seeks to undermine measures that seek to ensure that public health considerations are taken into account when granting patents, in compliance with the public health flexibilities within the TRIPS agreement. In its 2009 Special 301 report, the USTR challenged nine countries for not engaging the drug regulatory authorities in patent enforcement through patent linkage yet also criticized Brazil for engaging their health authority, National Health Surveillance Agency (ANVISA), in its patent approval process.

(4) The right to issue compulsory licenses for medicines

A compulsory license is an entirely legal mechanism to remedy patent abuses such as excessive pricing and to foster competition to increase access to patented medicines.

Compulsory licenses are not limited to declared national emergencies or circumstances of extreme urgency. However, these conditions – as identified by the country issuing the license – make the procedures for issuing compulsory licenses easier. Similarly a compulsory license need not be issued for "government use" only; however, where a compulsory license is issued for "public non-commercial use," the procedures are less extensive and do not require prior negotiation with the patent-holder.

Complusory licences are considered a standard feature of effective intellectual property rights legislation. The United States has frequently used and threatened to use compulsory licenses to override patents, including for health products and including for government use.

Yet in addition to the less direct ways of restricting compulsory licensing such as demands for data exclusivity and patent linkage,,the United States has also often consistently challenged developing countries who aim to use compulsory licenses for health products even though they are explicitly permitted under the TRIPS agreement. The TRIPS agreement includes no restrictions on the conditions for their use. The Doha Declaration confirmed that countries have "the freedom to determine the grounds upon which such licences are granted." Indeed negotiators explicitly rejected attempts to restrict the terms of compulsory licenses during the initial drafting of the Doha Declaration. It is unacceptable that the US still seeks to put pressure on countries to limit these rights.

Compulsory Licenses: The Case of Thailand

The importance of the use of compulsory licensing can be illustrated by the example of Thailand. 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, but not without challenges by the USTR to Thailand's legal use of TRIPS flexibilities to ensure a continuous and sustainable drug supply.

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% 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.

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."

Nonetheless, the USTR has unacceptably kept Thailand on the Priority Watch List. Such inclusion 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 subject to trade pressure from the United States.

(5) The right to define enforcement within the confines of the TRIPS Agreement
Under TRIPS, countries must allow for civil judicial procedures to enforce intellectual property violations through injunction, compensatory damages, or destruction of infringing goods.

USTR has repeatedly used pressure to increase enforcement measures for intellectual property violations beyond what TRIPS requires. USTR has, for instance, challenged countries for a failure to criminally prosecute alleged intellectual property violations. USTR has also urged heightened civil penalties for more effective "deterrence."

These TRIPS-plus enforcement measures are nowhere required by TRIPS and indeed could be bad policy for developing countries in the medicines context. The deterrent factor of criminal enforcement can deter potential generic competitors challenging a patent to bring affordable medicines to market. Moreover, limited criminal resources need not be utilized to protect private rights. TRIPS-plus civil enforcement mechanisms applied to pharmaceuticals may similarly deter generic competition.

Further, the USTR has called for greater intellectual property enforcement at country borders. Yet recent years have demonstrated the potential dangers of inappropriate border enforcement measures on the trade in legitimate generic medicines. In Europe in 2009, a number of shipments of legitimate generic medicines were seized inappropriately by border officials while en route to a non-European destination. These medicines, legitimate generic medicines legally produced in India, were destined for Nigeria, Brazil, and other countries, where they could be legally purchased under the laws of these countries.

Many countries do not have manufacturing capacity to produce medicines, or rely on importing more affordable generic medicines from abroad in order to treat their population. As such, the trade in legitimate medicines between countries is fundamental to ensuring access to medicines for millions. Provisions to ensure such countries can access medicines, enshrined in the Doha declaration and the WTO August 30th decision, cannot be implemented

effectively if on key transit routes the risk exists that supplies can be regularly subject to interception based on assertion of patent infringement in the transit country.

Finally, the USTR, along with the European Union, has been actively engaged in efforts to increase intellectual property enforcement measures, grounded in a challenge to "counterfeiting." This includes through the entirely non-transparent Anti-Counterfeiting Trade Agreement (ACTA) negotiations now ongoing. This agreement stands to put the legitimate trade of generic medicines at risk if it improperly includes patent enforcement and in-transit seizures. Relying on excessively broad definitions of "counterfeit" medicines can have harmful effects on access to affordable generic medicines, as has recently been seen in relation to the Anti-Counterfeiting Act in Kenya.

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.

CONCLUSIONS AND RECOMMENDATIONS

We urge USTR to refrain from:

- using the Special 301 report to increase pressure on developing countries to implement intellectual property measures into their domestic laws above and beyond the requirements contained in international law;
- using the Special 301 report against developing countries that are acting within their legal rights to overcome patent barriers in response to the health needs of their populations, or against countries embracing TRIPS flexibilities to ensure access to medicines; and
- establishing additional bilateral and multilateral agreements that establish TRIPS-plus measures which hamper the right of developing countries to introduce affordable medicines more quickly to their populations.

Rather than using the Special 301 report as a bully pulpit to impose a heightened intellectual property regime on low- and middle-income 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 means:

- 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 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 agenda;
- 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 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 agenda;
- encourage countries to fully implement the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property;
- encourage the use of diverse mechanisms that separate research and development (R&D) incentives from prices, for example through the use of innovation inducement

prizes that reward innovations that improve health outcomes and permit open competition for products; and

- support a system capable of delivering adapted and affordable drugs that respond to patients' needs. This should include the promotion of licensing of all publically funded biomedical research and development for use in the developing world. For example, AIDS medicines patents held by the U.S. government, through research institutions or universities, should be licensed to the AIDS medicines patent pool currently being established by UNITAID to support both innovation and access for AIDS medicines.