



HEADING ACTA and access to medicines: flawed process, rationale and agreement

The Anti-Counterfeiting Trade Agreement (ACTA) has been characterised by a flawed process of negotiations based on a flawed rationale, which has resulted in a flawed agreement, argue Sophie Bloemen and Tessel Mellema from Health Action International Europe. One of the concerns now is that – designed to be a global norm-setting instrument – ACTA could deter generic competition of medicines around the world.

ACTA's flawed process: a problem because ACTA strengthens substantive rights

Contrary to the claims of its proponents, ACTA not only enforces existing Intellectual Property Rights (IPRs), it strengthens the substantive rights of IP rights holders and goes well beyond the European Union (EU) acquis and the TRIPS Agreement. This expansion of rights makes ACTA's lack of transparency and accountability even more urgent: ACTA negotiations have not only bypassed existing multilateral institutions, like the WTO and WIPO, but also the European Parliament, and the voice of broader public interest groups.

Further, the establishment of the 'ACTA Committee' – designed to function as a new plurilateral institution and to operate behind closed doors – gives rise to serious concerns for the future accountability and transparency of global IPR enforcement norm-setting.

ACTA's flawed rationale: confusion between counterfeit and generic medicines

The rationale behind ACTA, adopting the label 'anti-counterfeiting' and linking it to public health, is frankly misleading. ACTA not only deals with counterfeits and pirated products, but targets many other kinds of IPR infringements. This contributes to a damaging confusion between crucial legitimate generics and counterfeit medicines. Counterfeit medicines are defined by the World Health Organisation (WHO) as 'medicines that are illegally and deceptively mislabeled with respect to identity and/or source'. TRIPS limits its definition of what constitutes counterfeit to clear cases of such fraud: the use of a sign that is identical to the brand owner's trademark. It is only this specific type of IPR infringement that can be directly linked to trade in dangerous counterfeits, patent infringement and civil trademark infringement have in principle nothing to do with this.

By conflating specific IPR enforcement measures to combat counterfeits with other types of IPR enforcement, the risk of right-holders using these measures to target legitimate generics is increased. This risk should not be taken lightly: the lesson learned from the DG Competition Pharmaceutical Sector inquiry in 2009 is that IPR enforcement provisions have been abused to

delay generic competition and hamper innovation. This has cost European health budgets and consumers billions of extra euros. The increase in global IPR enforcement proposed by ACTA does not therefore serve public health or EU consumers by definition.

Flawed outcome: ACTA's implications for access to medicines by chilling generic competition.

Although the exact impact of ACTA measures will depend on how signatory States use the limited space awarded for implementation, it is certain to have a chilling effect on generic trade. This happens especially when the threat or risk of sanctions or litigation becomes too high for generic companies or producers of active ingredients to engage in the production or trade of legitimate generics. ACTA offers IP right-holders several such far-reaching enforcement rights.

As mentioned, the scope of enforcement measures goes way beyond counterfeiting – which is the willful use of an identical trademark. For example, in ACTA's section on general civil IPR enforcement measures, patents are still in by default. Moreover, civil trademark infringements are included as a ground both for civil IPR enforcement measures and to detain generics at the border – whether destined for export, import or just passing in transit.

The lesson learned from Dutch & German seizure cases (2009) is that customs authorities' capacity to stop generics should be limited to cases of alleged counterfeiting. A broader scope strengthens IP right-holders' substantive rights and increases the risk and threat of right-holders abusing their right to request the detainment of goods at the border to hamper trade in generics.

Another problem is that ACTA's broad third party liability puts a large group of third parties at risk of criminal and civil enforcement measures: this group may even include suppliers of active ingredients for generics or NGOs procuring legitimate generics for treatment. This could act as a significant deterrent to anyone involved in the provision of affordable generic medicines.

Both the broad scope of IP rights, and broad third party liability, makes ACTA's bias in favour of IP right-holders of great concern. Especially since this bias is mirrored by an absence of sufficient abuse-deterrence mechanisms. Two biased enforcement provisions stand out in their potential chilling effect on generic competition: Firstly, ACTA puts parties involved in generic trade at risk of very high damages.

This risk may work as a disincentive for competitors to explore the inherently grey area of IP infringement. Secondly, ACTA provides the right-holder with the strong weapon of provisional measures – allowing them to issue a prompt injunction or request seizure of generics, without the other party being heard and without a full judicial review by the court – while providing hardly any procedural guarantees for the defendant.

Future implementation: special concern for impact developing countries

Considering ACTA's new IPR enforcement standard is intended to become the global norm, concerns become all the more immediate. It is likely that developing countries will not use the available room for implementation to adapt standards to local needs, as there will be pressure not to do so from ACTA's main drivers. The risk of chilling generic competition is even greater in the absence of proper competition laws to punish abuse and the resulting higher prices will have

an unacceptable impact on the affordability of medicines. Finally, the costs of implementation of this new body of law will present a burden for the limited public budgets of developing countries.

Increasing IP right-holders' rights requires a transparent and participatory approach with a clear view on the interests that the EU wishes to protect by such expansion and the impact on society. Instead, ACTA uses a blurred rationale and an undemocratic and opaque process to establish a global new standard of IPR enforcement, which is already reason for serious concern. In addition ACTA offers IP right-holders several far-reaching enforcement rights that could have a chilling effect on generic competition, crucial for ensuring access to affordable medicines around the world. The conclusion can only be that ACTA is unacceptable and the EU should not ratify it.

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