Comments on the Anti-Counterfeiting Trade Agreement to the Office of the United States Trade Representative

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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 nearly100 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.

Recommendations

Oxfam America recommends the United States should only sign the Anti-Counterfeiting Trade Agreement subject to the following understandings:

1. ACTA is an agreement about the enforcement of intellectual property rights, and is not intended to enlarge or diminish existing flexibilities to those intellectual property rights. In particular, the United States and all other negotiating parties should ensure that implementation of ACTA, including enforcement activities against third parties, shall not hinder the access and movement of legitimate generic medicines and shall be consistent with all public health flexibilities and safeguards under the TRIPS Agreement and the WTO Declaration on TRIPS and Public Health.
2. The U.S. government's implementation of ACTA will not extend to patents and the protection of undisclosed information pursuant to the obligations under Section 2 (Civil Enforcement) and Section 3 (Border Measures) of the Agreement.
3. The US government's implementation of ACTA will limit criminal procedures and penalties to willful trademark counterfeiting and copyright or related rights piracy on a commercial scale.
4. The US government should not use unilateral pressure, including the Special 301 Report, or new or existing free trade agreements, to demand that non-OECD countries which are non-parties to ACTA join the Agreement or abide by its terms. Furthermore, ACTA should not be promoted with developing countries as a tool or framework that can enable those countries to ensure medicines are of adequate safety and quality.
5. The ACTA Committee, which is established under this Agreement, should commit to the following two principles:
    a. The ACTA Committee should operate in an open, inclusive and transparent manner, taking into consideration the views of intergovernmental and non-governmental organizations and non-parties to the agreement.
    b. The ACTA Committee should not pursue any new or additional IP enforcement rules beyond what is established under the framework of ACTA, and especially any new rules or obligations that would limit access to affordable medicines.

Discussion

We appreciate the opportunity to offer our thoughts on the Anti-Counterfeiting Trade Agreement prior to U.S. signature of the Agreement. Our recommendations are based upon the following three areas of concern, which are discussed in detail below:

1. Transparency

2. Intellectual property rules that may undermine the Doha Declaration on TRIPS and Public Health and that can therefore create new barriers to affordable medicines in developing countries

3. The relevance of ACTA to developing countries, and especially the appropriateness of ACTA as a framework to reduce the proliferation of poor quality medicines.

Transparency

The Anti-Counterfeiting Trade Agreement was negotiated in a highly secretive manner with little or no input from relevant stakeholders. The lack of transparency was most often due to the unwillingness of the United States government to share the text of the Agreement with interested stakeholders not already serving on Industry Trade Advisory Committees (ITACs). Since most ITACs are dominated mostly by representatives of major multinational industries, with little or no public interest representation, ACTA was an Agreement often shaped without any balanced views that would better inform the U.S. government. Oxfam was highly disappointed with the U.S. government's lack of commitment to transparency throughout the course of ACTA negotiations.

Transparency would have been of benefit to all parties to the negotiation. Throughout the course of the ACTA negotiations, the few instances in which the text of the Agreement was publicly released led to major revisions due to glaring inconsistencies, either with U.S. law or with commitments to ensuring access to affordable medicines – especially the WTO Declaration on TRIPS and Public Health. Greater transparency throughout the course of the Agreement could have ensured that all new intellectual property (IP) rules negotiated under ACTA would have been properly balanced with public health and public interest considerations.

Under ACTA, a new committee will be established that will have considerable powers, including: reviewing the implementation and operation of the Agreement, amending the Agreement and determining the terms of accession of any new Party to the Agreement. At present, there is no guarantee that the Parties to the Agreement, and especially the United States, will operate any differently in carrying out obligations established through the Committee. Given the range and complexity of issues dealt with under ACTA, a commitment to establish a Committee that operates in an open, inclusive and transparent manner is critical to protecting the public interest and ensuring that ACTA does not create new barriers to affordable medicines in developing countries.

ACTA and its impacts upon public health

The ACTA Agreement disturbs the careful balance between the protection of intellectual property and the promotion of public interest established under the TRIPS Agreement. Since only two developing countries participated in the negotiations, many of the concerns offered by developing countries, especially the potential impact of ACTA upon public health, were only registered in other forums, including at quarterly meetings of the TRIPS Council.

The lack of balance in negotiations is reflected by the numerous new rules and obligations that require Parties to introduce and enforce intellectual property rules, compared with the lack of any new safeguards and flexibilities that are a critical part of any functioning intellectual property system. The TRIPS Agreement achieves a balance, however imperfect, between the protection of intellectual property and the promotion of public health. Critically, safeguards under the TRIPS Agreement have also been strengthened by the subsequent passage of the Doha Declaration on TRIPS and Public Health. While ACTA does reaffirm the Doha Declaration on TRIPS and Public Health under the preamble, and does incorporate Articles 7 and 8 of TRIPS under the second chapter, it does not introduce any new flexibility within the Agreement that could have preserved the sense of balance under TRIPS.

Furthermore, while efforts were made by various Parties, including the United States, to ensure that the most onerous rules under consideration were not included under the final text of the Agreement, some of the rules nevertheless included under ACTA will create new barriers to affordable medicines. This includes the following:

1) Extended border measures that would allow for seizure of legitimate medical products (Chapter 2, Section 3)
2) Heightened damages for IP infringement (Chapter 2, Section 2)
3) Rules that limit the discretion of judges who wish to avoid imposing injunctions (Chapter 2, Section 2)
4) Rules enabling third-party enforcement measures (Chapter 2, Section 2)

Going forward, Parties should review these provisions of ACTA and consider amending or removing them in the interests of ensuring a careful balance between the protection of intellectual property and the promotion of public health.

In addition, nothing under the text of the Agreement would preclude Parties from eventually introducing new intellectual property rules, either through amendments to the Agreement, through unilateral adoption of additional IP rules by the Parties, or through imposition of additional IP rules upon third parties that may accede to the Agreement in the future.

In particular, we are concerned with the potential future inclusion of patents and the protection of undisclosed information as additional obligations under Section 2, 3 or 4 of the Agreement. In particular, the United States and other Parties to the Agreement should not create new barriers to legitimate movement of generic medicines through border measures. The harmful effects of such barriers have been evidenced recently when at least 19 shipments of legitimate generic medicines, exported from India and China to other developing countries, were intercepted by customs officials in the European Union while in-transit. Under no circumstances should the U.S. enforce ACTA, or push for amendment of ACTA, in a manner that would enable or further such actions that undermine trade in generic medicines.

The experience with the seizures of medicines in the EU is illustrative of the adverse effects of such measures. It was due in large part to a revision of an EU internal customs regulation – 1383/2003 – which expanded the powers of border officials within the EU. This regulation directs border officials to seize counterfeit products, products that may infringe patents, and products that may be contested under a civil trademark-infringement dispute (wherein one party alleges that a competing product is 'confusingly similar' to its own product's registered trademark). This broadly-written law, once enforced, has had a serious, damaging impact on trade in affordable medicines. In particular, European customs officials started seizing shipments of generic medicines en route from India and China to other developing countries. Over a period of 12–18 months, at least 19 shipments of legitimate generic medicines, in transit through the EU, were seized or temporarily detained by customs officials for alleged infringement of patent rights. In one case, the consignment was seized under the 'confusingly similar' trademark-infringement standard.

All of these EU actions resulted from the misguided use of border measures by customs officials against legitimate generic medicines that were deemed to infringe patents or trademarks within the EU. Some seizures were done at the behest of multinational pharmaceutical companies seeking to enforce their IP rights within the EU. In other cases, customs officials used their own independent authority to seize products that they deemed to infringe IP rights. In each case, the medicines did not infringe any IP in the country of origin or in the recipient developing countries. Many of the seized medicines were of considerable public-health importance, including medicines to treat cardiovascular disease or HIV and AIDS. In one case, Dutch authorities seized a generic version of *abacavir*, a key second-line anti-retroviral medicine that had been purchased by UNITAID, the international UN medicines-purchasing facility. The medicine was being shipped from India to Nigeria, using logistical support offered by the Clinton Foundation. In seizing in-transit medicines with no connection to the EU market, the EU has sought to impose its domestic, TRIPS-plus standards of IP enforcement on the exporting and importing countries.

The TRIPS Agreement does not require the detainment of in-transit goods, or even the checking of the IP status of products that are in transit. The US government should not, under any circumstance, adopt this approach to IP enforcement domestically nor impose such provisions upon third countries that are not yet a party to the Agreement.

ACTA and its relevance to developing countries

Parties to the Agreement have repeatedly stated that it is their intention to introduce ACTA as a new standard for adoption worldwide. In doing so, it would undermine the carefully negotiated principle established under the TRIPS Agreement that left enforcement of intellectual property rights to the discretion of each WTO Member State, insofar that Parties adhered to certain minimum obligations. New enforcement rules will impose heavy, additional costs upon developing countries and will discourage the use of flexibilities that countries use to promote greater innovation as well as the sharing and diffusion of knowledge. The U.S. should not use either the annual Special 301 Reporting process or the on-going negotiations of the Trans-Pacific Partnership, as an opportunity to impose ACTA upon developing countries that played no part in negotiating the Agreement.

In addition, the imposition of ACTA would divert scarce resources from other priorities that may be more appropriate investments at the national level in developing countries. Oxfam is

concerned that ACTA may replace public health focused activities and interventions that are needed to improve the ability of developing countries to remove poor quality medicines.

Throughout the negotiations of ACTA, all parties to the Agreement often cited ACTA as an Agreement that would enable countries to eliminate poor quality medicines, and especially counterfeit medicines. Parties to ACTA seem to view the Agreement as appropriate for both their own countries, as well as developing countries that would ultimately be asked to join the Agreement. Yet this is not the case, as ACTA would do very little to address the problem of poor quality medicines in developing countries.

Indeed, limited 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 US Food and Drug Administration, which currently spends over US$1 billion per year to identify and remove substandard and falsified medicines.

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, US 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.