



Making Medicines Affordable

FINAL POSITION PAPER

**AMENDED PROPOSAL FOR A EUROPEAN PARLIAMENT AND COUNCIL
DIRECTIVE ON CRIMINAL MEASURES AIMED AT ENSURING THE
ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS**

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1. Introduction

The EGA welcomes the European Commission's initiative to propose a Directive aimed at providing Member States with measures and remedies to deal effectively with counterfeiting and piracy activities, which are often carried out by criminal organizations.

We note that the new Directive establishes criminal penalties to supplement the civil and administrative measures, procedures and remedies provided for in Directive 2004/48/EC.

However, the EGA has major concerns that the criminal measures provided to enforce Intellectual Property rights will be misapplied and misused by IP holders against legitimate competition in the areas of patents. It should be noted that Directive 2004/48/EC recognised 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*'.

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 patents¹. 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, (upon which the proposed Directive is said to be based) 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 this Directive.

In addition to this, the current draft contains no definition of counterfeit and piracy despite the European Parliament's declaration in 2000 that '*a definition was needed to distinguish between various kinds of infringements, taking into account wilful and fraudulent elements inherent in counterfeiting and product piracy*'. Directive 2004/48/EC on civil measures also failed to provide such a definition.

2. Counterfeiting of pharmaceutical products - A public health issue, not an IP issue.

It is important to stress that both original and generic medicines are counterfeited.

The severity of the public health consequences of counterfeit pharmaceuticals led the WHO to establish a working group of interested parties, which included 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. IP

¹ As well as supplementary protection certificates, short term patents and utility models.



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enforcement was not regarded as an appropriate measure². Counterfeiting of medicines does not necessarily lead to patent infringement, but rather to trademark infringement.

3. Implications of the proposed Directive for generic manufacturers:

If this Directive is approved in its current form, generic medicines will be like '*dolphins caught in a tuna net*'³, i.e. innocent and legitimate commercial actors caught by a draconian law with explicitly different objectives.

The proposed Directive will, in fact, provide an excellent tool to fight and punish counterfeiting and piracy, but it is not fully suited to the complex world of patents. Unfortunately, patents have been included in the scope of this legislation despite the existence of genuine disputes on patent validity. Patent infringement could be described as an everyday commercial risk for innovators due to the technical complexities of drug development⁴. A company may need to infringe intentionally a patent in order to demonstrate that the patent at issue is not valid. In addition to this, there are cases where the patent has indeed not been infringed or has been infringed on a patent attorney's erroneous advice given in good faith. In this context, the infringement should remain a civil matter as it is currently the case.

If the proposed Directive is adopted as currently drafted, patent infringement during the normal legitimate business development of a product would become a crime instead of remaining a civil matter.

3.1 Threats to Research and Science in the EU

Criminalization of patent infringement would deter innovators, and particularly academics, and SMEs from developing new innovations. This would undermine EU competitiveness and the overall Lisbon Agenda. It is important to note that in the United States patent infringement is not criminalized, but if a company provides false information to the US Patent and Trademark Office it will be regarded as fraud. Fear of criminal sanctions for EU innovators will place the European Union at even greater disadvantage to the United States as well as to other WTO countries.

3.2 Preventing legitimate competition in the pharmaceutical sector

The proposed Directive could become a dangerous tool for abusive strategies, allowing patentees to prolong their market monopolies by keeping competitors off the market. New market entrants will lose competitiveness not only due to unfair injunctions and

² IP 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.

³ Generics: "Dolphins Caught in the Tuna Net" - the deadly effect of the proposed IP enforcement directive on EU generic industries by Veronica Lowe published in the July/August 2003 issue of Competition Law Insight.

⁴ Patent infringement can be unintentional in many cases and can also have positive outcomes such as licensing agreements between parties.



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threats (i.e. Directive 2004/48/EC⁵), but also as a result of legalized harassment and threats of imprisonment.

If the proposed Directive is abused, persons within EU jurisdiction such as CEO/chairman/management team/legal, scientific or regulatory staff who knew of, were involved in, attempted to or instigated the infringement, will be subject to fines and prison terms.

Moreover, in the case of generic medicines this will represent a major loss to society, as consumers and health care systems will be deprived of access to substantially less expensive treatments. This loss to society will be permanent as the IP holder will not be held responsible for compensating patients or healthcare systems in the event of unjustified delays.

3.3 Misuse of Public Resources Fighting Crime

The resources of Member States must be used to combat the real threat to society, i.e. criminal activity in piracy and counterfeiting. Member State resources are already under immense pressure and unable to deal with organized crime which, together with terrorism, represents the single largest 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 be directed to this area where the problem is indeed criminal and life threatening.

Significantly, the rate of intentional patent infringement is minimal compared to deliberate copyright and trademark fraud. The impact study undertaken by the CEIPI⁶ on behalf of the Commission provides little evidence of patent infringement. Unfortunately, the study did not include the EGA in the consultation process. However, the European Federation of Pharmaceuticals Industries and Associations (EFPIA) was invited to participate in the consultation.

Current civil provisions are more than adequate to deal with patent infringements and disputes. Civil action is less costly to society and places no demands on the public police service.

⁵ Directive 2004/48/EC allows companies to be enjoined before a product is marketed in order to prevent possible patent infringement. Even if ultimately a court held that there was no infringement, the delay would seriously affect a smaller company including possible closure and bankruptcy. The Directive also enables the patent holder to demand court orders to freeze bank accounts and seize vital documents.

⁶ '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).



4. Conclusion:

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

Patent infringement disputes/Generic competition	Counterfeiting/piracy
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 organizations
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 in London as being safe and therapeutically equivalent to the originator.	Potential health/safety risk: counterfeit medicines are of course not approved for sale.
Products sold under 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

One of the arguments deployed in support of the Directive is that it merely harmonizes current Member State laws. However, there are at least six Member States where no penal sanctions exist for patent infringement⁷ (UK, Greece, Belgium, Ireland, Luxembourg and Poland). Consequently we can assume that criminal prosecutions will become more attractive and thus more common, especially in more lucrative markets.

The standard answer that *"we should rely on how accurately the Directive with its safeguards will be transposed in each Member State and on the good sense of national courts to interpret the legislation correctly"* does not stand up to scrutiny, as illustrated by the *'Epilady'* razor case⁸. In addition to this, it should be considered that a smaller court could be influenced by lawyers of the IP right holder and that judges not always have enough expertise to take neutral and independent decisions.

⁷ According to '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).

⁸ The Case of Improver vs Remington, 1990. The claimant won in 3 member states but in the UK and in 1 EEA state the defendant succeeded. This case shows that interpretation of patents can vary throughout Europe: you can have different decisions based on the same facts and patent.



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5. Proposals for amendments:

- The EGA proposes the EP to exclude patents from the scope by amending **Article 1**:

AMENDMENT 1: Paragraph 3 (new): Patents, utility models and supplementary protection certificates shall be excluded from the provisions of this Directive unless it can be demonstrated that an infringement of these rights would constitute a serious threat to public health or safety.

Justification: The scope of this legislation is to tackle counterfeit and piracy, particularly in the music, luxury goods, clothing industries and related sectors. However, the generic industry has serious concerns regarding the current approach when measures to combat counterfeiting and piracy are simply generalised as applicable to all forms of IP rights. It needs to be stressed that infringements of individual IP rights differ in nature and manner of infringement, which means that measures to combat infringements of individual IP rights should differ as well and should be strictly separated from each other. There is a distinction between patent infringements in the normal course of commercial activity, such as the legitimate development of products, and counterfeiting and piracy with fraudulent and deliberate intent. There are civil remedies for patent infringements and alleged patent infringers should not be equated with criminals like pirates and counterfeiters. A company may need to infringe a patent intentionally in order to demonstrate that the patent at issue is not valid. In this context, the infringement should remain a civil matter as is currently the case.

- The EGA proposes to Amend **article 3** in the following way:

AMENDMENT 2: Member States shall ensure that ~~all~~ only intentional infringements of an intellectual property right on a commercial scale, and attempting, aiding, or abetting and inciting such infringements, for the purposes of assisting organized crime and/or which constitute a serious threat to health or safety, are treated as criminal offences.

Justification: The EGA proposes the introduction of safeguards to protect innocent defendants from preventing abusive patent litigation⁹. Originator companies initiate legal civil/criminal proceedings against generic pharmaceutical companies irrespective of the strength of the case in order to prevent or seriously delay market entry of competitive generic medicines. Legal costs to major pharmaceutical companies are insignificant in comparison to the financial gains made by delaying competition. By contrast, the implications for companies producing generic equivalents, particularly SMEs, can be disastrous as vital revenues are lost and legal costs grow. Generic pharmaceutical companies are continually under attack by the researched-based companies for alleged infringement of their patents, be they valid or not. If the proposal as currently drafted is adopted, it will allow these companies to use another avenue to attack smaller generic companies.

It is important to distinguish between patent infringements in the normal course of commercial activity (legitimate development of products) and counterfeiting and piracy with fraudulent and deliberate intent, which are often carried out by criminal organizations.

⁹ As mentioned in the EC Working Document SEC(2005)848: Impact Assessment for the Proposed Framework Decision on criminal measures to enforce IP rights, page 27: 'Il va de soi qu'il convient cependant d'éviter le risque d'une utilisation abusive et a mauvais escient de la voie pénale par des titulaires de droits se prétendant a tort victimes.'