Submission for the Record to the Hearing:

"A Tangle of Trade Barriers:

How India's Industrial Policy is Hurting U.S. Companies."

Washington, DC - June 27, 2013

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Thank you for giving me the opportunity to provide testimony on behalf of Doctors Without Borders, also known as Médecins Sans Frontières, or MSF. My name is Rohit Malpani and I am the Director of Policy and Analysis at MSF's Access Campaign.

MSF is an international independent medical humanitarian organization created by doctors and journalists in 1971. Today, MSF provides impartial medical assistance in more than 60 countries, aiding those whose very survival is threatened by armed conflict, disease epidemics, malnutrition, exclusion from health care, or natural disasters.

MSF also works to raise awareness and galvanize action towards neglected crises, to challenge inadequacies or abuse of the humanitarian aid system, and to advocate for improved medical tools and protocols.

At the time that MSF was awarded the Nobel Peace Prize in 1999, the organization and many other treatment providers faced what seemed insurmountable barriers in meeting the critical health needs and saving the lives of our patients, particularly relating to the astronomical US$10,000 per-person, per-year price-tag for HIV/AIDS medicines, but also relating to the lack of effective and affordable tools to combat malaria, tuberculosis and many other tropical diseases that are some of the biggest killers of our time. MSF therefore launched the Access Campaign to advocate, on behalf of our medical teams, for affordable access to, and for the development of, needed medicines, diagnostic tests and vaccines for patients in MSF programs and beyond.

Part of the Access Campaign's remit is to identify and challenge the political, legal and commercial barriers that stand in the way of access to affordable medicines and that inhibit innovation for patients in developing countries. MSF's Access Campaign staff has expertise on patents and intellectual property rights, one of the major causes of high drug prices, and also on new models for innovation that better respond to patient needs while ensuring affordable access for all in need.

Today, MSF has been asked to provide testimony on India's patent law. As a medical treatment provider, MSF is able to speak generally about the relationship between

intellectual property rules and access to medicines, and in particular about India's patent law. I will address these issues shortly.

But I also want to make clear that this hearing cannot help but delve into issues much larger than the IP environment in India.

Firstly, whether the current medical innovation system works, and for whom.

I already mentioned briefly that the medical innovation system doesn't work for our patients. But even cancer doctors in the US believe the patent system is not working for their patients: when a new drug cost $11,000 per month, twice as much as an existing drug that worked just as well, they refused to offer it to their patients.

Secondly, how governments can best balance private commercial interests and public health in their IP laws?

These are questions that Congress is grappling with on the domestic front right now, and the U.S. government continues to make adjustments to its patent law to find the right balance.

For example, the U.S. Supreme Court recently affirmed the validity of the U.S.'s strict patentability criteria around genes, setting limits on what is patentable and taking into account public health needs and the vital importance of competitive markets for medical products.

The White House, in its FY2014 budget, has proposed steps to limit so-called 'evergreening' – abusive practices used to extend intellectual property monopolies, keeping prices high for as long as possible. The Administration also recently

introduced a package of executive actions and legislative proposals to stop abuse of the patent system by curbing lawsuits by 'patent trolls'.

As Supreme Court Justice Clarence Thomas, writing for the court last week in the Myriad Genetics case, said: "As we have recognized before, patent protection strikes a delicate balance between creating incentives that lead to creation, invention, and discovery, and impeding the flow of information that might permit, indeed spur, invention."

The same balance that the United States continues to define is under careful consideration in India also.

MSF has had medical operations in India since 1999. MSF provides health services to neglected and marginalized populations in the states of Bihar and Chhattisgarh, the disputed region of Kashmir, remote villages on the border with Myanmar, as well as the enormous city of Mumbai. Our operations include primary health care and routine vaccinations, nutritional support for children and pregnant women, and screening and treatment for malaria, HIV/AIDS, visceral leishmaniasis and tuberculosis, including multidrug-resistant tuberculosis.

India is an important manufacturer and supplier of quality generic medicines for millions of people around the world. MSF is highly dependent on the availability of affordable high-quality medicines to provide medical care, as are many of the Ministries of Health with whom we work. Ninety-eight percent of PEPFAR's HIV drug purchases are generic medicines from India. In fact, we call India the 'pharmacy of the developing world.'

Let me share an example of how generic medicines produced in India have changed the treatment landscape of an important disease like HIV/AIDS. From the US$10,000 price tag to treat one person for HIV ten years ago, market competition among multiple generic manufacturers in India brought HIV medicine prices down by nearly 99%, to roughly $100 today for the World Health Organization's recommended first-line antiretroviral, or ARV, treatment.

Currently, more than 9 million people are alive and on ARV treatment in middle and low-income economies, thanks to affordable prices that enabled treatment scale-up on a large scale. But many more are still waiting for access, and we need to continue scaling up treatment.

The generous contributions of the U.S. government in the global fight against HIV/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 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 treatment providers to access medicines at affordable prices. Affordable ARVs are critically important to PEPFAR, to the Global Fund, to MSF, and to many others.

Here's where the U.S. government's inconsistent policies on global health and international trade collide. While the U.S. runs PEPFAR and is the largest donor to Global Fund, the U.S. is also pursuing international trade policies that will make it

harder for countries to implement laws to promote market competition and to protect public health; it will be much harder for patients, governments, treatment providers like MSF and U.S.-donor supported programs to have access price-lowering generic drugs.

These policies don't just affect affordability – they also negatively affect innovation. Fixed-dose combination antiretrovirals, which combine multiple medicines into a single pill, make adhering to treatment easier for patients, and make it easier for treatment providers to scale up care to more people. But these were first developed by generic manufacturers in India: because India did not, at that time, grant patents on pharmaceuticals, the individual medicines weren't patented there, allowing them to be combined into one pill.

In 2005, India and other developing countries began granting pharmaceutical patents in accordance with TRIPS. India granted more than 2,000 pharmaceutical patents between 2005 and 2008, and the country continues to grant patents.

But as India prepared to change its legislation in order to do introduce patenting for pharmaceuticals, the World Health Organization and UNAIDS wrote to the Indian government to ask the country to safeguard its role as main supplier of affordable quality antiretroviral and other medicines used in the developing world, and to urge the country to use the existing international legal regulations to ensure the harm to access to affordable medicines would be limited.

Indeed, the WTO TRIPS agreement offers countries important policy and legal choices to limit the impact of the new obligations to grant patents, and to balance its

enforcement of IP policy with public health needs. The 2001 Doha Declaration, that both the U.S. and the Indian governments signed, reiterated the right to use legal tools, known as TRIPS flexibilities, to promote generic competition that saves lives. One of the most important policy choices that WTO member states can make is related to the use of these TRIPS flexibilities.

Two flexibilities in particular are worth examining here:

Compulsory Licenses

The first concerns compulsory licenses (CLs). CLs are a legally recognized means to overcome barriers in accessing affordable medicines under international trade rules.

The Indian Patent Office has had the possibility of using compulsory licenses for many years, but unlike the United States and others, had never used the tool until very recently. In March 2012, faced with a lack of access for Indian patients to a kidney and liver cancer treatment, the Indian government issued a compulsory license on German pharmaceutical company Bayer's patented drug sorafenib tosylate. Bayer appealed against the license but India's Intellectual Property Appellate Board (IPAB) in Chennai upheld the decision in 2013.

The compulsory license was granted to the generic company Natco for eight years - the cancer drug will remain patented in India (until 2020) - and against the payment of a royalty rate now fixed at seven percent.

MSF welcomed the decision as it will increase access to this specific medicine that Bayer had previously only made available to a small percentage of eligible patients (slightly above 2 percent). The Patent Controller concluded that price of Rs 280,000 per month (approximately US$5,500) was not "reasonably affordable." In the decision, Natco was required to make the drug available within India at a price of not more than Rs 8,800 (approximately US$175) for one month's treatment.

The decision by IPAB confirmed that the Indian government is able to use all means legally at its disposal, and in conformity with international trade rules, to check the abuse of patents and open up access to affordable versions of patented medicines. This potentially paves the way for compulsory licenses to be issued on other drugs, for example those patented in India and priced out of reach, to be produced by generic companies and sold at a fraction of the price. In our statement, we expressed the hope that, in the near future, compulsory licenses will be issued for the newest drugs to treat HIV and affordable generic versions will be available not only in India, but in the rest of the developing world. Indeed, MSF has started to switch HIV patients who develop drug resistance onto newer medicines, which are expensive. At our Mumbai clinic, a third-line drug like raltegravir is prohibitively priced at US$1,775 per person per year.

As the number of people living with HIV, tuberculosis or hepatitis grows, more people will need to be switched to newer, more expensive and more effective treatments; the availability of affordable generic medicines will be critical.

We urge the United States Government to acknowledge that many medicine prices are too high for developing country governments and patients, and to allow for mechanisms, in conformity with international trade rules, to be established that offer sustainable solutions for accessing life-saving medicines at affordable prices in developing countries.

Strict Patentability Criteria - The Novartis Case

The second key TRIPS flexibility concerns patentability criteria. In 2005, the Indian government set a higher patentability threshold to ensure that patents are only granted on new compounds by discouraging undeserving secondary and follow-on patents. This limits the practice of evergreening. In this regard, the Indian patent law has been leading the way on how to implement WTO TRIPS-compliant laws that prevent abusive patenting practices.

Patents allow companies to have a time-limited monopoly to impose high prices by preventing competition from others. This is the ultimate balance at the core of the patent system: in exchange for allowing society to benefit from access to the invention, the inventor is able to profit from it, for a limited duration, usually set at 20 years.

Yet patent-holding companies regularly pursue evergreening strategies to prolong their monopolies ever further, thus breaking that fundamental balance. One common evergreening practice is to obtain multiple patents on a single medicine. For example, after patenting a specific drug molecule, companies often seek

additional patents to cover one or more features of a medicine, including 'process', 'formulation', dosage, combination pills and new uses. As a result, a single medicine can be protected by a large number of secondary patents, each relating to a different aspect of the same medicine; if these patent filings are staggered over a period of years, the end result is that monopoly protection for that particular drug can extend well beyond the original 20 years. In the U.S., a recent study found that secondary patents add, on average, more than six years of patent protection for the drug.[1]

Another study identified 108 U.S. patents and patent applications filed by Abbott for lopinavir/ritonavir, an important second-line HIV/AIDS medicine that combines two existing drugs, lopinavir and ritonavir. These patents could be used to protect market exclusivity for until at least 2028, even though patents on the basic compounds expire by 2016.

However, India sought to prevent this practice. As part of a series of amendments to the India Patents Act to fulfill its WTO obligations and that took effect on January 1, 2005, the Parliament of India adopted Section 3(d). This statutory provision has been in force for more than eight years. Section 3(d) was a response to the concern that the introduction of pharmaceutical product patent protection in India would substantially inhibit the availability of medicines both at home and in developing countries abroad. Parliament thus sought to limit practices that might result in the granting of secondary and follow-on patents, used to evergreen or extend patent

[1] Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents, Kapczynski A, Park C, Sampat B (2012) PLoS ONE 7(12): e49470. doi:10.1371/journal.pone.0049470

terms beyond 20 years. Section 3(d) requires that patents for new forms of known substances should only be granted if they show a significant enhancement in efficacy.

Yet this provision, although fully compliant with international trade rules, came under immediate attack. Having been denied a patent on a drug to treat leukemia in 2006, Swiss pharmaceutical company Novartis first took the Indian government to court over Section 3(d) because it wanted a more extensive granting of patent protection for its products than offered by Indian law. In a first case before the High Court in Chennai, Novartis claimed that the Act did not meet rules set down by the World Trade Organization and was in violation of the Indian constitution. Novartis lost this case in 2007, but launched a subsequent appeal before the Supreme Court in a bid to weaken the interpretation of the law and empty it of substance.

All of Novartis's claims were rejected by the Supreme Court in April 2013. What the Supreme Court did is not only to reject a patent application by Novartis on a salt form of imatinib, but to confirm that the Novartis had failed to satisfy the requirement of inventive step as provided in the Patent law.

It is important to note what the Supreme Court did not say. It did not say that a new form of known compound may never be patented. It left open the question whether enhanced efficacy refers narrowly to curative effect, or more broadly to improved safety profile and reduced toxicity.

MSF very much welcomed the decision of the Supreme Court as our patients and doctors have already benefited from Section 3(d). Several secondary and follow-on patents, on key medicines such as tenofovir prodrug (TDF) for example, have been rejected in India for failing to meet the requirement of inventive step as stipulated in Section 3(d). The applicability of Section 3(d) of India patent law has meant that affordable generic versions of some HIV medicines adapted for babies and children (such as nevirapine hemihydrate) could be produced, as well as combination pills that include more than one drug in the same pill (e.g. tenofovir disoproxil fumarate and emtricitabine), and medicines better able to tolerate the heat. The Supreme Court's decision now makes patents and high prices on the medicines that we desperately need less likely.

When it comes to saving lives, 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 have accomplished something significant in terms of curative and therapeutic effects.

The Indian Supreme Court affirmed that India has adopted a standard of pharmaceutical patenting that is stricter than that followed by the U.S. or the EU. Having a stricter inventive step is not only allowed by international law and the WTO TRIPS agreement, but it is not even unprecedented in the United States. The U.S. used to have stricter criteria for patentability however today, the U.S. Patent Office and Federal Circuit will approve patents for very minor modifications.

This impacts U.S. consumers and the U.S. government in that it allows the manufacturers to market and sell higher-priced patent-protected versions of their popular drugs. In contrast, the Indian government, supported by the Supreme Court, has decided that Indian consumers should only pay for expensive patented products when those products represent a genuine advance over older versions of medicines.

The U.S. government continues to make adjustments to its patent system to achieve better balance and it should allow other governments, like India, to follow their own paths.

Conclusions: access AND innovation

The Novartis verdict sends a message to pharmaceutical multinational corporations to focus research on new drugs, rather than on ways to evergreen their patents. But the complex relationship between patents and medical innovation deserves a closer look. Are patents and monopolies the only way to reward expensive innovation? Could other mechanisms be better placed to answer our medical needs?

Relying on patent monopolies to drive forward research and development (R&D) and innovation is fundamentally flawed for two reasons; first, it means that it R&D is predominantly driven by commercial rewards rather than global health priorities. This means that research is steered towards areas that are the most profitable, leaving fundamental medical needs—particularly those that disproportionately affect developing countries like neglected tropical diseases or tuberculosis — unaddressed.

New data from MSF and the Drugs for Neglected Diseases *initiative,* a product development partnership co-founded by MSF and which focuses on developing treatments for diseases neglected by the market, shows that between 2000 and 2011, only 3.4% of drugs approved were indicated for neglected diseases while these disease represent 10.5% of the global burden. Of these 29 drugs, only 4 were new chemical entities (NCEs). The future is equally troubling: only 1.4% of a total of nearly 150,000 registered clinical trials were focused on neglected diseases, with very few of these trials for NCEs.

The second flaw is the inevitably high cost of the newer drugs, which are often priced out of reach of developing countries, and are increasingly becoming unaffordable in wealthy countries as well. As we have seen, high medicine prices are an issue of life and death for millions of people. In times of economic austerity when we learn with concern about possible budget cuts to PEPFAR, one of the most important US health programs, we should not only learn from the past - how HIV treatment was scaled up to more than 9 million - but we should continue looking for new ways to provide for the many still waiting, including the 25 million individuals that need urgent access to HIV/AIDS treatment.

We look to the U.S. Government to allow for mechanisms, in conformity with international trade rules, that offer sustainable solutions for accessing life-saving medicines at affordable prices in developing countries.

We also need to secure medical innovation that answers to the medical needs MSF sees in its medical programs.

Research and development is an expensive and risky process, and someone does need to pay. But how much does medical innovation actually cost? There is a commonly held misconception that the cost to develop a new drug is $1 billion or more. This number is usually mentioned by PhARMA representatives, including in Congressional testimonies. Andrew Witty, CEO of GlaxoSmithKline, recently called this $1 billion price tag, "one of the great myths of the industry."

It is difficult to determine what the research and development costs are for a given drug. Pharmaceutical companies keep this information confidential. But some have estimated that the cost for drug development is closer to hundreds of millions of dollars. What is well known is that companies invest much more on promotional and marketing practices than in research and development.

The current innovation system is failing too many. At MSF we believe the world needs to move towards a new framework for R&D that considers the specific needs of patients upfront, at the start of the innovation process; breaks the link between the cost of R&D and the price of products; ensures that the fruits of innovation are accessible and affordable; and moves beyond the ad hoc patchwork of limited efforts seen so far, transforming these individual successes into a sustainable R&D framework based on clear needs and agreed priorities. There are important conversations at the World Health Organizations on these new models for

innovation that the U.S. government and Members of Congress should strongly support and engage.

I want to finish this testimony by thanking you again for this opportunity.

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- MSF is an international independent medical humanitarian organization which provides impartial medical assistance in nearly 70 countries.
- As a medical treatment provider, MSF is able to speak generally about the relationship between intellectual property rules and access to medicines, and in particular about India's patent law.
- Critical questions that also need to be addressed include
    - Firstly, whether the current medical innovation system works, and for whom.
    - Secondly, how governments can best balance private commercial interests and public health in their IP laws?
- India plays a vital role as manufacturer and supplier of quality generic medicines for millions of people around the world. Generic competition and medicines from India have brought the price of antiretroviral medicines down by roughly 99%, allowing over 9 million people to be on HIV treatment today. Ninety-eight percent of PEPFAR's HIV drug purchases are generic medicines from India, known as the 'pharmacy of the developing world.'

- U.S. government policies on global health, through PEPFAR, are thus inconsistent with U.S. international trade policies, which negatively affect affordability of medicines.
- In 2005, India began granting pharmaceutical patents in accordance with TRIPS, granting more than 2,000 pharmaceutical patents in the three years after to 2008, and continues to grant patents.
- WTO TRIPS agreement offers **all** countries important policy and legal choices – known as TRIPS flexibilities – to balance enforcement of IP policy with public health needs. India has put in place legally sanctioned safeguards that prevent abusive patenting, as part of flexibilities granted in WTO TRIPS agreement in 2001.
- One such flexibility is to set a higher patentability threshold to ensure that patents are only granted on new compounds, by discouraging undeserving secondary and follow-on patents. This limits the practice of evergreening. In the Novartis Case, the Indian Supreme Court recently affirmed India's right to adopt a standard of pharmaceutical patenting that is stricter than that followed by the U.S. or the European Union countries.
- A second flexibility is the granting of compulsory licenses (CL), which are another legally recognized means to overcome barriers in accessing affordable medicines under international trade rules. When faced with a lack of access for Indian patients to a patented kidney and liver cancer treatment, the Indian Intellectual Property Appelate Board (IPAB) recently issued a CL, and the price

dropped by 97 percent, while the innovator company received a seven percent royalty.

- The U.S. government continues to make adjustments to its patent system to achieve better balance and it should allow other governments, like India, to follow their own paths.
- We look to the U.S. Government to allow for mechanisms, in conformity with international trade rules, that offer sustainable solutions for accessing life-saving medicines at affordable prices in developing countries.
- Relying on patent monopolies to drive forward R&D and innovation is fundamentally flawed for two reasons;
    - first, R&D is predominantly driven by commercial rewards rather than global health priorities. This means diseases that disproportionately affect developing countries are neglected.
    - Second, an inevitable consequence is the high cost of new medicines, which are priced out of reach of developing countries, and are increasingly becoming unaffordable in countries like the U.S.
- The current innovation system is failing too many. MSF believes the world needs to move towards a new framework for R&D that
    - considers the specific needs of patients upfront,
    - breaks the link between the cost of R&D and the price of products;
    - ensures that the fruits of innovation are accessible and affordable;

- There are important conversations at the World Health Organizations on these new models for innovation that the U.S. government and Members of Congress should strongly support and engage.