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BRIEF: ACTA, Democracy & Access to Medicines

Negotiations are not the end of the road - ACTA is a blank cheque for the future

In a move that would circumvent open debate and due scrutiny, the agreement proposes an annual meeting of signatories where amendments to the Treaty can be negotiated. Even some of the most contentious issues that have been removed during the negotiations could, within a year, be back in the text once ACTA is out of the public spotlight. Any future changes to ACTA must be subject to public scrutiny by all stakeholders and must receive parliamentary approval. **(ACTA, Art. 6.4: Amendments, Arts. 5.1.2. 5.1.4)**

Changing EU foreign policy through the back door: Circumventing WIPO and WTO

International agreements on intellectual property fall under the purview of the World Trade Organisation (WTO) and World Intellectual Property Organisation (WIPO). The EU has, together with the other ACTA negotiating parties, bypassed these multilateral institutions. ACTA is designed and intended to be expanded and become a global standard. Once ACTA is established, we are likely to see a push to expand the number of signatory states. ACTA effectively will establish a new institution where European Parliament scrutiny is absent and where stakeholders, such as civil society, are not represented as they are in these multilateral institutions. This is a regressive step with regards to EU democratic processes and multi stakeholder involvement.

The ACTA process constitutes an explicit de facto EU foreign policy choice which has far reaching implications for EU foreign policy. These EU foreign policy repercussions of ACTA have not been debated nor considered by the European Parliament, especially with reference to developing countries should be evaluated, studied and publicly debated.

ACTA will hurt Access to Medicines: remove patents from scope of the agreement

Generic competition is key for bringing down prices and ensuring access to affordable medicines around the world. The disproportionate enforcement measures proposed in ACTA: damages, injunctions and other remedies, will inhibit generic competition through excessive persecution of possible IPR violations, strengthen monopolies on medicines and enhance the rights of brand pharmaceutical companies at the expense of access for the poorest citizens. ACTA's IPR enforcement measures would be a strong barrier against price-reducing generic competition and would jeopardise the free flow of legitimate medicines across borders.

The name Anti Counterfeiting Trade Agreement does not accurately represent the contents of the agreement. ACTA would be better referred to as an 'Intellectual Property Enforcement Treaty' as it encompasses many categories of intellectual property rights. ACTA does not only affect counterfeiting, which relates to trademark law, but also patents, copyright, data protection, geographical indications, integrated circuit protections, trade secrets, and other laws. Counterfeiting is related to wilful and commercial scale trade mark infringement only. Raising patent protection will not protect patients but hurt them.

The scope of the agreement overreaches and is too broad: the agreement should be limited to commercial scale counterfeiting and piracy. Most importantly, patents and civil trademark infringement should be removed. **(ACTA, p6. Article 1.X: Definitions)**

Patents

Including patents in ACTA will without question hamper generic trade, innovation and access to medicines. As the equivalents of existing brand medicines, generics are closely linked to patent law, and can only enter the market when there is no patent or when the patent has expired. The level of protection for patents has already been established under the TRIPS Agreement, and there was an effort to balance IPR rights with the right to access to medicines. Advancing patent protection further by means of excessive enforcement provisions will undermine the balance found in TRIPS.

The EU negotiators have been pushing to include patents in ACTA whilst the US and other parties have included a footnote in brackets that excludes patents. To protect access to affordable medicines, patents must be excluded from the agreement. **(ACTA, Ch II.Sect. 2: Civil Enforcement)**

Damages, injunctions and other remedies: A chill on innovation and competition

The current wording on damages in the text could allow for excessive damages for infringement that go beyond current standards, and which could have a strong dissuasive effect on generic competition. By increasing the damages to this extent the agreement effectively expands the rights of the IP right-holder, increasing the risks and decreasing the viability for competitors seeking to enter the market. This will dampen innovation and the production and trade of generic medicines.

The proposed high levels for damages and penalties will affect the laws in some EU Member States. Damages based on suggested retail price go beyond the *acquis*. Regarding destruction of infringing goods and production facilities, the *acquis* has more checks and balances than ACTA. Injunctions against a third party are more limited in the *acquis* than under ACTA, the *acquis* also has broader exceptions. **(ACTA. Ch II.Sect.2. Art. 2.2)**

ACTA puts third parties—such as distributors and even non-governmental organisations or public health authorities—at risk of severe penalties

Third parties are at risk of injunctions, provisional measures, and even criminal penalties, including imprisonment and severe economic losses. All of these are *TRIPS-plus* and with potentially far-reaching consequences. This could implicate, for example, suppliers of active pharmaceutical ingredients used for producing generic medicines; distributors and retailers who stock generic medicines; NGOs who provide treatment; funders who support health programs; and drug regulatory authorities who examine medicines. This could act as a significant deterrent to anyone involved in the production, sale and distribution of affordable generic medicines. **(ACTA Ch. II, Sect. 4, Arts. 2. 14.4, 2.15, 2.16.)**

ACTA undermines due process and judicial guarantees

ACTA undermines the judiciary by allowing extra-legal processes: it would limit access to due process for IP challenges by permitting the seizure and destruction of medicines without notification of the owner, providing the owner with the opportunity to respond, or mandating judicial oversight. Such *ex parte* measures are susceptible to abuse. Even where judicial process is mentioned, the balance lies heavily in favour of the rights-holder alleging infringement. Under ACTA there is limited power to balance health issues against the interests of private companies. The cooperation of IPR rights holders proposed in ACTA with authorities should be balanced by fair, legal hearings with the participation of the parties accused of the violation. **(ACTA Ch. II, Sec. 3, Art. 2.11.1.)**

Inclusion of Civil Trademark infringement: A problem for Access to Medicines

ACTA could still constitute barriers to medicines going to developing countries

Civil trademark disputes on similar labelling do not pose threat to public health. Yet far reaching enforcement can pose threat to access to medicines.

ACTA could increase border searches and interfere with the transit of legitimate medicines. The border measures section no longer includes patents yet still includes civil trademark infringement with increased penalties. This means a customs official could initiate a seizure and even destruction of an allegedly infringing good without judicial review or even notification to the rights holder—on the basis of an assertion of a commercial trademark dispute. This is illustrated by the German detention case for alleged trademark infringement (regarding Amoxicilin). The scope should be limited to wilful commercial scale trademark infringement where fraudulent exact copying of the labelling and branding is the case.. (Compare ACTA Ch. II, Sec. 3 with TRIPS Ch. III, Sec. 4, Art. 59., ACTA Ch. II, Sec. 3, Art. 2.X: Scope of the Border Measures)

If ACTA is finalized, the following significant changes would be necessary:

- ACTA should only be applicable to wilful copyright infringement on a commercial scale. It should exclude both patents and civil trademark infringement from the scope of the agreement.
- No action should be taken by authorities without due process and full judicial review with the participation of the alleged infringer.
- Protections against abuse must exist, including access to information for the alleged infringer, and the obligation to consider proportionality and the public interest in setting the remedy.
- ACTA should not mandate excessive punishment for alleged civil infringement. Civil and criminal enforcement should not be *TRIPS-plus* or nor require a change in a state's laws or the *acquis*.
- ACTA should not establish third party liability nor penalties for "aiding and abetting".
- Any institutional structure established should be open and transparent. It should not have the authority to amend ACTA without public scrutiny and approval from democratic bodies, such as the European Parliament.
- The EU should commit to refraining from proposing the ACTA agreement as a requisite for EU- Third-party free trade agreements.