OXFAM MEDIA BRIEFING **09/2012**
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Public health at risk

US trade policy endangers access to affordable anti-retroviral medicines

Background

Less than a year after US Secretary of State Hillary Clinton shared her vision of the "end of AIDS", the entirety of the US Government is failing to support this goal. Notably, US trade policy is at odds with the goal of ensuring access to affordable AIDS medicines for people everywhere. As the United States seeks to conclude the 11-country Trans Pacific Partnership Agreement (TPPA), it is using TPPA negotiations, and the promise of greater access to the US market, to promote the commercial interests of its pharmaceutical industry at the expense of enabling other governments to ensure affordable medicine prices for their citizens. The United States is also using other forms of pressure to criticize and intimidate countries that are seeking to provide access to affordable quality medicines. This is effectively disabling them from scaling up the fight against AIDS.

The United States cannot be seen as a real partner in the fight against AIDS unless it:

- *Stops pushing for strict intellectual property (IP) rules through trade agreements with provisions that exceed IP obligations in the Trade Related Aspects on Intellectual Property Rights (TRIPS) Agreement*
- *Stops using commercial and diplomatic pressure, such as the Special 301 Report, to push developing countries to adopt strict IP rules that hinder their ability to safeguard access to medicines and the sustainability of public health programs;*
- *Stops pressuring developing countries to abandon their use of health safeguards enshrined in TRIPS to reduce medicine prices;*
- *Fully commits to implementing promises made by the United States under the Doha Declaration on the TRIPS Agreement and Public Health in November 2001.*

The fight against HIV and AIDS at a crossroad

As world leaders meet at the International AIDS Conference in Washington D.C. on July 22-27 to renew their commitment to "universal access to prevention, treatment and care," the barriers to this remain daunting. Hit by the global economic crisis, hopes for more funding, whether for development, health or to tackle HIV and AIDS, are increasingly under threat.

Treatment for HIV and AIDS has never been a better investment. The scientific evidence of the benefits of treatment as prevention is ever more widely accepted. Yet treatment remains a challenge because it is

costly, and has also been undermined by a chronic lack of investment in health care workers and health systems. Although the cost of today's first-line anti-retroviral medicines has dropped to less than $80 per patient per year, new and more effective treatments for HIV (many of which are under monopoly patent protection) are up to ten or even 50 times more expensive than that. This threatens to undermine the treatment of more than six million people and hinder governments and funding agencies from expanding treatment to millions more.

Every government and donor needs to use their scarce resources in more cost-effective ways in order to buy the highest-quality medicines at the lowest possible price. Often this points to generic treatments. Yet instead of supporting its trading partners to keep down the costs of new medicines, the United States is using its trade policy to push for higher medicine prices – including medicines for HIV and AIDS. The most glaring examples of this damaging policy are evident in the US negotiations for free trade agreements with countries that it helps financially in the fight against HIV and AIDS, and in the direct pressure it is placing on countries that produce low-cost generic medicines.

Trade and health policies interlinked

Oxfam believes that trade can be an engine for development and poverty reduction, provided the rules are fairly crafted in order to benefit developing as well as developed countries. Well-managed trade has the potential to lift millions of people out of poverty.

But to do that, trade agreements must help to improve livelihoods and reduce poverty in developing countries. Trade rules must always consider the disparities among trading partners. For instance, the differences in the economic and social development between the US and its lower-income trading partners must be taken into account when trade rules are negotiated between them. This is especially true of rules that govern the protection of intellectual property because they can be a huge barrier for the poorer partners being able to access vital new products, such as medicines.

The same IP rules developed for rich countries may impede rather than stimulate innovation and access to new products for emerging countries. To date, IP rules in trade agreements have been harmful to poor countries needing to access affordable medicines. Time and again, US trade negotiators have insisted on far-reaching IP rules that work to keep the prices of new medicines high. As well as harming patients and undermining the sustainability of public healthcare programs, this approach has discredited trade itself as a tool for poverty reduction.

Because of this – and because the WTO TRIPS Agreement already sets high global standards for the protection of intellectual property – Oxfam opposes the inclusion of *any* IP rules for medicines in trade agreements.

Treatment for HIV and AIDS – the opportunities and challenges ahead

Costs of first line anti-HIV/AIDS medicines have dropped dramatically over the last decade. Multinational drug companies used to charge nearly $10,000 per patient per year for their anti-retroviral (ARV) medicines. But thanks to competition from low-cost generic versions of those medicines, especially from India, the price of ARVs has dropped to less than $100 per patient per year.

But these gains were short-lived. New medicines to treat HIV and AIDS that are needed to replace old treatments are now unaffordable for donors, developing countries and poor patients. As more patients switch to new ARVs, the costs remain too high for most. Today, new ARVs are ten to fifty times more expensive than first-line treatments.

Treatment has never been more urgent. In 2010, nine million people in developing countries were waiting for treatment. This matters not only because their lives hang in the balance, but also because evidence shows that treatment is an effective way to reduce transmission.

Simply calling for more funding without cutting the cost of medicines will not be enough. The global economic crisis heads into its sixth year and funding for HIV and AIDS - with the exception of a few bright spots – is flat or declining worldwide. Doing more with less has never been more necessary. Reducing the price of ARVs is a sure-fire way to put more people on treatment.

"In recent years, policy-makers around the world have recognized that the costs of new AIDS medicines are increasingly unsustainable and in some places it has been called a 'treatment time-bomb'," according to Oxfam's Dr. Mohga Kamal-Yanni. "We need urgently to accelerate treatment for HIV and AIDS, so now is the time for new solutions to reduce the price of medicines and keep it down."

US trade policy undermines access to medicines

WTO members recognized the tension between IP protection on the one hand, and the need for affordable medicines on the other, so in 2001 agreed the "Doha Declaration on the TRIPS Agreement and Public Health". This states that nothing in the WTO rules on IP (the "TRIPS Agreement") should prevent countries from taking measures to improve access to medicines. This represented a political commitment among all WTO members, including the US, to prioritize health over IP protection.

However, the US has consistently failed to uphold this commitment. Instead it has continually pushed for rules in its trade agreements that prevent countries from taking the measures allowed for in the TRIPS Agreement and reaffirmed in the Doha Declaration. The US has even pushed for IP protections that exceed the TRIPS Agreement. These so-called "TRIPS-plus" rules have acted to delay generic competition and keep the prices of new medicines high, compromising patient welfare and the sustainability of public health programs – all of which is unacceptable for developing countries.

In recent bilateral and regional trade negotiations, the US has pushed for rules that extend the scope and duration of patent protection, such as:

- extending market exclusivity by blocking regulatory approval for generic medicines;
- providing "data exclusivity" that prevents generic versions of medicines from being registered for a specified period of time, based on test data from the originator company;
- patent linkage that prevents registration (regulatory approval) for a generic medicine if there is any patent – however frivolous – in force in connection with the originator product;
- patent term extensions, granted to compensate IP owners for delays in granting regulatory approval for a new product, or for delays in issuing a patent.

The impact of these rules is pernicious. Any delay in introducing generic competition after a patent has expired makes treatment programs more expensive. Moreover, these delays have been linked to lower market share for generics, even several years later. In other words, there is a longer-term impact of delaying generic competition than one can observe simply by calculating money wasted on originator medicines due to unnecessary delay in generic market entry.

Briefly in 2007, it seemed that US trade policy on IP and medicines was shifting. The US Congress and Bush Administration signed the "May 10th Agreement" that modified IP rules in certain trade agreements with developing countries, having recognized the potential harmful impact of TRIPS-plus rules on public health. Under this agreement, patent linkage and patent term extensions became optional, while data exclusivity was made more responsive to public health concerns. Although in Oxfam's view the agreement did not go far enough, it was a step in the right direction, particularly if applied in future trade negotiations with other developing countries.

However since then, the US has virtually ignored the May 10th Agreement. Instead, it continues to pressure its developing country trading partners to agree provisions that are virtually guaranteed to harm access to medicines and public health.

The Obama Administration has been negotiating the TPPA to include these same harmful provisions, such as data exclusivity, patent linkage and patent term extensions. Worse, the Obama Administration has gone even further by tabling additional provisions that would tie the hands of governments that want to manage the cost of drug reimbursement programs. And through the "Special 301" process, the US continues to pressure developing countries not to enact flexible IP rules that suit their public health needs and objectives, and not to use the health safeguards contained in the TRIPS Agreement. Finally, the administration negotiated and signed the Anti-Counterfeit Trade Agreement (ACTA) that requires signatories to enforce IP measures that have been demonstrated to interfere with sustained access to quality, low-cost generic treatments.

Despite reversing the positive new direction that US trade policy appeared to be taking after the May 10th Agreement, the Obama Administration still claims to be an ally in securing an "end to AIDS".

"It is beyond belief that in the face of clear evidence showing how strict IP rules undermine public health, the US continues to push these rules onto developing countries," said Kamal-Yanni. "The progress we saw in 2007 now seems an historical exception. Rather than standing up to the drug industry, the US Government has become its cohort in ramping up the price of new medicines through excessively long monopolies."

US trade policies undermine US HIV treatment programs

In an example of colossal hypocrisy and waste, US trade policy is undermining its own HIV treatment programs.

The PEPFAR program to fight HIV and AIDS, for instance, relies almost exclusively on generic medicines. At present, more than 90 percent of all ARVs used under PEPFAR are cheaper-version generics made in India. Without these, the US government would not have been able to afford to provide treatment to more than three million people with HIV under PEPFAR. And yet, the US is driving a TPPA that would undermine the effectiveness of PEPFAR by extending patent monopolies and delaying the availability of quality, affordable generic medicines.

Vietnam, which is both a beneficiary of PEPFAR and a TPPA negotiating partner, is a case in point. Between 2004 and 2009, Vietnam received $323.6 million for HIV/AIDS prevention, treatment, and care programs. It spent a significant portion of this on ARVs and medicines for opportunistic infections. In 2005, generics were not available to Vietnam under PEPFAR, but by 2008 generics made up 97 percent of the medicines Vietnam bought using PEPFAR funds. By shifting to cheaper generics, Vietnam and 15 other PEPFAR countries managed to save the US $323 million between 2005 and 2008, plus another $380 million in 2010.

The shift to generics shows that available resources can be stretched further in order to treat a greater number of patients.

However if Vietnam signs up to a TPPA containing the types of rules now being proposed by the US, then its ability to buy cheaper generic medicines would be threatened. These rules include data exclusivity, patent linkage and patent term extensions, all of which will help to delay the availability of cheaper generics and keep prices high.

They will also cause more burden for regulatory staff by creating new obligations for countries to meet before they can grant approval for generic medicines. Vietnamese regulatory staff are already stretched following the country's accession to the WTO. In addition, if the US succeeds in including harsh IP

proposals in the final TPPA, Vietnam will have to eliminate some of its current "pro-health" IP provisions, including the "pre-grant opposition" – a process that prevents patent approval for a medicine that is not truly innovative.

For the past decade, Vietnam has been upgrading its medicines regulations so that it can get better access to more affordable, high quality medicines. But stringent new IP rules in the TPPA could reverse that. For instance, Vietnam will only be able to get new treatments from originator companies – and for longer periods of time, because the TPPA will extend the scope and duration of the market exclusivity for new medicines.

The savings made by Vietnam (and by PEPFAR overall) in shifting to generics would be erased and more money would have to be spent on originator products. PEPFAR's growth overall will be stunted – and its sustainability perhaps threatened altogether – if it is forced to spend more on expensive patented medicines.

The impacts of US trade policy are also felt elsewhere. Each year the US issues its "Special 301" report in which it criticizes other governments for their standards of IP protection, especially on pharmaceuticals – despite the fact that these countries are meeting their obligations to the WTO.

In 2012 the US again criticized India for measures to ensure medicines are affordable. India is known as the 'pharmacy of the developing world' because of its vast generics sector. More than two-thirds of all generic medicines used in developing countries are made in India, including more than 80 percent of all medicines used to treat HIV and AIDS. The world's poorest countries, including those hardest hit by HIV and AIDS in sub-Saharan Africa, are particularly dependent on Indian-made generics.

This heavy-handed US pressure, alongside that of the big drug companies, could end up forcing India to increase IP protection for medicines. This would have a dramatic and long-lasting impact on generic medicines production, and on donors and countries that rely upon Indian generics. Among these donors is the US Government itself, whose HIV treatment programs rely on Indian generics for more than 90 percent of their anti-HIV/AIDS medicines.

"US efforts to push for strict IP rules around the world will directly undermine the global fight against HIV and AIDS, including in many of the countries the US works with today," said Kamal-Yanni. "Such efforts will also have a negative impact on the US AIDS treatment program, which itself relies on the same generic medicines whose production the US is seeking to undermine in its trade negotiations."

Toward better policies

The fight against HIV and AIDS requires renewed government efforts to meet global goals for universal treatment, prevention and care. What is not needed is a giant step backwards to a time before there were affordable, generic treatments, a time when drug companies charged thousands of dollars per patient a year for treatment in the world's poorest countries. Efforts by the US Government to increase IP protection in developing countries does nothing to promote public health and only strengthens the hand of big drug companies to charge high prices for life-saving treatments.

The positive steps of the recent past – especially under the May 10th deal – are not out of reach. The US Government should reconsider its approach on trade policy and access to medicines, in particular:

Coherence between trade and health: There should be a comprehensive, inter-agency review of the US trade agenda on IP to ensure that provisions for IP and pharmaceutical pricing do not undermine foreign assistance and other US policy objectives in partner countries.

May 10th Agreement: The 2007 agreement between the Bush Administration and Congress must, at a minimum, be upheld. In particular, the IP chapter of the TPPA should include more flexible provisions, in

line with public health concerns, with regard to patent term extensions, data exclusivity and patent-registration linkage. Other strict IP provisions should also be eliminated.

Pharmaceutical pricing: There should be no pharmaceuticals chapter in the TPPA, or any other trade agreement with developing countries. The US should not be negotiating programs that curb the ability of developing countries to manage the cost of drug procurement and reimbursement, or to enact international best practices in health and medicines policy.

Special 301 Report: The US should abandon using the Special 301 Report to criticize developing countries for using measures under global trade rules that are legal and fully consistent with their obligations to protect the human right to health.

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