



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

POSITION PAPER

**EGA STATEMENT ON COUNTERFEITING AND PATENT INFRINGEMENT IN
THE CONTEXT OF THE ANTI-COUNTERFEITING TRADE AGREEMENT
(ACTA)**

JUNE 2008



Making Medicines Affordable

EGA STATEMENT ON COUNTERFEITING AND PATENT INFRINGEMENTS IN THE CONTEXT OF THE ANTI-COUNTERFEITING TRADE AGREEMENT

1. Introduction

The EGA is the official representative body of the European generic and biosimilar pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector.

As such, the EGA welcomes the participation of the European Commission in the ACTA negotiations. ACTA's goal is to provide a high-level international framework that strengthens the global enforcement of intellectual property rights and helps in the fight to protect consumers from the health and safety risks associated with many counterfeit products, often distributed by criminal organizations.

However, the EGA has major concerns that the common enforcement practices proposed by ACTA in order to promote strong intellectual property rights could be misapplied and misused by intellectual property holders against legitimate competition in the areas of patents. It should be noted that Directive 2004/48/EC recognized this possible abuse and, in article 3.3, stated that *'the measures, procedures and remedies shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse'*. It should also be noted that in the proposal for a Directive on criminal measures to enforce IP Rights, the European Parliament, during the First Reading, voted an amendment excluding patents from the scope of the Directive. In addition, a joint statement by the Council and the European Commission concerning ACTA¹ negotiations recognizes that "criminal enforcement disciplines should not apply to patents".

Our industry also has serious concerns regarding the current approach of simply generalising measures to combat counterfeiting and piracy as applicable to all forms of IP rights. In particular, using a single approach is not justified for patents². In fact, abolishing the distinction between piracy/counterfeiting and alleged infringement of patent rights sets a dangerous precedent which equates all alleged patent infringements with criminal activity such as piracy/counterfeiting. It should be pointed out that article 61 of the TRIPS agreement distinguishes between trademarks, counterfeiting and copyright piracy on the one hand, and other IP rights disputes on the other. This division should be maintained in discussions on measures to tackle counterfeit. A report from the European Parliament on ACTA³ states in its executive summary that *"ACTA is an opportunity to add clarity to the TRIPS terminology, as the adoptions for clear definitions of counterfeiting and piracy are a good approach to avoid legal uncertainty and potential abuse of enforcement measures"*.

¹ See page 31 of the Policy Department External Policies of the European Parliament: Impact of counterfeiting on international trade: comments to the Anti-Counterfeiting Trade Agreement, May 2008. <http://www.europarl.europa.eu/activities/committees/studies.do?language=EN>

² As well as supplementary protection certificates, short term patents and utility models.

³ Impact of counterfeiting on international trade: comments to the Anti-Counterfeiting Trade Agreement, May 2008. <http://www.europarl.europa.eu/activities/committees/studies.do?language=EN>



Making Medicines Affordable

Therefore the EGA is of the opinion that ACTA should deal with the enforcement of copyrights and trademarks as a way to fight counterfeiting/piracy instead of covering the enforcement of all IP rights. The aim behind the EGA proposal is to exclude patent infringement from the scope of the agreement, thus avoiding any potential confusion between generic medicinal products and counterfeited medicines.

2. Counterfeiting of pharmaceutical products: a public health issue, not a patent issue

It is important to stress that both original and generic medicines can be the target of counterfeiters. The severity of the public health consequences of counterfeit pharmaceuticals has led the WHO to establish a task force of interested parties called IMPACT⁴, which includes both the originator and generic pharmaceutical industry sectors. This working group, of which the EGA is a member, made recommendations on how best to deal with counterfeit pharmaceuticals: stringent regulatory procedures, improved training for customs officers and quality control inspectors, improved policing, and increased public and health professional awareness. Patent enforcement was not regarded as an appropriate measure⁵. In fact, counterfeiting of medicines does not necessarily lead to patent infringement, but rather to trademark infringement.

3. Patent infringement and counterfeiting issues should not be confused

Increased intellectual property protection or more stringent enforcement measures, in fact, provide an excellent tool to fight and punish counterfeiting and piracy, but are not fully suited to the complex world of patent disputes. Patent infringement could be described as an everyday commercial risk for originators and generic producers due to the technical complexities of drug development⁶. There are many genuine disputes over patent validity. A company may need to infringe a patent intentionally in order to demonstrate that the patent at issue is not valid. In addition to this, there are many cases where a court decides that a patent has indeed not been infringed.

The EGA holds concerns that patent infringement during the normal legitimate business development of a product becomes – in the context of the ACTA agreement – a crime related to counterfeiting activities instead of remaining a civil private matter. For this reasons we maintain that patent enforcement should not be considered during ACTA negotiations as a tool to fight counterfeiting.

⁴ International Medical Products Anti Counterfeiting Task Force. Principles and Elements for National legislation against Counterfeit medical products. Text endorsed by IMPACT General Meeting, Lisbon 2007.

⁵ Patent issues have not featured within this context because the issue is primarily regarded as a public health issue, in which organised or local criminals carry out counterfeit activities, rather than as infringements of private rights.

⁶ Patent infringement can be unintentional in many cases and can also have positive outcomes such as licensing agreements between parties.



Making Medicines Affordable

An example of the confusion created between patent infringement and counterfeiting can be seen in the report by the EC Taxation and Customs Unit on “Community customs activities on counterfeit and piracy—results at the European border—2007”⁷. The report states the following⁸: “China, responsible for almost 60% of all counterfeit goods seized, continues to be the main source. However, in some categories, such as articles for personal care, other countries such as Georgia and Turkey are the main sources whilst Switzerland, India and United Arab Emirates top the list for medicines”. The report also shows in page 20 the number of products seized by provenance and product type: the highest rate of seized counterfeit medicinal products in 2007 came from Switzerland (39.21%). This “surprisingly high” figure for a developed EEA country in fact includes patent infringed products and for this reason Switzerland unfortunately ends up with the highest rate of counterfeit medicines in the world. This report not only points out an incorrect country as a major source of counterfeit products, but provides unclear messages as to the real problem.

3.1. Differences Between Patent Violations and Counterfeiting/Piracy Crimes

Patent Infringement Disputes / Generic Competition	Counterfeiting / Piracy Trademark / Copyright Violations
Complicated cases: infringement difficult to determine even for expert judges	Easy cases: product has been produced in the originator factory or elsewhere
Legal entities as opponents	Legal entities vs. criminal organisations
Civil jurisdiction works	Civil jurisdiction does not work
No health/safety risk due to independent regulatory process. Generic medicines are approved for sale by the European Medicines Evaluation Agency (EMA) in London as being safe, of quality and therapeutically equivalent to the originator.	Potential health/safety risk: counterfeit medicines are, of course, not approved for sale.
Products sold under their own label	Products usually sold under originator’s or generic producer’s label: trademark counterfeiting
Possible violation in regulated market	Possible violation in open markets much more difficult to control
Usually no criminal intention	Criminal intention through supply chain

⁷http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics2007.pdf

⁸ Executive summary, page 2.

http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics2007.pdf



Making Medicines Affordable

Significantly, the rate of intentional patent infringement is minimal compared to deliberate copyright and trademark fraud. The impact study undertaken by the CEIPI⁹ on behalf of the European Commission provides little evidence of patent infringement.

3.2. Misuse of Public Resources Fighting Crime:

The resources of Member States must be used to combat the real threat to society, ie the criminal activity, from piracy and counterfeiting. Member State resources are already under immense pressure and unable to deal with organised crime which, together with terrorism, represents the single largest current threat to society. Diverting these resources to deal with corporate disputes over patents is not justifiable. It would place these scarce resources at the disposal of well-funded corporations for pursuing legal actions which they would otherwise have to finance themselves. Moreover, in the pharmaceutical sector, trademark counterfeiting of medicines (both generic and originator) is a growing concern in Europe. Counterfeit medicines are often of low quality and have even killed patients. It is essential that resources this area be directed to where the problem is indeed criminal and life threatening.

4. Conclusion

In view of these considerations it is crucial that policy makers recognize that complex commercial patent disputes are unsuitable for criminal sanctions or harsher enforcement measures. They must ensure that the ACTA agreement focuses on the real threat of copyright and trademark abuses that are perpetrated intentionally by organised criminal groups.

In this context, the EGA supports the definition of counterfeit drugs developed by the WHO, to wit:

“a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”¹⁰

In conclusion, it is important to underscore that medicines which are not patented can also be counterfeited and that counterfeiting is essentially a trademark issue and not a patent issue. Consequently, counterfeiting is no reason to increase patent protection and we wish to raise serious concerns about attempts to confuse the anti-counterfeiting issue with patent enforcement. Unjustifiably treating generic medicines on a par with potentially dangerous counterfeit drugs in cases of alleged patent infringement will not increase public safety, but rather will hinder access to these affordable medicines. Counterfeiting of medicinal products must be tackled by criminal enforcement measures (ie, penal sanctions) and drug regulation (reinforced control by regulatory agencies, improved regulation related to good manufacturing and distributing practices), and not by increasing patent protection or by introducing harsher civil measures to enforce patents.

⁹ ‘Impacts de la contrefaçon et de la piraterie en Europe - Rapport Final pour la Commission Européenne’. Centre d’ Etudes Internationales de la Propriété Industrielle CEIPI, (juillet 2004).

¹⁰ http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf see page 8