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**Submission to the United States House of Representatives Committee on Ways and Means
regarding the April 3, 2014 Hearing on President Obama's Trade Policy Agenda**

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Médecins Sans Frontières/Doctors Without Borders (MSF) is an independent international medical humanitarian organization that delivers medical care to people affected by armed conflicts, epidemics, natural disasters and exclusion from healthcare in nearly 70 countries, with a workforce of 34,000 and an annual budget of over \$1.4 billion.

MSF thanks the Committee on Ways and Means for the opportunity to submit a written statement for consideration in the April 3, 2014 Hearing on President Obama's Trade Policy Agenda. Our engagement with trade issues is limited to the extent to which they impinge on our ability to exercise our medical/humanitarian mission and set standards which affect the global health objectives to which we, along with many other health organizations are striving.

In order to fulfill its mission, MSF requires access to affordable medicines, vaccines and other medical technologies. MSF's Campaign for Access to Essential Medicine was established with the financial element of the Nobel Peace Prize awarded to MSF in 1999. The campaign was established in response to a growing awareness that trade and intellectual property rules were key barriers to ensuring accessibility and affordability of essential medicines, vaccines and diagnostics. The Access Campaign therefore builds on MSF's experiences to influence reform of the legal and regulatory barriers of access to medical tools, the inadequacy of the current medical innovation system and to ensure trade and intellectual property laws and regulations do not jeopardize public health. As a medical treatment provider with more than 40 years of experience caring for vulnerable patients, MSF is able to speak about the relationship between trade, intellectual property (IP) rules and access to medicines, and about the role generics have played in driving down high costs of medicines and enabling access and innovation to life-saving medicines for millions around the world.

We are writing to express our deep concern with the trade policies pursued by the United States, specifically with the intellectual property, pricing and investment dispute settlement demands with trading partners, especially but not limited to India and TPP negotiating countries. We believe these threaten to restrict access to medicines and medical technologies for millions by delaying or denying generic competition and by impeding much needed public-health driven innovation.

Generic competition has proven to be the best way to reduce drug prices and improve access to treatment. MSF began providing antiretroviral (ARV) treatment for HIV/AIDS in 2000 when the cost of treatment was more than 10,000 USD per patient per year. MSF now treats 285,000 people in HIV/AIDS projects in 21 countries, mostly with generic drugs produced in Asia. These generics have reduced the cost of treatment by nearly 99 percent to less than 100 USD per patient per yearⁱ. Patients, Ministries of Health, medical treatment providers like MSF, and the U.S.-funded PEPFAR and the Global Fund to Fight AIDS, Tuberculosis and Malaria, routinely rely on affordable quality generic medicines to treat HIV/AIDS and a variety of other health needs and conditions.

Furthermore, over the past decade the U.S. has made a series of commitments to protecting global health including, but not limited to, the 2001 WTO Doha Declaration on TRIPS and Public Health and the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, and in bilateral agreements with developing countries like Colombia, Panama and Peru. MSF urges the U.S. to uphold these commitments and to respect legal public health flexibilities enshrined in international law in its relationships with trading partners.

Trans-Pacific Partnership Agreement (TPP): Trading Away Health

MSF is deeply concerned by provisions under negotiation in the Trans-Pacific Partnership Agreement (TPP) that threaten to restrict access to affordable medicines for millions of poor people, especially but not limited to those in low- and middle-income developing countries.

The TPP is being negotiated without opportunity for meaningful public input. Leaked texts now in the public domain, however, indicate that stringent intellectual property (IP) provisions proposed by the United States go well beyond rules established by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These demands will roll back public health safeguards and flexibilities enshrined in international law, and put in place far-reaching monopoly protections that will restrict generic competition and keep medicine prices unaffordable for millions for years to come.

We believe the U.S. demands in the TPP presents a direct threat to the future availability of affordable medicines for MSF's patients and for millions of others around the Asia-Pacific region. We are also concerned that the TPP, billed as a '21st century model trade agreement', could become a global standard, with worldwide damaging repercussions for access to treatment and medical care.

MSF is not alone in expressing concerns with the U.S. demands in the TPP. Many others, including UNITAIDⁱⁱ, International AIDS Societyⁱⁱⁱ, the Holy See^{iv}, Nobel-prize winning economists^{v,vi}, many U.S. and international civil society groups^{vii} and Members of U.S. Congress^{viii} share our concern that the TPP will restrict access to medicines unless harmful provisions are removed.

Below, we highlight some of the key concerns of TPP proposed provisions and their potential effects on access to medicines. For a more detailed analysis, including a reference to other

provisions under negotiation that will also affect public health, please refer to MSF's Open Letter to TPP Negotiating Countries and MSF's issue briefs and analysis, available [online](#).^{ix}

TPP proposes to lower standards of patentability

Under the WTO's TRIPS Agreement governing global intellectual property norms, governments have the right to define what does and does not deserve a patent in a way that addresses the needs of their own citizens and innovation system, as long as they abide by the patentability criteria and patentable subject matter norms agreed under international law. We think it is in the public interest for governments to retain these flexibilities, including to be able to strengthen patentability criteria and limit industry patent evergreening and other abusive patenting practices. The U.S. is contributing to this effort with a variety of recent Supreme Court decisions that narrow what deserves a patent under U.S. law.^x

The U.S. also recognizes that excessive patenting can undermine innovation and American economic productivity across many sectors. President Obama's State of the Union Address this year reflects this in his calls for reform of the U.S. patent system and limits to costly patent litigation that "[allow] our businesses to stay focused on innovation."

In the TPP negotiations however, the U.S. is proposing to mandate the granting of secondary patents, including for developing countries, forcing countries to grant patents on modifications of existing drugs and allowing pharmaceutical companies to extend patent monopolies beyond the 20-year original patent term. This is not only not required under international trade law but threatens to restrict or at best delay access to price-lowering generic competition. It is difficult to estimate how long monopolies will be extended, and most likely the effects will differ drug by drug and country by country, but a recent study found that granting secondary pharmaceutical patents extends the life of monopoly protections by an average of more than six years.^{xi}

In contrast, in India, where the patent law has tools to limit patent evergreening and secondary patenting, for example, the patent office rejected Novartis' patent application for a modification of an existing life-saving anti-cancer drug, imatinib mesylate. This patent rejection allowed generic competition that has brought down prices for this drug from over US \$2,400 per patient per year (ppy) to US \$200 ppy.^{xii}

The U.S. government continues to make adjustments to its patent system to achieve a better balance between rewarding innovation and providing for health and other public needs. It should allow other governments, like TPP negotiating countries, to do the same. Allowing for strict patentability does not undermine rewarding innovation through the patent system, but rather curtails the worst excesses, ensuring that innovators focus their energies on truly useful and new drugs and other medical technologies, rather than business strategies that extend existing patent monopolies with low or no inventive and societal contribution.

TPP mandates 12 years of data exclusivity for biologics

MSF is concerned by reports that the USTR is demanding 12 years of data exclusivity for a certain class of drugs known as biologics in the TPP. Biologics are already very expensive and

many times unavailable as a treatment option in many of the developing countries where MSF works.

Data exclusivity for any drugs is not required by international law. The U.S. is the only TPP negotiating country that currently requires 12 years of data exclusivity for biologics, but even within the U.S. the period of 12 years is challenged. As the Federal Trade Commission's analysis on the subject found, 12 years of data exclusivity for biologics is not warranted to promote innovation and is not even appropriate for the U.S., imperiling the public health and budgetary benefits to accelerate the entry of follow-on biologics.^{xiii} Furthermore, for four consecutive years, the Obama administration has proposed through budget proposals to reduce the term for biologic data exclusivity from twelve to seven years.^{xiv} As cited in the Administration's own proposal, in U.S. federal programs alone, reducing data exclusivity for biologics by five years would result in savings of at least US \$3 billion over ten years.^{xv}

Data exclusivity raises the price of medicines even when no patent exists. For example, in the U.S., the price of colchicine, a treatment used mainly for gout, rose more than 5000% after data exclusivity was enacted.^{xvi} Colchicine has been in use for thousands of years, costs almost nothing to produce, and cannot be patented. Therefore, generic formulations of the tablet have been widely available since the 19th century. However, a new monopoly on colchicine was created in 2009 when the FDA accepted clinical data from a one-week trial of the drug and granted data exclusivity to URL Pharma. URL Pharma subsequently sued to force other manufacturers off the market, and raised prices from \$0.09 to \$4.85 per pill.

MSF is opposed to any efforts by the USTR to export these contested and access-restricting U.S. regulations to trading partners, especially in developing countries where more affordable biosimilars or follow-on biologics are urgently needed.

Investor State Dispute Settlements are a public health risk

The USTR is proposing to include investor-state dispute settlement (ISDS) provisions in the TPP and to allow its applications to intellectual property and others policies that can affect public health. The ISDS clauses in the leaked text of the TPP extend and define Intellectual Property (including pharmaceutical patents or essential medicines) as assets, and provide rights to sue if governments take actions which are 'tantamount to expropriation' of these assets.

In addition the investment chapter of this trade agreement gives the right for investors to enjoy "treatment in accordance with international law, including fair and equitable treatment and full protection and security" in relation to their investments. This definition of fair and equitable treatment in accordance with international law is not a clear and obvious standard, and critically for public health, does not necessarily encompass the objectives of the Doha Declaration on Public Health.

It is the view of MSF that ISDS clauses pose an unnecessary risk to public health objectives – and in particular ensuring access to affordable medicines. MSF is concerned that this opens up the possibility of pharmaceutical companies suing governments for policies and strategies that promote public health, including governments who opt to use the TRIPS flexibilities (e.g. define

strict patentability standard to scrutinize and exclude patents for trivial changes of known medicines, or issuing a compulsory license for the production or import of a generic version of an essential medicine) arguing that this breaches the standard of fair and equitable treatment or may amount to expropriation of an asset.

If ISDS provisions are included in the TPP, it could undermine countries' ability to set patentability criteria to balance with public health needs of their population, for example, in direct contradiction with the rights and flexibilities afforded to them by international rules. For example, ISDS provisions included in the North American Free Trade Agreement (NAFTA) have allowed U.S. pharmaceutical company Eli Lilly to sue the government of Canada, seeking 500 million Canadian dollars in compensation following the invalidation of two of the company's patents by Canadian courts.

Patents are private rights given by governments and if they are infringed upon, patent-holding pharmaceutical companies can always go to national courts and seek for adequate remedies. However, investor-state dispute settlement provisions give corporations an additional right to sue governments in extrajudicial private tribunals if the regulatory environment or government practices negatively affects their expected profits. Furthermore, decisions made by these ISDS bodies are often unappealable and damages owed by developing country governments will be paid out of public funding.

In Ambassador Froman's testimony, he stated that USTR is considering safeguards that allow governments to "regulate as they see fit" in the public interest for health. However in other ISDS agreements with language included intending to safeguard government capacity to pass laws and regulations in the public interest (including for public health), exceptions in the language of these safeguards leave ambiguity. Legal opinion is far from unanimous on whether the wording in similar ISDS "safeguards" is strong enough to ensure public health protection.^{xvii} The carve out for exceptional circumstances in which government regulations intended to protect the public interest may not be protected is thought^{xviii} to give too much scope for lawyers to devise ways to circumvent this proposed safeguard.

In the case brought by Eli Lilly in Canada under NAFTA such a safeguard would not appear to be relevant because the matter contested relates to definitions of patent law and not public health regulations per se, although the ruling on the patentability criteria test might have a public health impact. Thus, a narrowly defined approach to safeguards would not prevent ISDS from being used in attacking legislative and regulatory measures that have a direct or indirect impact on health.

These so called safeguards do not ensure that public health measures will be free from contestation by pharmaceutical companies. Even if the settlement process is thought unlikely to be successful the mere threat of a lengthy and costly settlement process could be enough to dissuade governments, particularly those in low- and middle-income countries with significant resource constraints, from enacting public health measures like those facilitated by the Doha Declaration. Furthermore, with unappealable decisions being issued by these tribunals, countries will still have to consider the risks of unfavorable judgments from these extrajudicial tribunals without any ability to appeal.

Special/differential treatment proposal is not sufficient and not May 10 compliant

After years of opposition to their initial demands, in November 2013, the United States trade negotiators proposed a “differential treatment approach” to the TPP Intellectual Property chapter claiming to be extending some of the public health flexibilities included in the 2007 New Trade Policy (May 10 Agreement) to the developing countries currently negotiating the TPP. In his testimony, Ambassador Froman also claimed that the USTR proposal in the TPP was now consistent with the May 10 Agreement.

In February 2014, MSF joined a coalition of U.S. and international civil society organizations^{xix} in the criticism of this empty promise for balance. USTR’s proposal would impose unprecedented and excessive “TRIPS-plus” IP protections for both developed and developing countries. Such measures favor the expansion of drug monopolies at the expense of patients’ health and fails to preserve even the modest pro-access steps achieved under the May 10 Agreement. MSF is concerned about the mischaracterization of this proposal as being coherent with the May 10 Agreement.

The TPP imposes new and harsher measures for health that were never part of the U.S. trade agreements with Peru, Colombia and Panama and therefore were not considered in the May 10 Agreement. Yet all TPP countries are expected to adopt these new provisions, which include: lower patentability standards that will expand the scope of what can be patented and a special, extra-long additional period of data exclusivity for biologics that will block access to more affordable biotech medicines that are urgently needed to treat diseases such as cancer and hepatitis, as described above.

This differential treatment proposal is not only inadequate in scope – failing to fully incorporate the May 10 Agreement – it is unacceptably limited in scale. Under USTR’s proposal, only a few of the less wealthy countries will be eligible for differential treatment, and they would still be forced to adopt access-restrictive IP protections in the long-term. USTR’s differential treatment proposal simply consists of the limited application of some of the harmful provisions of the IP chapter (patent linkage, patent term extensions, and certain types of data exclusivity) for certain developing countries. Yet the terms of these provisions may still be more restrictive than those afforded to developing countries under the May 10 Agreement. Further, these different standards would only be available until those countries cross a certain income or number of year threshold. They also may not be available for other developing countries that may accede to the TPP in the future. By contrast, the terms offered to Peru, Colombia and Panama under the May 10 Agreement were permanent.

Lack of transparency

During his testimony Ambassador Froman cited the USTR’s new committee for public interests groups as evidence of transparency and consultation of “peer advisors” for the TPP. However, MSF remains concerned about the lack of transparency for TPP negotiations. Even if this new public interest group committee included an appropriate representation of technically qualified experts representing public health concerns to balance the many pharmaceutical and medical

technology representatives already included in USTR advisory committees, the terms of confidentiality that members of this committee will have to agree to does not resolve the lack of transparency. If public health experts reviewing the text cannot also speak on their concerns, then the value of providing comments directly to USTR by sitting on the committee may be far outweighed by the damage of restricting civil society's public voice. A true commitment to transparency would be to publicly release the negotiating text.

Punishing India for the promotion of life-saving generic competition

In his testimony Ambassador Froman highlighted the ongoing efforts by the USTR to pressure India over intellectual property policies and measures protecting access to medicines. MSF has expressed our concern before over this unwarranted pressure on India. A timeline outlining the strategies and the escalating frequency of these efforts can be found on our [website](#).^{xx}

In short, India's patent law and its judiciary are under pressure for policies that are entirely in line with its obligations as a WTO Member State and also a government that should be promoting public health-driven policies. In compliance with its international obligations, India has started to provide significant patent protection for medicines: between 2005 and 2008 India granted over 2000 patents for medicines, and continues to grant patents today - including on new antibiotics for TB treatments, which MSF urgently needs in our medical operations. Treatment providers are already seeing the impact of these patents, which delay generic competition, keeping newer medicines out of affordable reach. While India does grant patent monopolies to a vast number of pharmaceutical products, it is trying to strike a balance between providing intellectual property protection and having the flexibility to protect the constitutional right to health.

It does so in at least two ways:

The first way is by defining strict patentability criteria. As evidenced above, India has adopted a standard of patenting that is stricter than that in the U.S. or Europe, but which is in line with international trade rules.

Compulsory licenses are another legally recognized safeguard that allows a country to balance intellectual property protection with the right to protect public health. The U.S. government has threatened or used compulsory licenses for medicines in the past to meet public health needs, and stated that it would look to use them in the future if necessary.

India has had the ability of using compulsory licenses for many years, but unlike the United States and others – and despite the unaffordable medicine prices charged by multinational drug companies – had never issued one until very recently. In 2012, the country issued its first – and so far only - compulsory license in the interest of public health, when faced with a price-tag for a cancer drug which kept it out of reach of 98 percent of those eligible for treatment. Granting the compulsory license reduced the price by 97 percent. The Indian courts also recognized the innovation behind the drug, and obliged the generic manufacturer to pay a 7 percent royalty to the patent holder.

MSF hopes that where access barriers exist, compulsory licenses will be issued for the newest drugs to address critical health priorities, enabling affordable generic versions to be made available not only in India, but also in the rest of the developing world.

Conclusion: US trade policy should be promoting a better innovation system that ensures affordable access for all

MSF recognizes the need to reward innovation and the need to finance research and development (R&D). We are a humanitarian medical organization that needs and welcomes biomedical innovation to improve treatment options for our patients. R&D is important, and someone needs to pay.

However, the reality is that relying on high prices for medicines, backed up by intellectual property monopolies, is a flawed paradigm to pay for medical innovation. It creates both access problems due to high prices – as we have seen – and at the same time it does not stimulate innovation for many of the diseases affecting people in developing countries, where patients have limited purchasing power and the private sector sees no incentive. Today, we basically have a tradeoff between innovation and access. If you have wide access, says the industry, you aren't supporting innovation.

New approaches to medical innovation are demonstrating that significant medical breakthroughs with access are possible – in particular, models of innovation that break the link between the cost of research and development and the high price of the end product.

Seeking greater intellectual property norms through trade agreements like the TPP and through exerting pressure on countries like India that are the source of access for millions around the world, not only does little for innovation but also perpetuates a failed business model. Instead of aggressively pushing governments to ignore their legal rights under international trade rules to ensure affordable medicine prices, the U.S. government should promote trade policies that allow for investment in and development of new models of innovation that promote both innovation and access.

ⁱ MSF Untangling the Web of Antiretroviral Price Reductions, 16th Edition. [Online] July 2013 [Cited 10 April 2014] Available from: <http://utw.msfacecess.org/>

ⁱⁱ UNITAID. The Trans-Pacific Partnership Agreement: Implications for Access to Medicines and Public Health [Online] March 2014 [Cited 10 April 2014] Available from: http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report_Final.pdf

ⁱⁱⁱ International AIDS Society Statement on the TPP and Access to Medicines [Online] 1 July 2013 [Cited 10 April 2014] Available from: http://www.iasociety.org/Web/WebContent/File/IAS_TPPA_statement_2_July_2013.pdf

^{iv} Vatican Statement on TPP and Access to Medicines [Online] 3-6 December 2013 [Cited 10 April 2014] Available from: <http://keionline.org/sites/default/files/HolySeeMC9Bali2013.pdf>

^v Stiglitz, J. "On the Wrong Side of Globalization." New York Times [Online] 15 March 2014 [Cited 10 April 2014] Available from: <http://opinionator.blogs.nytimes.com/2014/03/15/on-the-wrong-side-of-globalization/>

^{vi} Krugman, P. "No Big Deal." New York Times [Online] 28 Feb 2014 [Cited 10 April 2014] Available from: http://www.nytimes.com/2014/02/28/opinion/krugman-no-big-deal.html?_r=0

^{vii} See for example: <http://www.citizen.org/USTR-IP-proposal-for-TPP-endangers-access-to-medicines-for-all-say-health-advocates>

^{viii} For recent examples, see: [Levin Statement on Trans-Pacific Partnership Negotiations](#), December 2013; [Representative McDermott, "Worlds Apart; Making Sure Trade Policies Improve Global Health,"](#) May 2013; [Representative Waxman sends letter to USTR expressing concerns for access to medicines](#), December 2013; [Six Members of Congress Write to President Obama on TPP and Access to Health Care](#), December 2013; [Five Ranking Members of House of Representative send letter to](#)

USTR expressing concerns for access to medicines in developing countries, January 2014; Rep. Grijalva, “The TPP is Terrible for Public Health” April 2014; 16 Members of Congress Write to USTR on TPP and concerns for May 10+ and secondary patents, March 2014

^{ix} MSF website on the TPP & impact on global health: <http://www.msfacecess.org/tpp>

^x For example, Mayo v. Prometheus and Association for Molecular Pathology v. Myriad Genetics

^{xi} Kapczynski, Park and Sampat. “Polymorphs, prodrugs and salts (oh my!): an empirical analysis of ‘secondary’ pharmaceutical patents.” PLOS One [Online] 5 December 2012 [Cited 11 April 2014] Available from: <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0049470>

^{xii} MSF. “Indian Supreme Court Decision on Novartis Case a Victory for Access to Medicines in Developing Countries.” [Online] 1 April 2013 [Cited 10 April 2014] Available from: <http://www.doctorswithoutborders.org/article/indian-supreme-court-decision-novartis-case-victory-access-medicines-developing-countries>

^{xiii} Federal Trade Commission. Emerging Health Care Issues: Follow-on Biologic Drug Competition. [Online] July 2009 [Cited 10 April 2014] Available from: <http://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>

^{xiv} White House Office of Budget and Management. FY 2015 Budget [Online] [Cited 10 April 2014] Available from: <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2015/assets/budget.pdf>

^{xv} White House Office of Budget and Management. FY 2014 Budget [Online] [Cited 10 April 2014] Available from: <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2014/assets/budget.pdf>

^{xvi} Shaffer, E., Brenner, J. “A Trade Agreement’s Impact On Access To Generic Drugs.” September/October 2009. Health Affairs vol. 28 no. 5 w957-w968.

^{xvii} Muse-Fisher. “CAFTA-DR and the Iterative Process of BIT Making: Towards a United States Takings Framework for Analyzing International Expropriation Claims’.” 2007. Pacific McGeorge Global Business and Development Law Journal 495 at 518-19.

^{xviii} Edsall, R. “Indirect Expropriation Under NAFTA and DR-CAFTA: Potential Inconsistencies in the Treatment of State Public Welfare Regulations” 2006. Boston University Law Review 931.

^{xix} Joint Civil Society Letter. “USTR’s Proposal for IP Chapter of the TPP Will Endanger Access to Medicines for All.” [Online] 12 February 2014 [Cited 10 April 2014] Available from: http://www.msfacecess.org/sites/default/files/MSF_assets/IP/Docs/140212_TPPJointStatementSDT.pdf

^{xx} MSF. A timeline of U.S. attacks on India’s patent law & generic competition. [Online] 2013 [Cited 1- April 2014] Available from: <http://www.msfacecess.org/about-us/media-room/press-releases/us-puts-unwarranted-pressure-india-taking-legal-steps-increase>