



*Making Medicines Affordable*

## **EGA Proposal for amendments**

### **Concerning**

**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**

**June 2003**

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: [Imallo@egagenerics.com](mailto:Imallo@egagenerics.com)  
Website: [www.egagenerics.com](http://www.egagenerics.com)



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## 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** as well as have **undesired effects on innocent parties**.

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**.

With respect to the scope envisaged for the proposed Directive, a fundamental difficulty concerns the separation between piracy and counterfeiting on the one hand and other intellectual property rights infringements on the other. In this vein, the European Parliament has stated in recital E of its report<sup>1</sup> on the Green Paper<sup>2</sup> **that a definition should be elaborated that distinguishes between various kinds of infringements**, thereby taking into account that **wilful and fraudulent elements are inherent in counterfeiting and product piracy**. The European Commission seems to have ignored this statement.

## AMENDMENTS

### AMENDMENT 1

#### Article 1

This Directive concerns the measures necessary to ensure the enforcement of intellectual property rights **against wilful counterfeiting or piracy**.

## JUSTIFICATION

*The scope of this legislation is to tackle counterfeit and piracy, particularly in the music industry 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 infringers should not be equated with criminals like pirates/counterfeiters. Clear definitions of “counterfeiting” and “piracy” are essential. In addition to this, sanctions that cover real patent infringement are already provided by the Community Patent Regulation<sup>3</sup> (art. 43 on Penalties), which will soon be approved by the Council of Ministers.*

<sup>1</sup> EP, 29.3.2000, A5-0096/2000 final

<sup>2</sup> COM [1998] 569

<sup>3</sup> COM(2000)412 final



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## **AMENDMENT 2**

### **Article 7 Evidence**

1. **In cases of wilful counterfeiting or piracy**, Member States shall lay down that, where a party has presented reasonably accessible evidence sufficient to support its claims, and has, in substantiating those claims, cited evidence which is to be found under the control of the opposing party, the judicial authorities may order that such evidence be produced by the opposing party, subject to the protection of confidential information.

2. In order to identify and prosecute the real beneficiaries of the **wilful counterfeiting or piracy infringement**, Member States shall take such measures as are necessary to enable the responsible authorities to order the communication or seizure of banking, financial or commercial documents, subject to the protection of confidential information.

### **JUSTIFICATION**

*The provisions on evidence provided in article 7 have to be proportionate in accordance with article 4. These provisions are indeed proportionate in cases of wilful counterfeiting and piracy but not in cases of alleged patent infringements in the normal course of commercial activity (see justification in amendment 1). These measures, which may well be appropriate for cases of genuine product piracy, can be excessive with regard to a “normal” infringement, which corresponds in its nature to a civil dispute that can happen in daily business between two serious pharmaceutical companies.*



## AMENDMENT 3

### Article 8

#### Measures for protecting evidence

1. **In cases of wilful counterfeiting or piracy**, Member States shall lay down that, where there is a demonstrable **and serious** risk that evidence may be destroyed even before the commencement of proceedings on the merits of the case, the judicial authorities may, in the event of an actual or imminent infringement of an intellectual property right, authorize in any place either the detailed description, with or without the taking of samples, or the physical seizure of the infringing goods, and, in appropriate cases, the documents relating thereto. These measures shall be taken by order issued on application, if necessary without the other party having been heard.

Where evidence-protection measures have been adopted without the other party having been heard, the affected parties shall be given notice immediately after the execution of the measures at the latest. A review, including a right to be heard, shall take place upon request of the affected parties with a view to deciding, **within a reasonable period ten calendar days** after the notification of the measures, whether the measures shall be modified, revoked or confirmed.

2. Member States shall lay down that physical seizure may be subject to the applicant's lodging of an adequate guarantee (**i.e a reasonable pre-estimate of likely loss**) intended to ensure **full** compensation for any prejudice suffered by the defendant if the proceedings instituted against him are subsequently judged to be unfounded.

3. Member States shall lay down that, if the applicant has not instituted legal proceedings leading to a decision on the merits of the case within **31 ten** calendar days of the seizure, the seizure shall be null and void, without prejudice to the damages which may be claimed.

Where the evidence protection measures have been revoked, or where they lapse owing to any act or omission by the applicant, or where it is subsequently found that there has been no infringement of any intellectual property right, the judicial authorities shall have be empowered to order the applicant, at the defendant's request, to provide the defendant with adequate **full** compensation for any injury caused by the measures.

#### JUSTIFICATION

*This legislation should respond to particular problems in the areas of wilful counterfeiting or piracy, particularly in the music industry and related sectors.*

*Concerning the physical seizure measure (if there is a "demonstrable risk" that the evidence may be destroyed) there should be a higher burden of proof<sup>4</sup> on the alleged infringed right holder as the stated measures for protecting evidence should only be undertaken under exceptional circumstances.*

*In addition to this, and concerning the amendment that shortens the period of time for a review (8.1), it should be considered that a physical seizure of goods is a very severe measure and therefore should not be granted unless the applicant is serious about instituting proceedings immediately.*

*Finally, the safeguard clause against unfair competition –i.e. adequate guarantee to ensure compensation (8.2, 8.3)- should be strengthened as much as possible.*

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<sup>4</sup> Larger pharmaceutical companies have developed a series of unfair strategies to prevent generic competition such as **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**. As a matter of fact, 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.**



## AMENDMENT 4

### Article 10 Provisional measures

1. Member States shall lay down that the judicial authorities may serve the alleged infringer, or the intermediary whose services are being used by a third party to infringe a right, with an interlocutory injunction intended to prevent any impending infringement of an intellectual property right, or to forbid, on a provisional basis and subject to a recurrent fine, the continuation of the alleged infringements of an intellectual property right, or to make such continuation subject to the lodging of guarantees intended to ensure the compensation of the right holder.

The judicial authorities shall ~~be empowered~~ **have the obligation** to require the applicant to provide ~~any~~ **all** reasonably available evidence in order to satisfy themselves with a ~~sufficient~~ **high** degree of certainty that the applicant is the right holder and that the applicant's right is being infringed or, that such infringement is imminent **and would cause serious damage to the applicant**.

2. Member States shall lay down that the provisional measures referred to in paragraph 1 may in ~~appropriate~~ **exceptional** cases be taken without the defendant having been heard, in particular when any delay would cause irreparable prejudice to the right holder. In the event of this happening, the defendant shall be so informed without delay after the execution of the measures.  
A review, including the right to be heard, shall take place at the request of the defendant in order to decide, within ~~a reasonable time~~ **ten calendar days** after notification of the measures, whether they are to be amended, revoked or confirmed.

3. Member States shall lay down that a prohibitory measure shall be revoked if the applicant does not institute proceedings leading to a decision on the merits of the case within ~~thirty-one~~ **ten** calendar days from the day on which ~~the right holder became aware of the facts on which it is based~~ **the prohibitory measure is granted**.

4. The judicial authorities may make the prohibition subject to the lodging by the applicant of adequate guarantees (**i.e a reasonable pre-estimate of likely loss**) intended to ensure any **full** compensation of the prejudice suffered by the defendant if the proceedings on the merits are subsequently judged to be unfounded.

### JUSTIFICATION

*Injunctions (10.1) shouldn't be granted nor used routinely. Consequently there should be a larger burden of proof<sup>5</sup> on the alleged infringed right holder. According to Article 3, which states that "the general principles of intellectual property rights law should not create barriers to legitimate trade", we believe that the injunctions should not be used abusively to keep unwelcome competitors out of the*

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<sup>5</sup> Larger pharmaceutical companies have developed a series of unfair strategies to prevent generic competition such as **initiating legal proceedings against generic pharmaceutical companies irrespective of the substantiation of legal grounds of the case in order to substantially delay market entry of competitive generic medicines**. As a matter of fact, 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.**



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*market or to hamper legitimate competition. If this article stays as it is, the plaintiff could, by means of minimal or unsubstantiated proof, readily obtain an injunction. The result would be (for the plaintiff) a cheap, simple and extremely commercially valuable way of blocking legitimate competition instantly without recourse to proper legal trials.*

*Concerning the amendment which shortens the period of time for a review and the institution of proceedings (10.2 and 10.3), it should be taken into account that an injunction is also a very severe measure and therefore should not be granted unless the applicant is serious about instituting proceedings immediately.*

*Finally, the safeguard clause against unfair competition –i.e. adequate guarantee to ensure compensation (10.4)- should be strengthened as much as possible (“**full compensation**”).*

## **AMENDMENT 5**

### *Article 11*

#### **Precautionary measures**

2 The judicial authorities ~~may~~ **must** make the measures provided for in paragraph 1 subject to the lodging by the applicant of guarantees adequate (**i.e a reasonable pre-estimate of likely loss**) to ensure possible **full** compensation for the prejudice suffered by the defendant if the proceedings on the merits are subsequently judged to be unfounded.

3. Where the precautionary measures are revoked, or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant adequate **full** compensation for any injury caused by these measures.

#### **JUSTIFICATION**

*This safeguard clause should offer legal clarity and security to an innocent defendant. Therefore the lodging of the guarantee should be mandatory. This amendment is aimed to provide legal clarity.*

*The safeguard clause against unfair competition (“**full compensation**”) should be strengthened as much as possible.*

## **AMENDMENT 6**

### *Article 12*

#### **Recall of goods**

**In cases of wilful counterfeiting or piracy, where a decision has been made on the merits of the case and,** without prejudice to the damages due to the right holder by reason of the infringement, Member States shall lay down that the judicial authorities may order the recall, at the infringer's expense in appropriate cases, of the goods which have been found to infringe an intellectual property right.

#### **JUSTIFICATION**

*The measures on recall of goods provided in article 12 have to be proportionate in accordance with article 4. These measures are proportionate in cases of trademark counterfeiting and copyright piracy but not in cases of alleged infringements of other IP rights. They can be excessive with regard to a “normal” infringement, which corresponds in its nature to a civil dispute that can happen in daily business between two serious pharmaceutical companies (see justification to amendments 1,2,3 and 4).*

## **AMENDMENT 7**



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*Article 13*

**Disposal outside the channels of commerce**

**In cases of wilful counterfeiting or piracy**, Member States shall lay down that the judicial authorities may order that the goods which have been found to infringe an intellectual property right, as well as the materials and implements used primarily for the creation or the manufacture of the goods in question, be disposed of outside the channels of commerce, without compensation being due.

**JUSTIFICATION**

*Same justification as amendments 1, 2 and 6.*

**AMENDMENT 8**

*Article 14*

**Destruction of goods**

**In cases of wilful trademark counterfeiting or copyright piracy**, Member States shall lay down that the judicial authorities may order the destruction of the goods which have been found to infringe an intellectual property right, without there being any entitlement to compensation.

**JUSTIFICATION**

*Same justification as amendments 1, 2 and 6.*

**AMENDMENT 9**

*Article 16*

**Alternative measures**

~~In appropriate cases, Member States shall lay down that, if the person liable to be subjected to the measures provided for in this Section has acted without fault or negligence but has nevertheless caused injury to the applicant, that person may, if execution of the measures in question would cause him disproportionate harm and if the injured party could reasonably be satisfied with pecuniary compensation, compensate that party in cash, with the latter's agreement.~~

**JUSTIFICATION**

*This article offends the rules of natural justice in that an innocent party is being made subject to penalty, notwithstanding the express absence of fault or negligence. This is a disproportionate legal innovation in what is fundamentally a dispute about property rights.*

*It also offends Articles 1 and 6 of the European Convention on Human Rights 1951. Article 1 guarantees a citizen peaceful possession of his property (including financial means and assets). If the state acts in the overall public good to deprive a citizen of his possessions, its action must be proportionate; not excessively burdensome; and may attract compensation.*

*Thus the citizen may claim compensation from the state or relevant public body for the compensation he has paid to another party. Article 6, guaranteeing a citizen the right to a fair trial, carries within in the concept that a citizen is innocent until proved guilty and cannot be punished unless found guilty by fair trial.*

**AMENDMENT 10**



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### *Article 17*

#### **Damages**

1. Member States shall lay down that the judicial authorities shall order an infringer to pay the right holder adequate damages in reparation of the damage incurred by the latter as a result of his intellectual property right being infringed through the infringer having engaged in an activity in the knowledge, or with reasonable grounds for knowing, that it would give rise to such an infringement.

To this end, the competent authorities shall award, at the request of the prejudiced party:

~~(a) either damages set at double the royalties or fees which would have been due if the infringer had requested authorization to use the intellectual property right in question; DELETE~~

~~(b) or~~ compensatory damages corresponding to the actual prejudice (including lost profits) suffered by the right holder as a result of the infringement.

In appropriate cases, Member States shall lay down that the prejudice suffered can also be deemed to include elements other than economic factors, such as the moral prejudice caused to the right holder by the infringement.

#### **JUSTIFICATION**

*This article offends the rules of equity in some EU countries where a compensatory payment for breach of property rights must relate to a genuine estimate of loss. Courts will not allow a penalty payment higher than the actual loss because it is unfair.*

### **AMENDMENT 11**

### *Article 20*

#### **Criminal law provisions**

1. **In cases of wilful counterfeiting or piracy**, Member States shall ensure that all serious infringements of an intellectual property right, as well as attempts at, participation in and instigation of such infringements, are treated as a criminal offence. An infringement is considered serious if it is intentional and committed for commercial purposes.

#### **JUSTIFICATION**

*This Article should not criminalise infringements in the context of commercial disputes such as those concerning the validity of patents.*