



Hearing Statement

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2010 Special 301 Review:
Identification of countries under Section 182
of the Trade Act of 1974

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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 over 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 written testimony is divided into three 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) An evaluation of existing intellectual property frameworks in three countries, India, Thailand and the Philippines.

Discussion

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. During the last Administration, 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 employing 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.

Such important efforts to change the US approach to IP provisions on pharmaceuticals in FTAs to address public health concerns were successful in part due to the willingness, particularly on the part of Congressional staff, to listen to a broad range of public interest groups. Oxfam hopes that the efforts of USTR to solicit input from public health and public interest organizations through the Special 301 process will also lead to a changed outcome from the Special 301 process.

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

¹ See: http://www.oxfam.org/en/policy/bp102_jordan_us_fta

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.

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. 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 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 public health care available in developing countries, they depend on inadequate private health care. 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 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.

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, 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 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. 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. While medicine prices are lower in LDCs and low and middle-income countries than in the developed world, the costs are far too high. 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'. 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.

3 An evaluation of IP frameworks in India, Thailand and the Philippines

The following section examines the intellectual property frameworks in three countries: India, Thailand and the Philippines. Oxfam works in each of these countries to promote access to essential services, particularly health and education, and works in partnership with local civil society organizations to increase access to medicines.

In each country, existing IP rules are consistent with minimum obligations under the TRIPS Agreement and in many instances exceed minimum obligations. Criticism of these countries' IP frameworks rests solely upon a long-standing US policy to pressure developing countries to

adopt US-style IP protections that exceed minimum WTO obligations. There is no legal obligation under WTO rules for these countries to increase their existing levels of IP protection. A separate document, which was submitted jointly by several public interest groups including Oxfam America as part of the process of comments for this 2010 Special 301 Review, explains why each country's IP framework is consistent with WTO TRIPS obligations.

The discussion below provides a public health and public interest rationale, consistent with the TRIPS Agreement and Doha Declaration, for introducing and enforcing flexibilities and safeguards in each country. It also examines the consequences of each country abandoning these safeguards and potentially adopting IP obligations that exceed minimum WTO obligations.

3.1 India

India was placed on the Priority Watch List in 2009. The report included three criticisms of India's IP framework for pharmaceuticals: an insufficient data protection regime (that does not provide for data exclusivity), a narrow scope of patentability, and inadequate enforcement measures for counterfeit medicines. These demands all exceed India's commitment under TRIPS. Imposing these changes upon India's intellectual property framework would: (1) limit access to medicines in India and across the developing world; (2) curtail innovation within India; and (3) divert resources away from addressing concerns with substandard medicines and instead would limit access to affordable medicines.

Limits on access to medicines: Pharmaceutical companies have called both for introduction of data exclusivity and changes to India's Patent Law, and particularly Section 3(d), which defines the scope of patentability for pharmaceuticals. Modifications either to India's data protection regime or an amendment to its scope of patentability would have widespread consequences for access to medicines, in India and elsewhere. Thanks in part to its robust generics industry, millions of people across the developing world have access to low-cost and high quality generic medicines.

In India, nearly 80 percent of the population relies on private sector health care to purchase medicines. As these medicines are paid for out-of-pocket, even slight increases in the cost of medicines can create difficult trade-offs for poor people, who must choose between medicines and other basic necessities, such as food, housing and education. Maximizing the use of public health safeguards enables India, through its local industry, to meet its own treatment needs.

Beyond domestic consumption, Indian generic medicines are purchased both by governments and by donors to meet treatment targets. In fact, PEPFAR, the US global program to treat HIV and AIDS, relies almost entirely on generic medicines produced by Indian manufacturers. Limiting the ability of India's generic manufacturers to produce medicines would increase the costs of ARVs and other medicines, greatly constraining the ability of the US government, other donors and developing countries to meet key Millennium Development Goals, including universal access to treatment.

Limits on innovation: Ever-higher levels of IP protection would also restrict innovation in India. Patent barriers and data exclusivity would create barriers to forms of innovation that can improve

access to medicines. Fixed-dose combinations of ARVs, which have played a critical role in improving treatment adherence in poor countries, was a critical innovation fostered by the generics industry in India. This was due solely to the lack of patents in India until 2005. While multinational pharmaceutical companies are starting to develop fixed-dose combinations, there are too few emerging from their pipeline.

Secondly, the pharmaceutical industry has called for revisions to Section 3(d), which was introduced in 2005 to ensure India's compliance with TRIPS. Section 3(d) includes crucial safeguards. In particular, it excludes patent protection for new forms or new uses (indications) of already patented medicines, a permissible limitation under TRIPS. By narrowing the scope of patentability, the government has prevented 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 India were to modify Section 3(d), it would encourage domestic and foreign innovators 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 US Food and Drug Administration (FDA) from 1989 to 2000 were identified as clinical improvements over products already on the market.

No improvements in the safety of medicines through strengthened IPR: A strengthened IP framework will not address the proliferation in India and elsewhere of substandard, adulterated or contaminated medicines; nor will it improve upon existing strategies to curtail counterfeits. Substandard medicines are generic or patented medicines of poor quality and efficacy. Removing substandard medicines from the supply chain requires investments into good manufacturing practices in production facilities and tighter regulatory oversight. By contrast, tightening IP standards for medicines does not reduce production of substandard medicines. There is no relationship between the quality, safety and efficacy of a medicine, on the one hand, and its intellectual property status, on the other.

Similarly, strengthening the existing IP enforcement framework for counterfeit medicines will not further reduce the incidence of counterfeiting. Under TRIPS, "counterfeit" has a particular meaning: a product that willfully infringes a trademark. However, the definition of counterfeits does not apply to an allegedly unauthorized generic version of a patented product, or to a substandard medicine that does not violate any trademark protection. Arresting the trade in counterfeit medicines is a legitimate aim. However, increasing IP protection in India will not address or resolve that problem.

Instead, it will achieve the opposite goal. Firstly it will divert scarce State resources away from monitoring the quality and efficacy of production of medicines and towards increased IP enforcement. Secondly, it will reduce access to medicines through excessive IP enforcement, which increases medicine prices and encourages a market in counterfeit or fake medicines since poor people in India will be unable to pay high prices for branded medicines.

3.2 Thailand

Thailand was placed on the Priority Watch List (PWL) in 2009. The Special 301 report lists multiple reasons for Thailand's inclusion on the PWL, including its use of compulsory licensing to increase access to medicines. This submission focuses specifically on the use of compulsory licensing in Thailand. Oxfam fully supports Thailand's use of compulsory licensing to expand access to medicines and strongly disagrees with any criticism of its legitimate use of compulsory licensing to protect public health.

In Thailand, the 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.

3.3 Philippines

The Philippines was placed on the Watch List in 2009. The report criticizes amendments to the country's IP law, which USTR alleges "weakens" patent protection for pharmaceuticals. Oxfam has worked in partnership with local civil society groups for inclusion of IP amendments for pharmaceuticals into the country's patent law and remains strongly supportive of these measures.

The Philippines is a low-middle income country with an average GDP per capita of USD 3,200 and 30% of the population below the poverty line. Despite high levels of poverty, the country is known to have the second highest level of medicine prices in Asia. The Philippines does not have a high prevalence of HIV and AIDS; yet it does have a significant burden of non-communicable diseases. For example, eight million Filipinos suffer from cardiovascular disease.

The country successfully introduced key TRIPS flexibilities to its intellectual property law in order to promote and protect public health. These provisions included: narrowing the scope of patentability to discourage ever-greening and frivolous patents; a Bolar-type (or 'early working') provision; authority for the government to issue compulsory licenses for non-commercial use; and expanded powers to implement parallel importation. These measures are all consistent with TRIPS and are already included in the intellectual property codes in many other countries at far higher levels of economic development. These measures will, to the extent they are enforced by the government, reduce medicine prices and expand access to affordable medicines.

Revisions to the IP code will also play a long-term role in promoting innovation. The Philippines, like India, revised its IP law to discourage the practice of ever-greening by pharmaceutical companies. These changes will ensure that the country's patent system creates incentives for pharmaceutical companies – domestic and foreign – to engage in innovative activities that produce medicines offering significant therapeutic improvements rather than 'me-too' medicines.

Conclusion

Innovation and access to medicines remains a critical issue in developing countries. Oxfam believes there is no "one-size-fits-all" level of IP protection, and that IP rules should not undermine the ability of people living in poverty across the developing world – whether in LDCs, low or middle-income countries – to get access to the medicines they need.

Oxfam America welcomes the opportunity to testify at the first public hearing held by the USTR on the 2010 Special 301 Review. In this year's Special 301 report, we urge USTR to take a fresh look at its approach to intellectual property provisions, taking into account concerns raised by Oxfam and other public health and public interest organizations. We hope that as a result, the report will do a better job of balancing the need for adequate protection of pharmaceutical company inventions with the public interest in ensuring that the benefits of those inventions are broadly shared to improve public health, particularly among the millions of people living in poverty across the developing world.