ACTA from an Access to Medicines Point of View

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This year, there were fireworks on both sides of the Atlantic for the 4th of July when the European Parliament (EP) made a landmark decision to reject the Anti-Counterfeiting Trade Agreement (2011), known as 'ACTA', by a majority of 478 votes out of 682. The European Union (EU), United States, Australia, Canada, Japan, Morocco, New Zealand, Singapore and South Korea had formally signed the agreement.

The stated aim of this controversial treaty is to fight counterfeiting by requiring signatories to establish and enforce very strict standards of protection for certain intellectual property rights (IPR) in their national laws. For many members of the EP, together with broad swaths of the European public and civil society groups, the requirements set out in ACTA significantly curb public interests in favour of IPR owners' interests.

While media attention has mainly focused on concerns about how ACTA would restrict freedom of access to the Internet, there are other grave concerns. One is that ACTA seriously threatens access to generic medicines for millions of people living in poverty around the world.

Under the guise of targeting counterfeiting, a subject matter that technically only deals with wilful misuse of a registered trademark (brand), ACTA significantly raises standards for the enforcement of a range of other IPRs including copyrights and patents. ACTA standards are 'TRIPS-plus', meaning they exceed the minimum obligations under global trade rules enshrined in the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement (1994) and often remove TRIPS safeguards (Flynn and Madhani, 2011). While contributing little or nothing to the protection of public health and safety, the TRIPS-plus rules in ACTA could have a profoundly negative impact on the global production and distribution of quality generic medicines. This would be particularly devastating for developing countries, potentially undermining access to medicines for millions of poor people in low and middle income countries.

Five mains elements of ACTA raise concern for public health and access to medicines.

ACTA's broad scope means that some generics with confusingly similar names or brands could be targeted as 'counterfeits'

ACTA could lead to the targeting of legitimate generic medicines, together with true counterfeit trademarked products. ACTA is dangerous because it is not strictly limited to countering trade in true 'counterfeiting', defined narrowly under the WTO TRIPS Agreement (1994) as "any goods, including packaging, bearing without authorization a trademark

which is identical to the trademark validly registered in respect of such goods" (Article 51, Footnote 14); in other words, a deliberate, fraudulent use of a trademark in order to deceive consumers. Instead, ACTA creates severe penalties in connection with a range of types of intellectual property (IP) infringement and IPR disputes, most of which have nothing to do with counterfeiting. For instance, TRIPS imposes rules regarding civil trademark infringement, which in contrast to criminal activities, are purely commercial disputes between companies defending their respective brands/products. However, under ACTA, such disputes are conflated with intentional, criminal counterfeiting activities. This benefits brand owners by giving them powerful tools to chase down competitors with similar brands/products.

Calling civil trademark infringement 'counterfeiting' is intellectually dishonest—and also very dangerous where medicines are involved. Legitimate generic medicines often have similar names, based on or derived from the mandated international non-proprietary name of the active ingredient, as their branded counterparts. They may also have the same pill shape, colour, or size as the branded product, which helps patients comply with their medicines regimens. Because ACTA defines counterfeits so broadly, quality generic medicines that are lawfully being produced and shipped in global trade could be removed from the market. This would hurt consumers not only in the countries implementing ACTA-style rules, but in countries outside of ACTA when medicines-in-transit are intercepted (see discussion below).

ACTA's civil enforcement measures could be applied with respect to patents, although such application is not required

Under Section 2 (footnote 5), which defines civil enforcement measures under ACTA, parties *may opt to* exclude patents and the protection of undisclosed information—but the inclusion of patents and the protection of undisclosed information is the default setting. And while infringement of rights related to patents and undisclosed information is excluded from the scope of Section 3, border measures, such as the seizure or destruction of the goods, may nonetheless be imposed on the basis of civil trademark infringement, which is unrelated to counterfeiting.

ACTA would interfere with trade in legitimate generics, curbing global availability

ACTA's border enforcement measures could undermine generic competition in ACTA signatories. ACTA could also affect countries that are not party to the Agreement by interfering with global trade in legitimate generic medicines. ACTA provides for the seizure, and even destruction, of in-transit medicines, regardless of whether they infringe any IPR in the place of production or consumption. ACTA rules would thus harm patient and public health globally.

As discussed above, ACTA provides for the seizure of medicines that may unintentionally infringe a registered trademark. This is because the Agreement also applies to products merely transiting through a signatory country. In other words, quality generic medicines that have been legally manufactured in one country could be seized en route to another

country in an ACTA signatory country as “counterfeits” just because they appear similar to branded products. Even if the products do not infringe any IPR in the place of manufacture or consumption, they could be targeted by ACTA countries as counterfeits and detained or even destroyed, thus depriving patients in the recipient countries of their medicines. This would create severe hardship for patients in developing countries where access to affordable generic medicines is critical.

ACTA includes many provisions similar to EU Regulation 1383/2003 (Council of the European Union, 2003) aimed at reinforcing customs actions to fight the trade on goods that infringe IPRs. It therefore introduces the same risk that gave rise to seizures of legitimate generic medicines intended for poor countries on the basis of suspected civil trademark infringement. In 2008, 2009 and 2011, in particular, at least 20 shipments of generic medicines that were produced predominantly in India and China, and intended for low income countries around the world, were seized by EU customs officials who were applying EU regulation 1383/2003 (Micara, 2012). Although most seizures involved putative patent claims, a shipment of generic ‘amoxillin’ was seized in Frankfurt, Germany, for example, because its name, although based on its international non-proprietary name (INN), was similar to that of the GlaxoSmithKline originator product, ‘Amoxil’, which was also named after its INN. This EU regulation has been challenged for hampering lawful trade in generic medicines by India (Balasubramaniam, 2011) and Brazil at the WTO and is currently being revised in the EP to comply with WTO trade rules and avoid further seizures.

Imposition of third party liability could create a chill for the global generics industry

ACTA includes a range of provisions that impose third party liability upon suppliers of pharmaceutical inputs and services, as well as other actors in generics supply chains. This could affect these entities’ willingness to participate in the global production and distribution of generics thereby creating a chilling effect for the industry and reducing global availability of quality, affordable medicines. For instance, following an IPR owner request, judicial authorities can order an alleged IP infringer to provide information regarding any entity that contributed to the alleged infringement (Baker, 2011). This provision does not protect against misuse, including use of the provision by an IP right holder to obtain details about the supply chains of its generics-producing competitors (Flynn and Madhani, 2011).

In addition to that, third parties may be subject to prompt and effective provisional measures in order to prevent infringement of IP, and/or to prevent allegedly infringing goods from entering channels of commerce (which are not defined under ACTA). Generics could be seized on short notice without the other party being heard and without a full juridical review by the court (Health Action International Europe, 2012).

Furthermore, under ACTA, parties are asked to ensure that criminal sanctions for *aiding and abetting* counterfeiting, or attempted counterfeiting, are provided in their national laws.Aiding and abetting targets third parties and could affect entities involved in supporting drug development, providing support for trade in and commercialisation of

generics, or helping to procure generic medicines, if generics are deemed to constitute counterfeits (Baker, 2011). Even well-known humanitarian organizations, such as Médecins Sans Frontières, that distribute and transport generic medicines for their health programs in developing countries could be liable to criminal sanction in addition to being subject to provisions in the civil enforcement section regarding injunctions (Article 8) and provisional measures (Article12) [Médecins Sans Frontières, 2012].

ACTA's civil remedies are excessive

Moreover, ACTA rules for calculating damages for infringement compound the disincentives for the generics industry because they would result in over-compensation of IP right holders and could deter entry of generics into the market (Flynn and Madhani, 2011). IP owners have the possibility to suggest ways of calculating the damages, including *lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price*. TRIPS safeguards are removed.

Finally, while ACTA included only two developing-country negotiators, Morocco and Mexico, civil society was concerned that other developing countries would be pressured to sign ACTA, or to agree to similar provisions incorporated in free trade agreements (Geist, 2012). Although ACTA itself does not expressly state such intentions, its key proponents, the US and EU, have stated their intention for it to become a global standard.

Conclusion

Ensuring medicines safety and quality, and fighting counterfeit medicines, are important challenges—but ACTA is not the solution. ACTA is counter-productive to the goal of improving public health, which is strengthened by measures that promote access to quality generic medicines and by improving the capacity of drug regulatory authorities to ensure the quality, safety and efficacy of all medicines. 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 (Oxfam, 2011).

ACTA would undermine the global availability of generic medicines and, at the same time, divert signatories' scarce resources toward extensive IP enforcement. This would impose unacceptable costs upon developing countries, especially—but not only—those that ratify the Agreement. Fragile gains in improving healthcare and access to treatment could be reversed if countries can no longer procure quality medicines at low prices for their populations.

In the last decade, IP protection and additional enforcement measures have been extended in ways that curb access to affordable treatment. TRIPS-plus IP provisions in free trade agreements have delayed generic competition in developing countries (Oxfam, 2007). This trend is highly regrettable considering that most patients in developing countries must still pay for medicines out of pocket, and competition created by generic medicines remains the most efficient way to decrease the price and broaden accessibility of medicines and health

care.

European Trade Commissioner, Karel De Gucht, championed ACTA and advocated fiercely for its approval. He should refrain from re-introducing any new version of ACTA, and the EC should avoid re-submitting a new version of ACTA to the EP's approval once the European Court of Justice responds to the question of the conformity of ACTA with the Lisbon Treaty and the European Charter of Human Rights. For good reason, ACTA provoked significant outcry throughout the world; it should not be resurrected from its ashes. Moreover, the EP democratically decided to reject ACTA and its decision should be respected.

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