

Oxfam Statement regarding ACTA and Public Health

I. Introduction

The Anti-Counterfeiting Trade Agreement (ACTA), a pluri-lateral trade agreement between ten countries and the European Union, sets new, TRIPS-plus standards for the enforcement of intellectual property (IP).¹ ACTA will undermine access to affordable medicines by impeding trade in quality generic medicines. Concerns with ACTA are based in part upon the adverse impact that similar provisions, for instance those in EU Regulation 1383/2003, have had on international trade in generics.

ACTA will undoubtedly impact access to affordable medicines in the EU and other signatories by curbing generic competition. There are great concerns that ACTA's impact will extend beyond those countries that initially sign the Agreement, potentially undermining access for millions of patients in developing countries who depend on affordable, quality generics. ACTA provides for the seizure of in-transit medicines that do not infringe any IP in the place of production or consumption; such actions could interfere with international trade in lawfully available products. Moreover, the Agreement could lead to imposition of civil and criminal liability for third parties supplying inputs and other services to generic producers targeted as IP infringers. These provisions could create an important chilling effect for production of and international trade in generics.

In a variety of forums, IP protection and additional enforcement measures have been extended in ways that curb access to affordable treatment. Even prior to the completion of ACTA, TRIPS-plus IP provisions in FTAs have delayed generic competition in developing countries.² Reduced generic competition results in higher medicine prices, thereby diminishing access and undermining public health. ACTA will compound this problem by imposing new, TRIPS-plus IP enforcement standards on low and middle-income countries, either through inclusion of similar provisions in future trade agreements or through pressure to accede to ACTA.

II. Oxfam Concerns that ACTA will Harm Public Health

This section identifies several concerns about ACTA from a public health perspective. It identifies two inter-related problems: first, the excessively broad scope of ACTA, which redefines a "counterfeit" to include forms of IP infringement unrelated to counterfeiting, and, second, the onerous enforcement measures included in ACTA which result in additional barriers that undermine the movement of generic medicines and/or dis-incentivize the production and sale of generic medicines.

A. The scope of ACTA is unduly broad and could lead to legitimate generic medicines being targeted together with true “counterfeits”, which are products that are intended to deceive consumers.

Counterfeiting constitutes a criminal activity if carried out willfully and on a commercial scale. According to signatories, ACTA is intended to help them “effectively combat the proliferation of counterfeiting and piracy”, and to protect consumers from potentially dangerous products like counterfeit medicines.³ However, the Agreement does not limit itself to addressing “counterfeits”, a category of products that is defined narrowly in the WTO TRIPS Agreement as involving the deliberate, fraudulent use of a trademark in order to deceive consumers.⁴

Instead, ACTA targets all forms of intellectual property infringement under the guise of targeting counterfeiting.⁵ For instance, ACTA civil enforcement measures apply broadly in connection with “IP infringement”, which includes civil trademark infringement and patent infringement; although the Parties have the option of excluding patents and undisclosed information from the scope of the civil enforcement section, their inclusion is the default setting.⁶ And goods that are suspected of infringing IP, broadly defined, may be seized by customs officials under ACTA.⁷

This is misguided, since neither civil trademark infringement nor patent infringement have any bearing upon whether or not a product is counterfeit. In particular:

- Civil trademark infringement: Multinational pharmaceutical companies often have trademark infringement disputes with generic firms because the generic medicine has a similar name, trade dress (shape, color), or package as the originator medicine. In some situations, generic medicines may have an unintentional name-resemblance to a branded medicine, particularly if both the branded and generic medicines are named based on the international non-proprietary name (INN). Generic medicines may also feature trade dress similar to that of an originator product precisely because the products are bioequivalent and designed for consumers’ interchangeable use. Such trademark disputes do not involve fraudulent misrepresentation or criminal activity, and are resolved through the courts.
- Patent infringement: Multinational drug companies and generics companies are constantly locked in bitter legal disputes over patent infringement, with each side claiming the other is at fault. While patent claims should be settled predictably and fairly in a court of law, patent disputes should never be confused with enforcement actions that seek to target counterfeit medicines. And public resources should not be used to police or enforce private IP rights.

That ACTA fails to reflect these critical distinctions is worrisome from a public health perspective. When a broad range of products are considered counterfeits, and/or when anti-counterfeit measures conflate civil and criminal trademark infringement, lawfully available generic medicines may be targeted together with products that are intended to deceive consumers. Expansive anti-counterfeit provisions may lead to the unnecessary removal of quality, affordable medicines from the market.

Moreover, stronger IP enforcement is not the best solution to the problem of medicines safety. Extensive anti-counterfeit provisions are costly to implement, particularly in low-income countries with few resources. If the goal is to protect the public from potentially dangerous products, available resources could be more effectively used to build and improve drug regulatory capacity, including market surveillance. Fundamentally, an IP enforcement approach to a public health problem is extremely limited in what it can achieve, particularly since many medicines that should be removed from the market do not infringe any IP.⁸

B. ACTA includes a range of onerous enforcement measures that undermine generic competition in ACTA signatories – and even in countries that are not party to the Agreement.

1. ACTA could lead to seizures of legitimate generics that are in transit through ACTA signatories, and that do not infringe any IP in the place of production or consumption.

ACTA border measure provisions, which are TRIPS-plus on several grounds,⁹ constitute a grave threat to trade in generics. The customs detention of legitimate generics in transit through the European Union demonstrates the adverse impact that such border provisions can have on public health on a global scale. Implementation of the EU Regulation 1383/2003 at the national level resulted in at least twenty seizures of generic medicines, including life-saving medicines to treat HIV/AIDS and heart disease that were en route to patients in developing countries.¹⁰

Under ACTA, such seizures could continue. The Agreement provides for the imposition of border measures following request by a rights holder or as a result of *ex officio* action by customs officials.¹¹ They may be imposed in connection with “suspect goods” that are believed to infringe (but not confirmed to have infringed) intellectual property rights.¹² And ACTA provides for the application of border measures to goods that are merely in transit through a signatory – even if they do not infringe any IP in the place of production or where they will be consumed.¹³

ACTA creates a risk that legitimate generic medicines could be detained by customs officials, interrupting the international supply of affordable medicines. Suspected patent infringement is excluded in ACTA as a basis for border measures.¹⁴ This was a victory for public health advocates, as several well-publicized EU detentions of in-transit generics have been carried out in connection with suspected *patent infringement*, on the basis of the “manufacturing fiction” under Dutch law. While the legal basis for these EU seizures still exists,¹⁵ at least ACTA does not provide a basis for instituting the same, problematic patent-related provisions in other jurisdictions.

However, in-transit generics have also been detained in the EU due to suspected *trademark infringement*.¹⁶ Under ACTA, suspected trademark infringement could provide a basis for interrupting trade in generics, even if they do not infringe any IP in the countries of production or destination. And ACTA provides for action in connection with any suspected infringement of intellectual property, which means that even civil trademark infringement could lead to border action. In other words, even generics that unintentionally infringe a trademark could be seized, for instance because they seem “confusingly similar” to the relevant trademarked product.

2. ACTA provisions on third party liability could create a chilling effect for the global generics industry.

Under ACTA, third parties supplying inputs or services in support of the manufacture or commercialization of allegedly IP-infringing products could be subject to civil and criminal sanctions. The imposition of so-called third party liability may dissuade suppliers from selling inputs and services to generics producers that could be targeted as IP infringers, particularly since ACTA defines IP infringement to include civil trademark infringement. This could create a chilling effect for the generics industry, which, in turn, could reduce the availability of quality affordable medicines for patients everywhere.

Under the civil enforcement section, ACTA requires that officials be granted the authority to issue injunctions, including for third parties contributing to alleged infringement of IP, in order to prevent infringing goods from entering channels of commerce.¹⁷ In addition, third parties may be subject to “prompt and effective provisional measures” in order to prevent infringement of intellectual property, and/or to prevent allegedly infringing goods from entering channels of commerce.¹⁸ Unlike TRIPS, ACTA does not define “channels of commerce” as those within the territory, raising questions as to whether action could be taken in order to prevent goods from entering commerce in another jurisdiction.¹⁹

ACTA requires that criminal sanctions be imposed “at least in” connection with counterfeiting and piracy that is willful and carried out on a commercial scale, and for attempted counterfeiting.²⁰ In addition, ACTA requires that parties ensure that criminal sanctions for “aiding and abetting” counterfeiting or attempted counterfeiting exist in their national laws.²¹

ACTA language on aiding and abetting could affect providers of inputs, including those that unknowingly supply labels, materials, or services to IP infringers. In addition, entities involved in supporting drug development, providing support for trade in and commercialization of generics, or helping to procure generic medicines may be held liable under this provision, if generics are deemed to constitute counterfeits.²² Some believe that even NGOs like Medecins San Frontieres/Doctors without Borders (MSF) could be liable under this provision, in addition to being subject to provisions in the civil enforcement section regarding injunctions and provisional measures.²³

In addition, under ACTA, on the basis of a request by an IPR owner, judicial authorities can order an alleged infringer (of any IP) to provide information regarding any entity that contributed to the alleged infringement.²⁴ ACTA states: “Such information may include information regarding any person involved in any aspect of the infringement or alleged infringement and regarding the means of production or the channels of distribution of the infringing or allegedly infringing goods or services, including the identification of third persons alleged to be involved in the production and distribution of such goods or services and of their channels of distribution”.²⁵ This mechanism could be used by originator companies to harass generic competitors as alleged infringers, along with entities in their supply chains.

3. ACTA rules for calculating damages for infringement would overcompensate rights holders and deter entry of generics into the market.

ACTA provides that an infringer who knowingly engaged in infringement, or who reasonably should have known he was engaged in infringement, may be ordered to pay damages in order to compensate for injury to the rights holder,²⁶ and introduces TRIPS-plus rules for calculating such damages. Notably, ACTA requires that judicial authorities be able to consider specific approaches to quantifying injury that have been suggested by the affected IP owner, including “lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price”.²⁷ According to analysts, the obligations for judicial authorities to consider compensation based on “lost profits” would over-compensate originator companies for harmful pricing strategies, which target elites and in the absence of competition, leave the majority of patients without access to medicines.²⁸ Unduly high damages for IP infringement could also “over-deter” generics from contesting markets.²⁹

III. Conclusions and Recommendations

Oxfam, as part of a broad coalition of civil society organizations, has consistently opposed ACTA due to its likely widespread, harmful impact on access to medicines and public health. Above all, Oxfam recommends that ACTA not be ratified or implemented. If this cannot be achieved, Oxfam recommends that:

- **Parties implementing ACTA should limit the scope of application of the Agreement wherever possible.** For instance, they should exclude patents and the protection of undisclosed information from the civil enforcement section,³⁰ and criminal sanctions should be applicable strictly to counterfeiting as defined under TRIPS.³¹ Enacting ACTA provisions in as limited manner as possible could lessen the threat to the international supply of quality generics.
- **Parties implementing ACTA must take steps to safeguard continuing availability of affordable, quality generics.** Implementation of the agreement by the Parties, especially the EU which is a major hub for transshipment, could seriously undermine global availability of generic medicines. Before imposing border measures or third party liability, signatories should carefully weigh the health impact of such actions - for patients abroad as well as at home.
- **Developing countries that are not party to ACTA should not be required to enact ACTA-style IP enforcement measures.** No developing countries should be made to accede to ACTA as a condition in bilateral trade or other agreements, and ACTA-style provisions should not be incorporated in trade agreements with developing countries.
- **In order to protect their populations against unsafe medicines, including but not limited to counterfeit products, countries should focus on upgrading their drug regulatory authorities.** Health, not IP, solutions are best-suited to addressing health problems. Developing countries should focus on upgrading DRA capacity, rather than modifying law enforcement priorities in order to target IP infringement.

¹ ACTA was negotiated by Australia, Canada, EU, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland, United States. It was signed by all but Switzerland and the EU on 1 October 2011. <http://www.ustr.gov/acta>.

² See Oxfam briefing paper “All Costs, No Benefits”, March 2007, at http://www.oxfam.org/en/policy/bp102_jordan_us_fta. See also CPATH briefing paper “A Trade Agreement’s Impact on Access to Drugs”, August 2009, at <http://www.cpath.org/sitebuildercontent/sitebuilderfiles/cpathhaonline8-25-09.pdf>.

³ USTR ACTA Fact Sheet at <http://www.ustr.gov/acta-fact-sheet-march-2010>.

⁴ Footnote 14, Article 51, WTO TRIPS Agreement.

⁵ The ACTA civil enforcement section applies to “IP” broadly. The parties *may opt to* exclude patents and the protection of undisclosed information from its application. Inclusion of patents and the protection of undisclosed information is the “default setting”. Footnote 2, Section 2, ACTA.

⁶ See Endnote 5.

⁷ Patents and undisclosed information are excluded from the scope of the border measures section. Footnote 6, Article 13, ACTA.

⁸ See Oxfam Briefing Paper “Eye on the Ball”, February 2011, available at <http://www.oxfam.org/en/policy/eye-ball>.

⁹ TRIPS, in contrast, requires border action only in connection with “counterfeit trademark goods” and “pirated copyright goods”, narrowly defined as fraudulent products that are intended to deceive consumers. Footnote 14, Article 51, TRIPS. TRIPS does not provide any basis for action against in-transit products; Article 52 refers to “the laws of the country of importation” as the basis for determining whether there is evidence of infringement to justify border measures.

¹⁰ Following the seizures, India and Brazil initiated dispute settlement proceedings against the EU at the WTO. Information about these disputes, which are still pending, is available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm and http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm.

¹¹ Article 16(1), ACTA.

¹² Article 13, Article 16, ACTA. ACTA (footnote 6, Article 16) explicitly states that patent infringement and the protection of undisclosed information are not within the scope of the section on border measures.

¹³ See endnote 12.

¹⁴ Footnote 6, Article 13, ACTA.

¹⁵ See Oxfam Statement, “Oxfam Reaction to the May 2011 Proposal for a Regulation of the European Parliament and of the Council Concerning Customs Enforcement of Intellectual Property Rights (replacing Council Regulation 1383/2003)”, August 2011. See also Baker, Brook, “Settlement of EU/India WTO Dispute re: Seizures of In-Transit Medicines: Is the Proposed EU Border Regulation Good Enough?”, August 2011.

¹⁶ In June 2009, the customs officials in Frankfurt, Germany, seized a shipment of generic “amoxillin”, named based on the INN for the medicine, since the name was similar to the name of the GSK originator product, “Amoxil”, which is also named based on the INN.

¹⁷ Article 8, ACTA. The corresponding provision of TRIPS, Article 44, does not address third parties.

¹⁸ Article 12, ACTA. The corresponding provision of TRIPS, Article 50, does not address third parties.

¹⁹ Article 50, TRIPS. While TRIPS refers to “channels of commerce” within the territory of the WTO member, ACTA does not define “channels of commerce”. This raises concerns as to the scope of this phrase, and whether action could be taken in one jurisdiction in order to prevent products from entering into commerce in another jurisdiction. See Baker, Brook, “ACTA – Risks of third-party enforcement for access to medicines”, *American University International Law Review*, 26:3, August 2011. See also Flynn, Sean, and Madhani, Bijan, “ACTA And Access to Medicines”, September 2011, at <http://rfc.act-on-acta.eu/access-to-medicine>.

²⁰ Attempted counterfeiting is defined in the Agreement as trade in labels and packaging, under certain conditions. Article 23 (1) and (2), ACTA. Both ACTA and TRIPS set forth minimum standards, which means that signatories could provide criminal penalties for other types of IP infringement (additional to counterfeiting and piracy that is willful and on a commercial scale).

²¹ Article 23(4), ACTA. TRIPS is silent on third party criminal liability.

²² Baker, Brook, “ACTA – Risks of third-party enforcement for access to medicines”, *American University International Law Review*, 26:3, August 2011.

²³ Articles 8 and 12, ACTA. See endnote 22.

²⁴ Article 11, ACTA.

²⁵ Article 11, ACTA.

²⁶ Article 9, ACTA.

²⁷ TRIPS Article 45 does not require judicial authorities to consider any approach recommended by the IP owner.

²⁸ Flynn, Sean, and Madhani, Bijan, “ACTA And Access to Medicines”, September 2011, at <http://rfc.act-on-acta.eu/access-to-medicine>.

²⁹ See endnote 28.

³⁰ See footnote 2, Section 2, ACTA.

³¹ See Article 23 (1) and (2), ACTA, and Articles 51 and 61, TRIPS.