



Hearing Statement

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For the United States Trade Representative

Public Hearing

**2011 Special 301 Review:
Identification of countries under Section 182
of the Trade Act of 1974
USTR-2010-037**

I. Notice of Intent to Testify

Oxfam America hereby files its notice of intent to testify. Rohit Malpani shall testify on behalf of Oxfam America.

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II. Hearing Statement

Overview

Oxfam America is an international development and humanitarian relief agency working for lasting solutions to poverty and social injustice. We are part of a confederation of 14 Oxfam organizations working together in nearly 100 countries around the globe. Oxfam believes that trade can be an engine for development and poverty reduction as long as the rules of trade work to benefit poor people and developing countries. Well-managed trade has the potential to lift millions of people out of poverty. To achieve such a goal, trade agreements, which set the rules for ongoing trade relations, need to work to improve livelihoods and reduce poverty in developing countries. To that end, it is important that the US take into account economic disparities with our trading partners in the formulation and implementation of trade policy. We have one fundamental message: sustainable economic development must be a core objective of US trade policy.

This testimony is divided into four sections.

- (1) An overview of Oxfam's approach to intellectual property and access to medicines.
- (2) An explanation of why stricter intellectual property rules are inappropriate in middle-income and low-income countries.
- (3) Our perspective on the 2010 Special 301 Report
- (4) A public health approach towards intellectual property rules for pharmaceuticals under the 2011 Special 301 Report

Discussion

Oxfam America was pleased with the opportunity afforded public health and public interest organizations to offer their views in the run-up to the Special 301 Report in 2010. We welcome the opportunity that USTR has again provided for public interest and public health organizations to participate in this process in 2011.

1. Intellectual property and access to medicines – an overview of Oxfam's perspective

Ensuring access to affordable medicines is a core element of the human right to health. Yet over two billion people still lack regular access to affordable medicines, due in part to the high price of existing medicines and the lack of new medicines needed to treat diseases that disproportionately affect poor people in developing countries.

Strict intellectual property (IP) protection strengthens monopolies and restricts generic competition, which leads to higher medicine prices that are unaffordable for most people in developing countries. Although justified in the name of innovation, strict IP rules fail to stimulate medical innovation to address diseases that disproportionately affect people living in poverty. All World Trade Organization member countries have adopted IP protections in line with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), although least-developed countries have until 2016 to comply with TRIPS provisions. These protections are

considered by independent analysts to be more than adequate to balance the need to provide incentives for innovation with the obligation to the public of ensuring access to the benefits of the invention (in this case, medicines).

In 2001, all WTO members adopted the Doha Declaration on TRIPS and Public Health, which reaffirmed the primacy of public health over the protection of intellectual property for medicines. This Declaration rested upon global acknowledgement that high medicine prices charged by brand-name pharmaceutical companies through IP-based monopolies exact a serious and unacceptable toll upon the poor. As such, the Doha Declaration empowers developing countries to employ public health safeguards and flexibilities to foster generic competition as a means to ensure affordable medicine prices.

Yet with the strong influence of the pharmaceutical industry, US trade policy has instead been used to extend monopolies for brand-name medicines and disable the right of developing countries to use public health safeguards, thereby limiting generic competition and worsening the public health crisis in developing countries. Over the last decade, a succession of free trade agreements (FTAs) imposed increasingly strict levels of IP protection in developing countries. When the ink was barely dry on the Doha Declaration, the US entered an FTA with Jordan that introduced stricter IP rules than required by TRIPS. These rules have had real public health consequences in Jordan and subsequently in other countries that have concluded similar agreements. An Oxfam study conducted in Jordan and published in 2007 concluded that stricter IP rules led to dramatic increases in the price of key medicines to treat cancer and heart disease, which are the main causes of death in the country.¹ Higher medicine prices, due in part to these stricter IP rules, are now undermining Jordan's public health system. Effects are similar in other countries, but are only manifested over time because it takes several years for newer medicines to go through the pipeline.

USTR has pursued stricter IP rules as a cornerstone of US trade policy through various means. Oxfam has been particularly concerned that the Special 301 Report has been employed to punish countries for adopting legitimate measures to protect public health. Placement on the Special 301 list puts enormous pressure on developing countries to abandon measures needed to provide affordable health care. Oxfam has been supportive of recent efforts to scale back some policies that have imposed stricter levels of IP protection. In particular, IP rules included in FTAs already signed but yet to be considered by Congress were modified in order to address public health concerns as part of the May 10th (2007) Agreement. This Agreement between Congressional leadership and the previous administration achieved an unprecedented reversal in the decade-long trend of increasingly stricter IP provisions. Oxfam applauded this important initiative, even if it fell short of addressing all our concerns, as it clearly illustrates how trade policymaking can be improved.

2. Intellectual property, innovation and access to medicines in low and middle-income developing countries

Oxfam is concerned that the Special 301 Report has pushed for inappropriately high levels of IP protection in low and middle-income countries. Such provisions limit access to medicines in all developing countries, including least developed countries, and adversely affect their ability to foster innovation-based economies.

¹ See "All costs, no benefits: How the US-Jordan FTA affects access to medicines", Oxfam Briefing Paper (April 2007) at http://www.oxfam.org/en/policy/bp102_jordan_us_fta

2.1 Strict IP rules threaten access to medicines in low and middle-income countries

The pharmaceutical industry has traditionally sought higher levels of IP protection in low and middle-income countries as part of a broader strategy to target wealthy elite with high-priced medicines. Arguably, the wealthiest 20 percent of these populations can afford to pay high prices for pharmaceuticals. Yet most people in developing countries are near or below the poverty line or part of a modest middle class. There are high levels of inequality between wealthy elite and the rest of the population.

In middle and low-income countries, the poorest 20 per cent comprise those living on two dollars a day or less. For example, in the seven largest emerging market countries (Brazil, China, India, South Africa, Mexico, Indonesia, and Russia), nearly 1.7bn people fall into this category.² This segment of the world's population can barely afford generic medicines. When they have to purchase medicines, it is at immense personal sacrifice unless medicines are provided by governments and aid agencies. The middle 60 per cent of these populations are individuals who sit above the poverty line but are still extremely vulnerable to changes in income, economic crises, and prices of medicines. Given the limited reach of budgets for public health care in developing countries, they depend on private health care, which is often not affordable. They have little access to preventive health care and tend to be diagnosed late, leading to a dependency on medicines as their sole means for treatment, usually paid out-of-pocket. Any increase in prices for medicines can overwhelm their limited incomes and drive them below the poverty line. US trade policy must account for these realities in developing countries and ensure that IP rules promoted by the United States do not exacerbate the difficulties facing millions of poor people and their governments.

2.2 Strict IP rules limit the ability of developing countries to develop innovation-based economies

IP protection plays a critical role in fostering or hindering the use of technology to promote national development and innovation. The role of technology in development follows a fairly standard path, with all countries initially growing by imitating and adapting existing technologies. As they approach the global "technological frontier", they move into innovation. Historically, IP legislation has followed development; as countries have grown richer, and as they evolve from imitation to innovation, they have introduced more stringent IP laws. For example, chemical substances remained un-patentable until 1967 in West Germany, 1968 in the Nordic countries, 1976 in Japan, 1978 in Switzerland, and 1992 in Spain, by which time the chemical industries in those countries had established themselves.

Developing countries have faced an entirely different approach to IP over the last two decades. Implementation of the WTO TRIPS Agreement and subsequent FTAs, as well as use of the Special 301 process, has foisted far higher levels of IP protection on developing countries than was applied in developed countries throughout the 20th century. Instead of promoting innovation, ever stricter IP rules prevent developing countries from imitating and thereby cultivating innovation-based cultures that can contribute to economic development and the broader public good. While low and middle-income countries may eventually adopt stricter IP

² For a broader discussion of the high levels of poverty in middle income countries, please see: "Global poverty and the new bottom billion: Three-quarters of the World's poor live in middle-income countries", Institute of Development Studies, September 2010 at <http://www.ids.ac.uk/go/idspublication/global-poverty-and-the-new-bottom-billion-three-quarters-of-the-world-s-poor-live-in-middle-income-countries>.

rules, these countries should be afforded the policy space to identify whether and when to introduce stricter patent standards.

2.3 Stricter levels of IP protection in emerging markets harms access to medicines in least developed countries

Higher levels of IP protection in low and middle-income countries harms access to medicines in least developed countries (LDCs). Affordable generic medicines are manufactured mostly in low and middle-income countries for domestic consumption. These countries are also the critical, and often the only, supplier of medicines to LDCs, which have little or no capacity to themselves produce medicines that can address their public health challenges.

Indian generic companies, which have earned India the title of “pharmacy of the developing world”, export to LDCs two-thirds of the generic medicines they produce overall. Stricter levels of IP protection in low and middle-income countries, including but not limited to India, will have severe consequences for access to medicines in LDCs. With the introduction of ever-higher levels of IP protection, generic manufacturers in these countries will be unable to produce low-cost versions of patented medicines for either domestic consumption or export to poor countries. In fact, it was only due to the lack of intellectual property protection in India until 2005 that prices for first-line anti-retroviral medicines (ARVs) fell from 10,000 USD per patient per year to its current price of less than 100 USD per patient per year. These low prices, and the ability of Indian generic companies to combine these medicines into fixed-dose combinations, was a critical prerequisite to expanding treatment with ARVs to nearly four million people today. The U.S. global AIDS assistance program, PEPFAR, relies heavily upon generic medicines manufactured in India to ensure sustainable and affordable HIV and AIDS treatment.

Pharmaceutical companies have argued that generics companies can continue to produce medicines on behalf of LDCs through use of the Paragraph 6 Amendment (also known as the August 30th Decision), and through voluntary licenses that are negotiated between branded and generic pharmaceutical companies. Other companies have argued that their efforts to introduce tiered pricing can adequately compensate for the lack of generic competition. Yet these arguments are not valid.

- 1) The August 30th Decision, due in large part to the complexity of the mechanism, has been widely viewed as a “solution wrapped in red tape”. Since its inception in 2003, it has been used only once by Canada to export medicines to Rwanda. Many countries, including the United States, have yet to even introduce executing legislation. Recently, developing countries, especially those that produce generic medicines, have noted more openly that the Paragraph 6 Amendment in its current format is not appropriate to produce generic medicines on behalf of poor countries due to its complexity and difficulty of use. Even if use were simplified, political pressure by developed countries, including through U.S. Special 301 report, not to use TRIPS flexibilities could reduce or preclude its use.
- 2) Voluntary licenses provide generics companies with restricted access to intellectual property in order to manufacture generic versions of patented medicines. Yet in spite of limited success, there are numerous problems. Firstly, these licenses are dependent entirely upon the philanthropic whims (or concerns of reputational loss) of multinational pharmaceutical companies and are limited to a far too narrow scope of diseases. A few companies have introduced voluntary licenses for anti-retroviral medicines. Yet no companies have considered or introduced voluntary licenses for other key infectious or

non-communicable diseases affecting developing countries, thus leaving millions of people suffering from ill-health without the affordable medicines they need. Secondly, even when companies are issuing voluntary licenses, the “field of use” excludes many developing countries. This has two consequences: it excludes millions of people who are poor but live in countries whose GDP exceeds an arbitrary line drawn by the pharmaceutical industry; and it leads to higher medicine prices even in those countries included in the “field of use” due to the inability of generic companies to achieve sufficient economies of scale.

- 3) Tiered pricing can increase access to medicines in developing countries in a limited manner. Yet tiered pricing offered by pharmaceutical companies cannot match the low prices offered for medicines by generics companies through unfettered competition, and therefore cannot ensure access to medicines for the poorest throughout the developing world. This was recently reaffirmed by Nils Daulaire, the Director of the US Office of Global Health Affairs, who said at the 2011 WHO Executive Board meeting that “recent studies have demonstrated that differential pricing does not always have the impact on the pricing of medicines that robust generic competition does.”

The use of tiered pricing for second-line anti-retroviral medicines is a useful illustration of its limitations. Multinational pharmaceutical companies have earned patent protection for new ARVs in many developing countries. To improve access to medicines, most companies have instituted tiered pricing schemes in developing countries. Yet while medicine prices are lower in LDCs and low and middle-income countries than in the developed world, the costs are still far too high to ensure treatment for all who need it. Currently, costs of new ARVs needed to keep millions of HIV and AIDS patients alive are five to twenty times more expensive than first line ARVs. With millions of people already on treatment and millions of other HIV positive individuals initiating treatment in the next few years, many observers, including a parliamentary group in the United Kingdom, have labeled the future costs of second line ARVs a “treatment time bomb”.³ Furthermore, as with voluntary licensing, pharmaceutical companies have not applied tiered pricing to their entire portfolio of medicines, including those needed to treat other key infectious diseases and non-communicable diseases that pose public health risks in developing countries.

3. Oxfam America’s perspective on the 2010 Special 301 Report

Oxfam had hoped that USTR, in the 2010 Special 301 Report, would recognize, honor and integrate key public health principles enshrined under the Doha Declaration. USTR, in the introductory language to the report, did acknowledge the Doha Declaration and the right of developing countries to use key safeguards, such as compulsory licensing, to protect public health. However, the 2010 Special 301 Report stopped short of endorsing all relevant language included under the Doha Declaration, in particular affirming the right of countries to use all TRIPS flexibilities to the full” and ensuring that the TRIPS Agreement “can and should” be interpreted and implemented to promote access to medicines “for all”.

Furthermore, we were disappointed that the U.S. continued to push for strict interpretations of key intellectual property rules that would limit access to medicines, while continuing to raise vague procedural concerns with the use of key TRIPS safeguards, and especially compulsory licensing, that developing countries should be able to use to promote and protect public health.

³ See: “The Treatment Time Bomb”, All-Party Parliamentary Group on AIDS, July 2009 at <http://www.aidsportal.org/repos/APPGTimebomb091.pdf>.

The next section considers these relevant provisions and offers our perspective on an approach that would do more to protect public health, that would meet U.S. obligations under the Doha Declaration on TRIPS and Public Health, and that at a minimum would also reaffirm the U.S. approach to intellectual property for pharmaceuticals achieved under the May 10th Agreement.

4. A public health approach towards intellectual property rules for pharmaceuticals under the 2011 Special 301 Report

4.1 Data protection

Throughout the 2010 Special 301 Report, the U.S. Government calls upon developing countries to implement TRIPS-plus data exclusivity requirements that exceed WTO obligations. These rules, which are not required under the TRIPS Agreement, create serious new barriers to affordable medicines, and override the use of the patent system in developing countries to determine whether a product is truly innovative and worthy of monopoly protection. The U.S. should not pressure developing countries to introduce data exclusivity rules as it creates serious barriers to affordable medicines.

Public health concerns with data exclusivity

Over the last decade, the U.S. has successfully pushed for inclusion of data exclusivity into the intellectual property laws of poor countries around the world. In the last few years, studies have started to demonstrate the impact of data exclusivity upon public health. An Oxfam study conducted in Jordan, which introduced data exclusivity as a condition of its free trade agreement with the U.S. in 2001, concluded that stricter IP rules led to dramatic increases in the price of key medicines to treat cancer and heart disease, which are the main causes of death in the country.⁴ Higher medicine prices, due in part to these stricter IP rules, are now undermining Jordan's public health system. Furthermore, in direct contrast to claims of the pharmaceutical industry, the inclusion of data exclusivity in Jordan's intellectual property law did not catalyze new forms of foreign direct investment or increased local research and development. In fact, over a five year period (2000-2005), there was nearly no foreign direct investment in Jordan despite the high levels of IP protection established under the free trade agreement, whereas in Egypt, which has no intellectual property protection (due to a transition period, until 2005, provided by the WTO), multinational pharmaceutical companies invested approximately USD 223 million into local manufacturing for the Egyptian and regional market.

A second study in Guatemala has also revealed the impacts of data exclusivity upon access to medicines.⁵ Guatemala, which introduced data exclusivity in 2000 (followed by repeal), and then a second time in 2005 as a condition of the U.S. - Central American Free Trade Agreement (CAFTA), has already had to contend with severe impacts to public health. As in Jordan, the prices of numerous key medicines needed in the public health system were significantly more expensive due to the imposition of data exclusivity. Furthermore, due to the imposition of data exclusivity, numerous generic medicines of public health significance were found to already be available in the United States and not in Guatemala, due solely to the term of data exclusivity that had been imposed in the country.

⁴ See "All costs, no benefits: How the US-Jordan FTA affects access to medicines", Oxfam Briefing Paper (April 2007) at http://www.oxfam.org/en/policy/bp102_jordan_us_fta

⁵ See: "A trade agreement's impact upon access to generic drugs", Ellen Shaffer and Joseph E. Brenner, Health Affairs, August 2009 at <http://content.healthaffairs.org/content/28/5/w957.abstract>.

Oxfam fully expects the adverse effects in other countries will be similar to those in Jordan and Guatemala. But these effects are only manifested over time because it takes several years for newer medicines to go through the pipeline.

4.2 Patentability requirements

The 2010 Special 301 Report criticized developing countries, and especially India and the Philippines, for its efforts to introduce WTO compliant flexibilities to their patentability requirements for pharmaceuticals. These measures, under both India's and the Philippines' IP law, incorporate crucial public health safeguards which improve access to medicines.

In particular, provisions adopted exclude patent protection for new forms or new uses (indications) of already patented medicines, a permissible limitation under TRIPS. Furthermore, provisions also require an applicant to demonstrate increased efficacy as a condition for acquiring a patent for a pharmaceutical. Both provisions, by narrowing the scope of patentability, prevent the pharmaceutical industry from abusing the patent system via 'ever-greening' – or by introducing 'new' medicines that are only second forms or indications of older medicines and are neither novel nor innovative.

If either country were to modify their intellectual property law, as demanded by the U.S. government, it would encourage domestic and foreign pharmaceutical companies to engage in rent-seeking behavior in lieu of increasing innovation. In fact, the majority of research conducted by the multinational pharmaceutical industry is for higher-priced and similar versions of existing medicines ('me-too' medicines with little added therapeutic benefit), or monopoly extensions for new uses of old medicines. These medicines are rarely innovative: only 15 per cent of the new drug applications approved by the U.S. Food and Drug Administration (FDA) from 1989 to 2000 were identified as clinical improvements over products already on the market.

Separately, the 2010 Report registers 'concern' with Brazil's sanitary regulatory agency (ANVISA) review of patent applications that have public health implications. This process, which has been supported by the Pan American Health Organization, should not be criticized under the Special 301 Report. It does not violate the TRIPS Agreement and it provides a critical opportunity to ensure that pharmaceutical products for which patents are filed are actually new and useful.

The TRIPS Agreement provides all countries with the flexibility to determine the scope of patentability that best suits its domestic innovation environment, insofar that the product or process are "new, involve an inventive step, and are capable of industrial application." U.S. trade policy and the Special 301 report should not be used to force developing countries to define the scope of patentability according to U.S. standards, especially since it could export problems, such as ever-greening, that have plagued the U.S. patent system.

4.3 Patent extensions

The TRIPS Agreement requires WTO Member States to grant patents for a period of protection of 20 years from when the patent application is first filed. Furthermore, the U.S., under the 'May 2007 New Trade Deal for America', made patent extensions voluntary under the terms of the Agreement. Yet the Special 301 Report in 2010 pressured countries to adopt patent term extensions. Oxfam hopes that such measures are not called for under this year's Special 301

Report, and that the USTR honors both its obligations under the Doha Declaration on TRIPS and Public Health as well as reaffirming its standing on this issue under the May 10th Agreement.

4.4 Enforcement of intellectual property rights

The Special 301 Report should not be used to either introduce new IP enforcement obligations in developing countries or to expand or modify the definition of a counterfeit medicine so that it could be confused with either generic medicines or with substandard or falsified products (which like counterfeits, should be removed from the market). In the 2010 Special 301 Report, the definition of a counterfeit medicine is too vague. Oxfam is concerned that a vague definition of a counterfeit invites confusion in developing countries, and could result in expansion of the term 'counterfeit' to go beyond what is required under the WTO TRIPS Agreement. Secondly, Oxfam is concerned that pressure placed by the U.S. upon developing countries to introduce new IP enforcement rules diverts scarce resources away from needed public health interventions, jeopardizes access to generic medicines and distorts the focus at the national level to one that only prioritizes the removal of counterfeits, as opposed to the removal of all poor quality medicines.

What is a counterfeit?

The TRIPS Agreement defines 'counterfeit trademark goods' as goods that bear, without authorization, a trademark that is identical to, or which cannot be distinguished in its essential aspects from, a registered trademark. Article 61 of TRIPS says that criminal counterfeiting activities involve trademark infringement that is willful and carried out on a commercial scale. Criminal trademark infringement, or counterfeiting, can be distinguished from so-called 'civil' trademark infringement in that it involves the intentional misrepresentation of the product as the trademarked article, when in fact it is an unauthorized copy.

The United States should adhere to the WTO definition of a counterfeit when examining the intellectual property laws and standards enforced in other countries. In no case should the term counterfeit be confused with legitimate generic products, with generic products that allegedly infringe a patent or that may infringe a trademark that is 'confusingly similar'. Furthermore, counterfeit products should not be confused with substandard or falsified products.

Imposing additional IP enforcement rules upon developing countries

Under the TRIPS Agreement, WTO Member States are required to criminalize counterfeiting, together with copyright piracy, in their national legislations. Countries have some flexibility in that they may define 'willful' and 'commercial scale' as they deem appropriate to their national contexts, provided that they comply with the minimum obligations in Article 61. This flexibility, which was recently confirmed by a WTO panel, is reflected in the differences across jurisdictions as to what constitutes criminal trademark infringement, or counterfeiting. Criminal trademark infringement is different from the types of civil trademark infringement that may occur during the normal course of business. Companies in the pharmaceutical sector regularly dispute whether the names, packages, or trade dress of competing branded or generic products are similar to the extent that they might create confusion for the consumer and therefore infringe a trademark. Often, any existing similarity is unintentional. For instance, if two medicines containing the same active pharmaceutical ingredient are named after the scientific name for that substance, the International Non-Proprietary Name (INN), the products' names

may be very similar. This may give rise to a dispute. This type of dispute is resolved in civil (not criminal) proceedings, in accordance with national laws.

The Special 301 Report in 2010 pushed for additional forms of IP enforcement at the national level. These additional measures, if combined with a broad definition of a counterfeit, could lead to additional barriers to affordable medicines.

In addition, a framework that focuses on enhanced IP and law enforcement is inappropriate for developing countries, as it overemphasizes concerns with counterfeits to the detriment of other equally urgent priorities. The vast majority of poor quality medicines (substandard or falsified) do not violate any intellectual property right. Pressuring developing countries to introduce additional intellectual property rules diverts scarce resources from other priorities that may be more appropriate investments at the national level in developing countries. Limited and well-targeted IP enforcement and law enforcement measures are needed to remove counterfeit products. Yet counterfeit products are only a small subset of the broader problem of poor quality (substandard) and falsified (fake or falsely labeled) medicines; studies conducted by USAID and the World Health Organization illustrate that the vast majority of poor quality medicines are substandard, and not counterfeit products.

Substandard and falsified medicines most often do not infringe any intellectual property rights (patents and trademarks). To remove these medicines from the market, countries must invest in and establish robust drug regulatory authorities – much like the U.S. Food and Drug Administration, which currently spends over US\$1 billion per year to identify and remove substandard and falsified medicines from the market.

Yet if ACTA is introduced into developing countries, it would force them to prioritize new investments into additional customs and law enforcement activities that would not address the largest threat to public health and safety – poor quality medicines. In lieu of pushing developing countries to agree to ACTA, U.S. government resources should be used to invest in building the capacity of developing countries to strengthen their drug regulatory authorities, through direct bilateral assistance or via the World Health Organization.

4.5 Compulsory licensing

Article 31 of the TRIPS Agreement provides all countries the right to enforce compulsory licensing as a key safeguard to protect and promote public health. This right was reaffirmed under the Doha Declaration on TRIPS and Public Health in 2001.

In the past, the Special 301 Report has been used by the United States to criticize countries for the use of compulsory licensing. In particular, the 2009 Special 301 Report harshly criticized Thailand's use of compulsory licensing. The 2010 Report did not criticize Thailand harshly for its approach to compulsory licensing in the pharmaceutical sector. However, the report does state that:

The United States encourages Thailand to engage in a meaningful and transparent manner with all relevant stakeholders, including owners of intellectual property rights, as it considers ways to address Thailand's public health challenges while maintaining a patent system that promotes investment, research, and innovation. In addition, the United States reiterates its support for the 2001 Doha Declaration on the TRIPS Agreement and Public Health, as described in Section I of this Report.

While the report does acknowledge support for the 2001 Doha Declaration on TRIPS and Public Health, it calls upon Thailand to engage in a 'meaningful and transparent manner' with relevant stakeholders, including owners of intellectual property rights. We are concerned that this statement is ambiguous and is being used by the U.S. government to place informal constraints upon Thailand's ability to use compulsory licensing when legitimately needed to protect public health. In particular we would note that the TRIPS Agreement contains no provision that calls upon parties to implement flexibilities and safeguards in a 'meaningful and transparent manner'. Government-use compulsory licenses, which Thailand implemented to reduce prices for medicines to treat cancer, heart disease and HIV and AIDS, do not require prior notification or negotiation with the patent holder. However, it should be noted that the Thai Government, in the run-up to issuance of each compulsory license, did openly negotiate with the patent holder and offered a clear and often lengthy window of opportunity to reduce medicine prices.

More generally, Oxfam continues to strongly support the use of compulsory licensing to reduce medicine prices when the multinational pharmaceutical industry markets medicines at prices that are unaffordable for the government or the majority of households. Thailand has made enormous gains in its public health system through robust public investment that has been strengthened by the legal and legitimate use of compulsory licensing.

In particular, the Thai government ensures access to free health care through its public health system, including free treatment for HIV and AIDS. While treatment is available for all major causes of morbidity and mortality in the country, the government has had to make difficult choices, including not providing key medicines through its public health system due to high prices charged by multinational pharmaceutical companies.

Thailand employed compulsory licensing to reduce high medicine prices and expand treatment for HIV and AIDS, cancer and heart disease, consistent with the guidelines enumerated under the TRIPS Agreement and Doha Declaration. HIV and AIDS, cancer and heart disease all cause significant morbidity and mortality in the country. More than one million women, men, and children have contracted HIV in Thailand and more than 500,000 people have died of AIDS since the outbreak of the epidemic. Currently, in spite of Thailand's widespread and comprehensive efforts, 610,000 people are living with HIV and AIDS. Similarly, cancer and heart disease are major public health burdens; these diseases are two of Thailand's leading causes of death and disability.

Each of the compulsory licenses issued by the government was for a medicine that is essential to prolong a patient's life or provides significant and critical therapeutic improvements over other medicines. In each case, prices charged by the multinational pharmaceutical industry were too high for either the government or for most people in Thailand to pay out of pocket without causing significant economic dislocation.

For example, Plavix (clopidogrel), for which a compulsory license was issued in 2007, is an anti-platelet medicine commonly used in patients with heart disease. In Thailand, there are approximately 300,000 people living with heart disease. Clopidogrel is the most effective medicine available for patients needing a coronary heart stent. Yet only 30,000 patients, or those who can access private health care, could previously afford the medicine due to an unaffordable cost of two dollars a day. Sanofi-Aventis, the patent holder, refused to reduce the price, despite repeated attempts by the government to negotiate. This meant all poor patients who received medical care through a government program could not obtain the medicine as it

was too expensive for the government health budget. By reducing the price by a factor of 10 to approximately 20 cents per day, the government was able to expand treatment with Plavix to approximately 40,000 patients.

Due to its use of compulsory licensing, Thailand has expanded treatment for cancer, HIV and AIDS and heart disease to thousands of poor people who otherwise would receive, at best, inadequate treatment for their diseases. Pressuring Thailand to abandon its selective and legitimate use of compulsory licensing would consign thousands of poor people to lives of ill-health, suffering and untimely death.

Oxfam recommends that the U.S. government continue to acknowledge that Thailand's use of compulsory licensing is legally compliant with the WTO TRIPS Agreement and the Doha Declaration on TRIPS and Public Health, and remove recommendations under the 2010 Special 301 Report concerning 'meaningful and transparent' engagement with all stakeholders.