During the first week of March 2013, trade negotiators from the US will continue a decade-long effort to promote stricter levels of intellectual property (IP) protection in developing countries. These efforts ignore US commitments under original World Trade Organization (WTO) rules and subsequently in 2001 under the Doha Declaration on TRIPS and Public Health and, if successful, would undermine global access to affordable medicines.

In Singapore, the US will resume negotiations for the Trans Pacific Partnership Agreement – a plurilateral agreement involving ten other countries, and potentially many more, from across Asia and Latin America. At the same time, the US will meet with WTO members in Geneva to determine whether the world’s poorest countries (least developed countries, or LDCs) can avoid implementing IP rules until they are able to graduate from extreme poverty.

Success for US negotiators will enable the brand-name drug industry to charge unaffordable prices for medicines in poor countries, but will not spur innovation to address health-care needs in these countries. And for millions of people lacking access to medicines today, these new rules could mean that medicines will not be affordable, for themselves, their families and generations to follow.

The US has taken positive steps in the past to improve access to medicines, especially through generous foreign aid programs. But for the US to have a truly positive impact, especially when foreign aid declines, it must take immediate steps to stop using trade rules to restrict access to medicines.
Access to medicines: a public health crisis across the developing world

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.

High medicine prices leave governments and households in developing countries with impossible choices. Governments that seek to provide medicines free of charge find that they cannot pay high prices for medicines while also training and retaining adequate numbers of health-care workers and building and maintaining clinics and hospitals.

In most developing countries, the cost of medicines falls most heavily upon households. Out-of-pocket expenditures for health care can account for up to 80 percent of all health-care financing in poor countries, and most often the single largest expenditure is for medicines. As such, most people in developing countries are highly sensitive to even small changes in the price of medicines. Unaffordable prices require families to either go without treatment or make difficult economic sacrifices.

The impact of trade rules upon medicine prices

Until the inception of the World Trade Organization (WTO) in 1994, all countries were free to set their own levels of IP protection, including for pharmaceuticals. Concerned over the impacts that monopoly power has upon the price of medicines, most developing countries historically had introduced few or no IP protections for medicines. This enabled countries to manufacture or import generic versions (copies) of high priced medicines, ensuring that low-income governments and people living in poverty could pay for new medicines. Generic competition, or when multiple manufacturers of generic medicines enter a market to sell copies of patented medicines, is the only proven method to reduce medicine prices in a sustainable manner.

The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, introduced with the inception of the WTO in 1994, marked a dramatic expansion of IP protection worldwide. Instead of enabling countries to set their own levels of IP protection, TRIPS mandated that all countries introduce one standard of monopoly protection – irrespective of a country’s level of development or concerns over the ability to pay for medicines.

Concerned over the impacts that the rules would have upon medicine prices, developing countries negotiated a range of flexibilities to protect public health. This included a set of public health safeguards that enable governments to override monopoly protection when patented medicines are unaffordable or unavailable, and to ensure that generic medicines can enter the market immediately after patent protection expires.

Crucially, developing countries also negotiated a transition period to implement TRIPS. Least developed countries (LDCs) were given an exemption for TRIPS implementation that was first set to expire in 2005 and was subsequently extended until 2016 with respect to pharmaceuticals (and until mid-2013 with respect to other IP protections). Other developing countries also negotiated transition periods – for example, India was granted the right to delay implementation of TRIPS until 2005.
The right to use TRIPS safeguards was reaffirmed by WTO members, recognizing the tension between IP protections on the one hand, and the need for affordable medicines on the other. In 2001, all WTO Members agreed to the “Doha Declaration on the TRIPS Agreement and Public Health”, which 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.

During the transition period, Indian generic companies, which produce up to 70 percent of the world’s generic medicines, were able to produce numerous low cost generic medicines for use across the developing world – and especially in LDCs, which also had not implemented TRIPS. This led to dramatic reductions in prices for many life-saving medicines. For example, the cost of anti-retroviral medicines to treat HIV and AIDS was reduced from an unaffordable $10,000 per patient per year to less than $350 overnight thanks to generic competition by Indian producers. This enabled a significant expansion of HIV and AIDS treatment worldwide. Today over 8 million people are on treatment, including 6.2 million people in sub-Saharan Africa. However, 11 million people in sub-Saharan Africa are eligible for treatment today, which means approximately 5 million patients are still being left behind.

**Medicine prices – the worst is yet to come**

While most developing countries benefited from low medicine prices even after the inception of TRIPS, the situation is now rapidly changing. With the exception of LDCs, all other countries have introduced TRIPS, including India.

With the introduction of IP rules, the onset of generic competition has been significantly delayed. This has resulted in dramatic increases in the cost of treatment. Thus, even while the cost of older treatments for HIV and AIDS are now less than $80 per patient per year, newer medicines under patent are anywhere from 3 to 20 times more expensive, and thus are unaffordable to most developing country governments and citizens.

And while LDCs have not been required to implement IP rules, many key medicines which are urgently needed at a low cost are not available at an affordable price because generic versions cannot be produced in countries which manufacture low-cost generic medicines (due to patent barriers).

Concerns with the price of medicines are not limited to HIV and AIDS. Medicines to treat numerous other communicable and non-communicable diseases – such as Hepatitis C, cancer and heart diseases – are too expensive. For Hepatitis C treatment, the cost of essential medicines comprises 90 percent of the overall cost of treatment. This often forces low-income countries to forego treatment, leaving patients to fend off serious side effects, such as liver cancer, and death.

**US trade policy – the straw that broke the camel’s back?**

The US – as a signatory to the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health – has committed to prioritizing public health over IP protection for medicines.

However, the US Trade Representative (USTR) has consistently failed to uphold this commitment. Since 2001 the USTR 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. In addition, USTR has pushed for IP protections that exceed the TRIPS Agreement. These so-called “TRIPS-plus” rules have acted to further 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.

Since 2001, the USTR has especially used regional and bilateral trade agreements to push for IP rules that extend the scope and duration of patent protection, such as:

- Extending monopoly power by enabling approval of patent applications filed by drug companies for slight, even trivial variations of existing medicines that have already received patent protection;
- Providing “data exclusivity” – giving monopoly protection to test data from the originator company, which prevents generic versions of medicines from regulatory approval for marketing during a specified period of time;
- Patent linkage that prevents regulatory approval for a generic medicine before verifying patent status, placing the burden on regulatory authorities to enforce patents on behalf of multinational pharmaceutical companies; and
- 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 smaller market share for generics, even several years later. In other words, there is a longer-term impact of delaying generic competition beyond the money wasted on high-priced originator medicines due to unnecessary delay in generic market entry. Generics can take a lengthy period of time to establish market share, especially as patients and doctors, supplemented by aggressive marketing by the drug industry, opt for known brands.

Oxfam examined the impacts of these IP rules in Jordan, which signed a free trade agreement with the US in 2001 that included a range of TRIPS-plus rules. From 2002 through mid-2006, medicine prices rose 20 percent in the country, and one of the key contributors to higher medicine prices was stricter IP rules. Key medicines to treat heart disease and cancer were two to ten times more expensive due solely to the existence of strict IP rules introduced as a result of the US FTA. And it is expected that over time the impacts of these rules will only lead to even more severe impacts.

In 2007, it seemed that US trade policy on IP and medicines was shifting. After several years of debate, a newly-elected Democratic Congress negotiated a revised standard for IP rules in US trade agreements with the Bush Administration. This new standard, known as the “May 10th Agreement”, allowed the Bush Administration to move forward on several new trade agreements with support from the opposition party in the Congress. The May 10th Agreement 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.
The week ahead: US trade negotiators at their worst

Unfortunately, under the Obama Administration, the USTR has virtually ignored and disavowed the May 10th Agreement and reverted to an unbalanced and aggressive push for higher IP protection at the expense of public health. Instead, the USTR continues to pressure its developing country trading partners to agree to provisions that will clearly harm access to medicines and public health. The week of March 4th is emblematic of a US approach that could harm access to medicines for most countries in Africa, Asia and Latin America.

The Trans Pacific Partnership Agreement

In 2009, the Obama Administration initiated a new trade agreement, the Trans-Pacific Partnership Agreement (TPPA), which includes these same harmful provisions that had been reversed by the May 10th deal – data exclusivity, patent linkage and patent term extensions. Worse, the USTR has gone even further by tabling additional provisions that would extend monopoly protection for medicines by enabling drug companies to file hundreds of trivial patents for slight variations of existing medicines. The practice of filing additional trivial patent applications to extend the monopoly term, known as ‘ever-greening’, has been blamed in large part for driving up medicine costs around the world. For example, an investigation by the European Commission found that European consumers paid an additional 2 billion Euros in costs for medicines due in large part to ever-greening. At the same time, the US is also tying the hands of governments that want to manage the cost of drug reimbursement programs.

The TPPA includes a mix of rich and poor countries - the US, Canada, New Zealand, Australia, Singapore, Brunei, Mexico, Peru, Vietnam, Chile and Malaysia. Oxfam’s own research in Vietnam indicates that the US-proposed IP rules would have a dramatic impact upon the country’s public health system. Already Vietnam has some of the highest medicine prices in Asia, straining the government’s finances and obliging households to pay very high out-of-pocket costs for medicines. Half of all health-care costs in Vietnam are paid for out-of-pocket, with medicines being the single largest out-of-pocket payment.

The high prices of medicines, due in large part to the ineffective implementation of policies to manage medicine prices, have meant that for many life-threatening diseases, such as Hepatitis C and cancer, the Vietnamese government’s national health insurance system cannot afford to pay for medicines. At the same time, households in Vietnam cannot afford to pay either. A course of treatment for peg-interferon, the most effective treatment for Hepatitis C, can last up to 48 weeks and requires up to 400 days of salary of an average government worker. Due to the high prices of cancer treatment, new, patented cancer medicines are not paid for through the national health insurance system, and are unaffordable in the private sector except for a tiny elite.

Of greatest concern in Vietnam is that high medicine prices are not yet due to the onset of IP rules. Vietnam only introduced TRIPS recently, and through well-balanced policies has managed to ensure that even as it protects IP, it has not granted excessive monopoly protection that unnecessarily delays access to low-cost generic medicines. With the introduction of the TPPA, medicine prices will increase at an accelerated rate, making it even more difficult for the government to control medicine prices and provide free treatment, or for ordinary people to pay for medicines out-of-pocket.
The next round of the TPPA negotiations will be held in Singapore on March 4-13. Even though nearly every negotiating partner country has rejected the US IP proposal on pharmaceuticals, the US has refused to offer a new proposal or show willingness to achieve some balance between IP protection and public health, such as the approach taken by the US under the May 10th deal.

The TPPA is an immediate threat to low- and middle-income countries already participating in negotiations. Yet over time, the ambition of the US is to expand the agreement broadly to countries across Asia and Latin America. If US negotiators are successful, it would mean that many more low-income countries in those regions will be forced to introduce impossibly high and inappropriate standards of IP protection.

**Least Developed Country Extension of TRIPS Waiver**

On March 5-6, the TRIPS Council – a coordinating body that oversees the implementation of the TRIPS Agreement globally – will convene in Geneva for a quarterly meeting. The most critical and controversial item under discussion is whether to grant a request by LDCs to extend an existing waiver for TRIPS implementation. In previous years, LDCs were granted two extensions – a waiver that delays implementation of IP rules for medicines until 2016, and a waiver on all other IP rules until June 2013. These waivers were meant to provide LDCs with time to develop a technological base, with the assistance of wealthier countries, while also maintaining maximum flexibility to enable imports or production of low-cost products, including medicines.

Least developed countries are the poorest countries in the world, with approximately 80 percent of all people in LDCs – more than 750 million people – living on less than $2 per day. Without the capacity to manufacture most products, including medicines, these countries often rely on imports from other countries to provide necessities. A lack of IP protection ensures that low-cost versions of medicines produced elsewhere can be imported into LDCs. In addition, some LDCs – including Uganda and Bangladesh – have made enormous strides in producing generic medicines locally. Local production of medicines, often possible because of the lack of IP barriers, has enabled these countries to provide low-cost medicines to their own citizens and even to export these medicines to other LDCs for their own use.

Today, LDCs find themselves with many of the same technological and economic barriers that necessitated the original waiver of TRIPS. As such, in November 2012 LDCs requested they be granted an indefinite extension of the waiver, to remain in place for every LDC until it is able to ‘graduate’ from LDC status. This would apply not only to IP rules set to be introduced this year, but also to IP rules for medicines. Such a waiver would enable LDCs to improve their technological base without IP barriers, while also ensuring any and all measures can be taken to reduce prices for various products, including medicines. Finally, a waiver would enable LDCs to forestall the expense of implementation and enforcement of IP rules, which can cost a country up to $1 million per year.

**LDCs are guaranteed the right to request, and be granted, such a request under TRIPS.**

Yet in spite of the concrete benefits that flexible IP rules can provide in poor countries, the US and other rich countries have taken an aggressive stance against the LDC
request. While LDCs would prefer a waiver for the entire group without any precondition, the US is actively seeking to undermine the LDCs request and appears likely to openly oppose the request at the upcoming TRIPS Council meeting. Instead of allowing the entire LDC group an indefinite extension, the US is working behind closed doors for a limited moratorium instead – after which the US and other countries will have the right to sue LDCs at the World Trade Organization for failing to implement IP rules.

If LDCs are granted their request, it would also automatically extend the 2016 deadline (which addresses intellectual property for pharmaceuticals) for each country until it graduates from LDC status. This would enable LDCs to invest confidently in their health care systems, including commitments to provide low-cost medicines, which would also provide an incentive for low-cost generics manufacturers to supply affordable medicines in their markets.

If the US is successful, it would mean that at least 34 of the world’s poorest countries would have to start implementing nearly all IP rules immediately (8 LDCs have not yet entered the WTO and 9 countries are actively negotiating their entry), with heavy financial costs associated with implementation. At the same time, it would leave LDCs in limbo with respect to the pharmaceuticals extension in place until 2016. This would undermine investments that LDCs should make to provide medicines through their public health care system to invest in local production of low-cost generic medicines and would likely discourage low-cost manufacturers of generic medicines from investing in production for these markets.

Between the TPPA negotiations and the meeting of the TRIPS Council, the US will seek in one week to dramatically expand IP rules across most countries in Asia, Latin America and Africa, with damaging public health consequences.

**Ensuring trade doesn’t undermine public health**

Ensuring access to affordable medicines requires adequate financing, effective public health care systems, well-trained health-care workers, and affordable and appropriate medicines. US policy is going the wrong way by preparing to take 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.

Oxfam believes that trade can be an engine for development and poverty reduction, provided the rules are crafted fairly 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 rules 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 fully taken into account when negotiating trade rules.

Trade rules have direct and profound impacts upon public health, particularly through intellectual property rules. The same IP rules meant to generate innovation and new products in rich countries may impede rather than stimulate innovation and access to new products for emerging countries. To date, IP rules promoted by the US 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 health-care programs, this approach has discredited trade itself as a tool for poverty reduction.

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.

At a minimum, the May 2007 Agreement between Congress and the Bush Administration must 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 be eliminated, and there should be no pharmaceuticals chapter in the TPPA. Specifically, the TPPA should exclude any additional provisions designed to extend monopolies and limit generic competition in pharmaceuticals, such as expanded scope of patentability, over-zealous enforcement measures, prohibition of pre-grant opposition systems, and regulations on pharmaceutical pricing that curb the ability of developing countries to enact international best practices in health and medicines policy.

The US should also fully support the LDC waiver that was requested unanimously by LDCs in November 2012 and abandon any attempts to undermine its passage. In lieu of opposing the LDC request, the US should explore ways on its own, and through its companies, to facilitate the transfer of technology.