



ACTA's impact on generics questionable

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Taken at face value, the international Anti-Counterfeiting Trade Agreement (ACTA) should have little effect on access to generic medicines that are shipped to the developing world via other countries because patents are expressly excluded from the scope of its border enforcement measures, says Phil Carey of law firm Winston & Strawn.

Furthermore, the pact recognises that the World Trade Organization's agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) should not be an obstacle to access for least developed countries.



However, the situation is not as straightforward as it appears. Although ACTA's title refers to counterfeiting, its aim is to provide an international framework for the effective enforcement of all intellectual property rights, and therein lies the rub. Under the agreement, signatories are required to adopt or maintain procedures that allow customs authorities to detain imports and exports that are suspected of IPR infringement (for suspect in-transit medicines, enforcement is left to the discretion of each signatory).

But ACTA, which was signed by the US, Australia, Canada, Korea, Japan, New Zealand, Morocco and Singapore on 2 October, does not exist in a vacuum, points out Carey. Europe, for example, has anti-piracy legislation (Council Regulation 1383/2003) that allows patents to be enforced by border officials. As for trade mark infringements, the scope of the EU legislation is limited to counterfeits and pirated goods rather than infringements in general.

This disparity between ACTA and EU legislation could mean customs officials acting under the international pact "will no longer be restricted to looking out for fakes, where trade mark infringement is often blatant, but could also be asked to carry out an assessment of more subtle issues such as the likelihood of confusion," says Carey.

He notes that the EU regulation is currently undergoing a revision, with proposals on the table that could potentially extend detention periods and expand the scope to include suspected trade mark infringements. The fact that ACTA does not explicitly set out detention timeframes, whereas the EU regulation does, could further complicate matters.

ACTA's stance on suspect in-transit shipments - despite the EU's heavily criticised track record for detaining shipments en route to third-world countries - increases the uncertainty surrounding the agreement's true impact on generics, according to Carey.

These provisions could raise new questions about where exactly the suspect shipments potentially infringe IPR, thus "introducing a new dimension to the territorial scope of IPRs and the

jurisdiction of national courts to police IPRs outside their borders," he says.

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