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SUBMISSION TO THE U.S. TRADE REPRESENTATIVE REGARDING THE 2014 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 2014 Special 301 Review Process.

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.

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 USTR will have on access to affordable generic medicines for patients and our 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.

We remain disappointed that most of the issues that we raised in our 2010[1], 2011[2] and 2012[3] submissions remain unaddressed. The inadequate standards of intellectual property that USTR is pursuing though the Special 301 Process are a direct threat to generic competition and to the treatment that we provide to our patients.

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

[1] MSF submission to 2010 Special 301 process: http://www.msfaccess.org/content/msfs-statement-regarding-2010-special-301-review
[2] MSF submission to 2011 Special 301 process: http://www.msfaccess.org/content/2011-special-301-review
[3] MSF submission to 2012 Special 301 process: http://www.msfaccess.org/content/submission-us-trade-representative-regarding-2012-special-301-review-process

intellectual property protections more extensive than those under international law and the WTO TRIPS agreement, through for example the TPP negotiations. Our recent statements and analysis on the USTR demands in the Transpacific Partnership Agreement[4] negotiation should therefore also inform this process.

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 of any public health legal safeguards or flexibilities permissible under international law.

In this year submission, MSF would like to emphasize the role that India has played in enabling access to life-saving medicines for millions and ask that USTR does not penalize the Indian government and the Indian judiciary system for actions that promote access to medicines, as we did in our reaction to last year report[5].

In 2001, MSF faced what seemed like insurmountable barriers in meeting critical health needs and saving the lives of our patients. In particular, we faced an astronomical 10,000-dollar per-person per-year price-tag for life-saving HIV medicines, which barred millions from treatment and prevented us from being able to reach more than a very limited number of people.

But a solution was found in India. The legal safeguards introduced in the country's 1970 patent law excluded patents on life-saving medicines and resulted in boosting the manufacture of low-cost, quality generic medicines for a fraction of the existing price. In 2001 the cost to treat someone with HIV fell by over 96 percent – literally overnight – to 360 dollars per person per year. Since then generic competition has seen the cost fall even further.

As a result, nearly 10 million people worldwide today receive treatment for HIV, many of those from PEPFAR and other U.S. government-funded programs like the Global Fund to fight AIDS, TB and Malaria. India's role in this treatment scale up has been – and continues to be – a critical one. As the 'pharmacy to the developing world', and as the biggest source of quality generic medicines, governments and donors such as the United States rely heavily on Indian generic medicines. According to the latest data, 98 percent of the medicines used in the American taxpayer-funded PEPFAR program rely on low-cost generic medicines. This represents important cost savings that stretches America's significant investment in global health further and saves millions of lives.

According to the last U.S. government budget, in fiscal year 2014 this U.S. Government investment amounts to more than 7 billion dollars just for HIV/AIDS, TB and malaria alone. The generous contributions of the U.S. government in the global fight against HIV and AIDS have been pivotal in bringing us to the point where we can, for the first time, talk about reversing the AIDS epidemic as a feasible policy objective. We welcome new

[4] MSF on the TPP negotiations impact on access to medicines: http://www.msfaccess.org/tpp
[5] MSF reaction to 2013 Special 301 Report: http://www.msfaccess.org/content/us-penalises-india-promoting-access-medicines-strategies-placing-it-trade-watch-list

ambitions and efforts on the part of the U.S. government to translate the new science – that HIV treatment is, in fact, prevention – into policies that will scale up access to treatment. But the ability to implement these policies is directly linked to the ability of patients, treatment providers and donors, including the U.S. government, to access medicines at affordable prices.

HIV/AIDS is just one example. We need access to affordable treatment for a variety of medical problems that affect our patients, including both communicable and non-communicable diseases.

International trade and intellectual property rules govern what it is governments can and can't do to protect public health and access to affordable medicines. Member States of the WTO – including the U.S. and India – have agreed to these rules which set standards for what deserves a patent, and for how long a patent should last. In 2001, WTO Member States, including the US and India, also signed the Doha Declaration on TRIPS and Public Health, which enshrines the right of governments to implement safeguards and flexibilities to protect public health.

In recent years, the U.S. has made additional commitments to recognize the importance of public health. For example, through the 2007 New Trade Policy, the U.S. recognized the importance of public health safeguards for developing countries. The U.S. again committed to the importance of public health in the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

India's patent law and its judiciary are under pressure for policies which we consider are entirely in line with its obligations as a WTO member. In compliance with it is 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 we urgently need 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.

Take HIV for example again – although first line treatment has benefited from important price reductions, more people need to be switched to newer and more effective medicines. MSF has started to switch HIV patients who develop drug resistance onto newer medicines, which are expensive because they are under patent and there is no competition. At our clinic in Mumbai, India, salvage regimen drug raltegravir is prohibitively priced at 1,775 dollars per person per year.

New medicines to treat Hepatitis C, which affects around 180 million people worldwide, provide another critical illustration. New medicines entering the market, including the recently approved sofosbuvir, will be priced by brand-name companies as high as 1,000 dollars per pill in the U.S. While it is likely that these medicines will be less expensive in India and other countries, we know that without generic competition, affordable and effective treatment for millions of people living in developing countries will not be possible.

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:

(1) Strict patentability criteria

The first way is by defining strict patentability criteria. Under TRIPS, governments have the right to define 'scope of patentability' – what does and does not deserve a patent - in a way that addresses the needs of their own citizens, as long as they abide by international agreements. The U.S. recently contributed to its own definition when the Supreme Court reaffirmed strict patentability criteria for gene patents.

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.

There are numerous examples of how India's application of strict standards of patentability has resulted in improved access to medicines. For example, a secondary patent application on a life-saving cancer drug, imatinib by Novartis was rejected because it was for a modified form of an already known substance. Novartis challenged this decision. When the Indian Supreme Court upheld the decision of the patent office last year, it was legally validating a choice by the Indian parliament to better define standards of patentability for medicines. While a patent should reward innovation, in reality the overwhelming majority of patents are applied for incremental developments on existing medicines.

In contrast to India's stricter patentability criteria, the U.S. has patent standards which allow for the granting of secondary patents for very obvious modifications of existing medicines. This practice, known as 'ever-greening,' acts to delay generic competition and keep prices high, and is a common tactic by which the pharmaceutical industry extends their monopoly on drugs beyond the original patent's 20 years. A recent study found that evergreening extends patent protection by an average of more than 6 years. Allowing companies to extend patent protection and keep prices high is expensive for U.S. consumers and the U.S. government.

For example, the patent on the active ingredient in imatinib, marketed as Gleevec, the cancer drug at the heart of the Novartis case, will expire next year in the US. However, secondary patents will extend Novartis's market monopoly in the US until 2018, preventing more affordable generics from entering the market

The U.S. recognizes that excessive patenting can undermine innovation and American economic productivity across many sectors. President Obama's State of the Union Address 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."

The U.S. government continues to make adjustments to its patent system to achieve a better balance between rewarding innovation and providing for public health needs. It should allow other governments, like India, to do the same. The measures taken by the Indian government do not undermine rewarding innovation through the patent system,

but rather curtail the worst excesses of it, ensuring that companies focus their energies on scientific innovations and research for new drugs, rather than business strategies that extend existing patent monopolies with low or no inventive contribution.

When it comes to incentivizing innovation, determining the right balance for governments to strike in deciding what deserves a patent and what does not is a complex matter. MSF supports the Indian government decision that patents should only be granted for innovations that satisfy rigorous criteria to assess inventive step and have accomplished something significant in terms of therapeutic efficacy.

(2) Compulsory licenses

Compulsory licences 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.

The Indian Patent Office 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 will be available not only in India, but in the rest of the developing world. With new HIV, cancer and hepatitis C medicines priced beyond the reach of patients and treatment providers, the use of public health safeguards in India will be necessary to ensure that medicines are affordable to the millions who require treatment.

Need for reform

Make no mistake - MSF recognizes the need to reward innovation and the need to finance research and development. 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 and other medical technologies, 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 trade off 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.

Conclusion

Every country has the right to take steps to increase access to medicines and implement a patent system in line with its public health needs. We strongly object to the pressure exerted by the U.S. government on developing countries, including India, for using legal flexibilities to protect public health. India's measures are fully compliant with global trade rules and with the laws of India. These attacks undermine the global trading system as well as the independence of the Indian judiciary, which was responsible for some of decisions under discussion.

Most importantly, the measures India has implemented to safeguard public health are of critical importance to protect the health of millions of people across the world. India has been nicknamed the 'pharmacy to the developing world' in recognition of this fact. Losing this 'pharmacy' would be devastating for patients and for treatment providers around the world. MSF urges USTR to evaluate the decisions made by the Indian government and judiciary under international trade rules, taking in consideration its impact on public health.

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. Seeking greater intellectual property norms in countries like India that are the source of access for millions around the world, not only does little for innovation but it perpetuates a failed business model. Instead of aggressively pushing governments, such as India, to ignore its legal rights under international trade rules to ensure affordable medicine prices, the U.S. government should work with India and other countries, to invest in and develop new models of innovation that promote both innovation and access.