



*Making Medicines Affordable*

**Preliminary  
EGA Position Paper**

**On**

**The Proposal for a Directive of the European Parliament and of the  
Council on measures and procedures to ensure the enforcement of  
intellectual property rights**

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The EGA represents over 500 companies in Europe  
dedicated to the production and supply of affordable generic medicines.

P.O. Box 193, B-1040 Brussels 4  
Phone + 32-2 736 84 11  
Fax + 32 2 736 74 38  
E-mail: [info@egagenerics.com](mailto:info@egagenerics.com)  
Website: [www.egagenerics.com](http://www.egagenerics.com)



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## Preliminary EGA Position Paper

### On the Proposal for a Directive on measures and procedures to ensure the enforcement of intellectual property rights

#### 1. Introduction

The EGA understands and fully supports the basic principles of the proposed Directive, which is the prevention of counterfeiting and piracy.

However, the European generic medicines industry has major concerns that the measures provided to enforce Intellectual Property rights might be misapplied and misused by IP holders against **legitimate competition**.<sup>1</sup>

We note that the explanatory statement of the proposed Directive says that “*the fight against counterfeiting and piracy must not be used to try to keep unwelcome competitors out of the market or to hamper legitimate competition...*”. In addition to this, we welcome Articles 3 and 4, which state that “*the general principles of intellectual property rights law should not create barriers to legitimate trade*”.

However, concerning the safeguard clauses introduced by the proposed Directive in order to protect innocent defendants from abusive litigation, the EGA is concerned that these are **not in fact achieving the right balance**.

Our industry also 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.<sup>2</sup> In particular using the same approach is not justified for patents. It is in fact a dangerous precedent to abolish distinction between piracy/counterfeiting and alleged infringement of patent rights - this would mean to equal all alleged patent infringers with criminals like pirates/counterfeiters.

#### 2. Counterfeit of pharmaceutical products – A public health issue not an IP issue.

Counterfeit of pharmaceutical products is a growing problem, but occurs almost exclusively in developing countries and certain countries in economic transition. **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 including both the originator and generic pharmaceutical industry sectors. The working group, of which the EGA is a member, made recommendations on how best to deal with counterfeit pharmaceuticals including stringent regulatory procedures, improved training for customs officers and quality control inspectors, improved policing, and increased public and health professional awareness. However, IP enforcement was not regarded as the most appropriate measure.<sup>3</sup>

<sup>1</sup> EGA thinks that these measures might have **undesired effects on innocent parties** and consequently believes that adequate safeguards must be provided in order to protect legitimate competition.

<sup>2</sup> In this context it seems important to emphasize that the infringement of various types of IP rights (patents, trademarks, designs, registration dossiers, copyright etc.) should be strictly separated from each other.

<sup>3</sup> IP issues have not featured within this context since the issue is primarily regarded as a public health issue where organised or local criminals carry out counterfeit activities rather than as infringements of private rights.



### 3. Preventing legitimate competition in the pharmaceutical sector.

One of the main features of the pharmaceutical market in the EU is the growing importance of the role of off-patent affordable generic medicines. Generic medicines are universally seen as both a way to meet requirements of health care budgets and as a stimulant to pharmaceutical innovation.

However, due to the both the nature of generic competition (i.e. that competition begins at time of patent expiry) as well as the large value of the markets involved, originator companies have developed a series of strategies to prevent generic competition. Amongst these many strategies is included:

**Initiating legal proceedings against generic pharmaceutical companies irrespective of the strength of the legal case in order to substantially delay market entry of competitive generic medicines.** The European Commission and the European Parliament should not overlook, that in the case of medicines with hundred of millions of annual turnover, each day unwelcome generic competitors are kept from the market, brings several millions of Euros in extra sales per day to the litigating company. Legal costs to major pharmaceutical companies are insignificant in comparison to the financial gains made by delaying competition. In contrast, the implications on companies producing generic equivalent, particularly SMEs, can be disastrous as vital revenues are lost and legal costs grow. Moreover, there is major loss to society as consumers and health systems have lost access to substantially less expensive treatments. **This loss to society is permanent since the IP holder gives no compensation to patients or healthcare systems in the event of an unjustified delay.**

**In view of these issues it therefore critical that policy makers ensure that the proposed Directive cannot be abused to prevent legitimate competition in the pharmaceutical sector and that adequate safeguards are in place to meet this.**

### 4. Comments on key Articles

#### *Article 8 – concerning evidence protection measures*

- Physical seizure if there is a “*demonstrable risk*” that the evidence may be destroyed. ***This threshold should be higher. Shouldn't the applicant have to show that there is a strong prima facie case of IP infringement also?***
- Physical seizure *may be subject to the lodging of an adequate guarantee* by the applicant to ensure compensation for any prejudice suffered if the proceedings prove unfounded. ***How will an “adequate guarantee” be calculated, as the court will not be looking at the merits of the case at that stage? The same applies to Article 10- interlocutory injunctions- and to Article 11 seizure of fixed and non-fixed assets. Will the compensation include moral prejudice caused to the defendant as noted under Article 17 below?***

## Articles 10 - concerning Injunctions

- According to article 10, it seems to be quite easy for the plaintiff to obtain an injunction: he only “ has to provide any reasonably available evidence”.
  - ***EGA thinks that there should be a larger burden of proof on the alleged infringed right holder.***
  - ***“a sufficient degree of certainty” needs to be defined***
  - ***The plaintiff can thus, by means of minimal or unsubstantiated proof, readily obtain an injunction. The result would be (for the plaintiff) a cheap and extremely commercially valuable and simple way of blocking legitimate competition instantly without recourse to proper legal trials. In this context we would like to question the real aim of injunctions, if we take into account that the value gained by blocking generic medicines is significantly greater than the cost of trials...***
- Injunctions or seizures will **only** be revised if the defendant makes a request. This could be a lengthy and costly procedure. Meanwhile the plaintiff has stopped any generic medicine from entering the market.
- Furthermore, an injunction/seizure is a **deadly threat**: it may “kill” the product, since it might not ever return to the market (even if innocence is proven), such can be the market dynamics.
- ***“... a prohibitory measure shall be revoked if the applicant does not institute proceedings leading to a decision on the merits of the case within 31 calendar days...” This period should be shorter. An injunction should not be granted unless the applicant is serious about instituting proceedings immediately.***

## Articles 8, 10 and 11- concerning the compensation mechanism.

- EGA considers that the **vague compensation requirements**, i.e refundable guarantee or compensation provided by the Directive for cases in which action is found to be unfounded, is **NOT satisfactory**: it is very difficult to evaluate losses of profit as a result of the generic medicine not entering the market. In addition to this, the amount is not specified.
- In case of unfounded action, will the compensation be **sufficient** for the loss suffered as a result of the imposed measures? As a matter of fact, defendants’ damages, once innocence has been proven, are unquantifiable.
- And finally, no **moral compensation** (such as loss of reputation or of brand image) seems to have been taken into account.

## Article 16 - concerning alternative measures

- If an infringer has acted *“without fault or negligence”* but has caused prejudice to the applicant, that person may, subject to agreement with the injured party, *“make a compensation for said prejudice”*, if the execution of the measures in question would cause him disproportionate damage and if *“the prejudiced party can reasonably be satisfied with pecuniary compensation.”*  
***If an infringer is innocent, did not know and had no reasonable grounds for supposing that the right infringed existed, should he have to pay any damages at all?***



## Article 17 - concerning damages

- “... elements other than economic factors may be taken into account in calculating the damages, such as the moral prejudice caused to the right holder by the infringement.”

*Does the defendant get compensated for moral prejudice should the claim be unfounded?*

## 5. Conclusion

The European Commission’s proposed Directive on measures and procedures to ensure the enforcement of intellectual property rights has two major flaws:

- It fails to provide adequate safeguards to protect innocent defendants from abusive litigation. Therefore the proposed Directive **could** “be used to try to keep unwelcome competitors out of the market or to hamper legitimate competition”.
- It abolishes the distinction between piracy/counterfeiting and alleged infringement of patent right. This would equate to all alleged patent infringers being treated the same as criminals, pirates/counterfeiters.

**The European Parliament and EU Member States must therefore seek to amend key parts of the following articles:**

- **Article 8 (evidence protection measures)**
- **Article 10 (injunctions)**
- **Article 11 (compensation mechanism)**
- **Article 16 (alternative measures)**
- **Article 17 (damages).**