ACTA and Access to Medicines: A Flawed Process, Flawed Rationale and Flawed Agreement

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POLICY BRIEF

Introduction

The Anti-Counterfeiting Trade Agreement (ACTA) is characterised by a *flawed process* of negotiations based on a *flawed rationale,* which has resulted in a *flawed agreement* that could deter generic competition and have a major negative impact on global public health.

Generic competition is key for bringing down prices and ensuring access to affordable medicines, not only in Europe, but around the world and in the poorest settings. In the case of some essential medicines, even temporary delays in the trade in generics can be potentially life-threatening. A free and unburdened trade in legitimate generics is crucially important for access to safe, affordable and quality assured medicines.

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

The new mode of global governance that ACTA embodies not only bypasses the normal procedures of existing multilateral institutions, but also the European Parliament, and the voice of broader public interest groups and consumer and patient organisations. This lack of transparency and accountability is of fundamental concern, because ACTA does not only enforce existing Intellectual Property Rights (IPRs) as the Commission claims[1], it also strengthens the substantive rights of IP rights holders, and goes beyond the European Union (EU) *acquis* and the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[2]

What looks at first sight like enforcement measures may in fact be an expansion of IP right-holders' substantive rights. For example, this is the case when an enforcement provision entitles an IP right-holder to exercise its IPRs in an *in transit* area – where such rights cannot normally be exercised. *De facto* expansion of rights also occurs when potentially high damages start to work as a disincentive for competitors to explore the 'infringement grey area' of IPRs.[3] Both such measures and potentially high damages can be found in ACTA.[4] Increasing IP right-holders' substantive rights requires a transparent and participatory approach with a clear view on a) the interests that the EU wishes to protect by such expansion and b) the impact on society. [5] Instead, negotiations leading up to ACTA have lacked accountability and transparency. This is unacceptable where the position of the IP right-holder is strengthened to the detriment of other stakeholders with a crucial interest in the outcome of the medicines market.

ACTA also gives rise to serious concerns for the future accountability and transparency of global IPR enforcement norm-setting for it establishes the ACTA Committee. This

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Committee is designed to function as a new plurilateral institution operating behind closed doors, beyond the reach of established expert multilateral institutions, and without parliamentary oversight or public scrutiny (ACTA chapter V).

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

That ACTA adopts the label 'anti-counterfeiting' is misleading, because ACTA not only deals with counterfeits and pirated products, but targets many other kinds of IPR infringements. ACTA therefore mixes and confuses IPR enforcement measures to fight counterfeits with IPR enforcement more generally. This conflation of terms contributes to a damaging confusion between crucial legitimate generics and counterfeit medicines.

Counterfeit medicines are defined by the World Health Organization (WHO) as 'medicines that are illegally and deceptively mislabelled with respect to identity and/or source'.[6] 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[7], and patent infringement and other types of civil trademark infringement have in principle nothing to do with trade in counterfeits.[8] Moreover, the main public health concern lies with the *quality* of the medicines, which has nothing to do with IP enforcement, but should be addressed by better regulation through quality standards.[9]

By conflating counterfeits with other types of IPR infringements, ACTA increases the risk of right-holders using ACTA's IPR enforcement measures to target legitimate generics. The lesson learned from the *DG Competition Pharmaceutical Sector inquiry* (2009) is that IPR enforcement provisions and patent strategies have been abused to delay generic competition and hamper innovation. As a result company practices have contributed to an inflated expenditure of billions of Euros for EU health systems.[10] 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 trade, production and use of generics

Although the exact impact of ACTA measures are hard to predict and will depend on how signatory States use the limited space awarded for implementation, it is certain to have a chilling effect 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.[11] ACTA offers IP right-holders several such far-reaching enforcement rights[12]:

A. Scope enforcement measures beyond counterfeits

- In the civil enforcement section, patents may be excluded but are in the text by default. Although parties have the freedom to exclude patents, the default gives reason for serious concern as it is quite conceivable that developing countries will be persuaded into adopting this default position (ACTA art. 7).

- In the border measure section, patents are explicitly excluded. Civil trademark infringements are, however, still included as a ground to detain generics at export, for import and passing *in transit*. The lesson learned from the Dutch & German seizure cases (2009) is that customs authorities' capacity to stop generics should be limited to cases of alleged counterfeiting - the

wilful use of an identical trademark.[13] This does not include the broader scope of civil trademark infringements which increases the risk (and threat) of right-holders abusing their right to request the detainment of goods at the border to delay trade in generics (ACTA art. 17).

B. Broad third party liability puts the whole generics supply chain at risk of illegitimate enforcement measures

ACTA puts a broad group of third parties at risk of criminal and civil enforcement measures, including injunctions, provisional measures and claims for high damages. In the trade in generics this group of third parties can potentially include suppliers of active ingredients for medicines or NGOs procuring and distributing legitimate generics for treatment. This liability – especially the criminal liability - could act as a significant deterrent to anyone involved in the production, sale and distribution of affordable generic medicines (ACTA art. 8.1, 12.1(a), 23.2, 23.4).[14]

C. Enforcement measures biased in favour of IP right-holders

The wide scope of application of the enforcement measures, not explicitly limited to counterfeits and pirated goods and potentially applying to a large group of third parties, makes the bias in enforcement measures and corresponding stronger position of right-holders, a serious concern. This renders these measures more susceptible to abuse by the rights-holder, which in turn contributes to the risk of a chilling effect on generic competition.

- Damages (ACTA art. 9.1). The calculations of damages introduced by ACTA, which can for example be based on the suggested retail price, go well beyond the EU *acquis* and exceed any real economic loss suffered by the right holder. These high damages can work as a constraint for generic competitors to explore the inherently grey area of IPR infringement.

- Provisional measures (ACTA art. 12). This provision is a strong weapon for right-holders, because it allows them to issue an injunction or request seizure of generics at short notice, without the other party being heard and without a full juridical review by the court. This may be used as an effective means to (temporarily) delay the production or trade in generics. That this is potentially such a strong weapon makes ACTA's lack of reference to procedural guarantees for the defendant an issue of serious concern.[15]

- Insufficient abuse deterrence (ACTA art. 12.5, 18). ACTA does not provide sufficient mechanisms to adequately deter abuse of enforcement provisions by rights-holders.[16]

Future implementation: special concern for impact developing countries

Considering ACTA's new IPR enforcement standard is designed and intended to be expanded and become the global norm, concerns become all the more immediate. Firstly, it is likely that on importation and adoption of these norms, developing countries will not use the available room for implementation to adapt standards to local needs.[17] Secondly, in developing countries the risk of chilling generic competition is even greater in the absence of proper competition laws to punish abuse. The resulting higher prices will have an unacceptable impact on access and affordability of life-saving medicines. Thirdly, the costs associated with the implementation of this body of law are substantive and present a burden and opportunity cost on the limited public budgets of developing countries. [18]

Conclusion

ACTA conflates the need to combat the trade in counterfeits with IPR enforcement in general. ACTA using a blurred rationale and an undemocratic and opaque process to establish a global new standard of IPR enforcement is already reason for serious concern. This policy brief also shows how ACTA in its current form offers IP right-holders several far-reaching enforcement rights that could have a chilling effect on generic competition, which is crucial for bringing down prices and ensuring access to affordable medicines around the world. The conclusion can only be that ACTA in its current form is against the interests of public health and is thus unacceptable to EU citizens and consequently we urge political representatives to reject ACTA in its current form.

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Endnotes

[1] As De Gucht mentioned in his recent press statement on ACTA of 22 February 2012. http://trade.ec.europa.eu/doclib/press/index.cfm?id=778.

[2] A detailed analysis on the compatibility with TRIPS can be found in the report on ACTA ordered by the Greens and the EFA: Sean Flynn and Bijan Madhani (June 2011), '*ACTA and Access to Medicines', American University Washington College of Law*. http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1024&context=research;
A detailed analysis on compatibility with TRIPS and EU law can be found in the '*Opinion of European Academics on Anti-Counterfeiting Trade Agreement*', 3 December 2010. http://www.statewatch.org/news/2011/jul/acta-academics-opinion.pdf.

[3] Seuba, Xavier, Joan Rovira, and Sophie Bloemen. 2010. *Welfare Implications of Intellectual Property Enforcement Measures*. PIJIP Research Paper no. 5. American University Washington College of Law, Washington, DC, p 7-9. http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1005&context=research

[4] See for example: ACTA art. 17 (border measures) and art. 9 (damages).

[5] The Commission has, in this respect, ignored the EP's request for an impact assessment (*European Parliament Resolution of 12 March 2010 on the transparency and state of play of the ACTA negotiations*, P7_TA(2010)0058).

[6] The WHO further explains that 'counterfeiting can apply to both branded and generic products and counterfeit products may include products with correct ingredients or with wrong ingredients, without active ingredients, with insufficient ingredients or with fake packaging.

[7] This is also the definition of a counterfeit trademark adopted in (a) TRIPS: footnote 14, Article 51, and in (b) ACTA art. 5(d).

[8] To give an example: A claim of civil trademark infringement can also arise when there is a dispute between the producers of branded and generic medicines if they both use a name similar to the international non-proprietary name (INN).

[9] Oxfam Briefing Paper, 2 February 2011, Eye on the ball: Medicine regulation – not IP Enforcement – can best deliver quality medicines, p. 22-26

[10] 'However, additional savings of some € 3 billion could have been attained, had entry taken place immediately. As indicated, the findings of the inquiry suggest that the behaviour of originator companies contributes to the delay of generic market entry.'' p. 521 (1561) *Final Report Pharmaceutical Sector Inquiry (2009),* See also: pp. 80-81 (217, 219) http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf & p. 6 *Preliminary report Pharmaceutical Sector Inquiry (2008)*

[11] ibid 3.

[12] ACTA raises the standard of IPR enforcement on two levels (1) at the border of signatory countries – by customs authorities – on goods not only entering the country but also passing in transit, and (2) within signatory countries by means of civil and criminal enforcement measures.

[13] *Dutch seizure puts pressure on access to medicines in developing countries* 6th February 2009 http://haieurope.org/wp-content/uploads/2010/11/6-Feb-2009-Press-release-Dutch-seizure-of-generic-medicines.pdf,

Another seizure of generic medicines destined for a developing country, this time in Frankfurt. 5June2009 http://haieurope.org/wp-content/uploads/2010/11/5-Jun-2009-Press-release-Seizure-of-generic-medicines-in-Frankfurt.pdf.

[14] As regards criminal enforcement measures, ACTA not only directly mentions third party liability, it also puts (innocent) third parties in a more indirect way at risk of criminal penalties: ACTA's definition for criminal offences in the case of counterfeit refers to the intentional importation and use of the counterfeit *product*, rather than such criminal offence being limited to the act of counterfeiting – wilfully applying a brand owner's trademark to the product. This creates potential *criminal* liability for (for example) suppliers of generics unknowingly importing a counterfeit product (ACTA art. 23.2).

The pharmaceutical sector enquiry mentions how: 'litigation can also be an efficient means of creating obstacles for generic companies, in particular for smaller ones. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants', *DG Competition Pharmaceutical Sector Inquiry (2009): executive summary* paragraph 3.2.2., http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

[16] ACTA only provides for liability for the damages incurred by the defendant. The abusing right-holder does not incur any additional penalties. As these damages may not exceed the commercial benefit of delaying or hindering trade in competing generics, this may prove insufficient deterrence against abuse (ACTA art. 12.5, 18).

[17] Developing countries often lack technical expertise and through technical assistance programs and corporate sponsored workshops, laws on IP are often drawn up in a way that benefits western IP rights holders and is in line with EU & US IPR policy. Also, trade pressure through for example the USTR 301 list and the EU enforcement in third countries strategy influences what are considered sovereign policy choices. See '*NGO views on African IP summit'*: http://www.keionline.org/node/1356.

[18] Seuba, Xavier, Joan Rovira, and Sophie Bloemen. 2010. Welfare Implications of Intellectual Property Enforcement Measures. PIJIP Research Paper no. 5. American University Washington College of Law, Washington,DC.http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1005&context=research.