



EGA Position Paper

TRIPS Article 34 and 50 do not require Automatic Interlocutory Injunctions

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The EGA represents over 400 companies in Europe
dedicated to the production and supply of affordable generic medicines.

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1. The issue

Article 34(1) of the TRIPS provides for the reversal of the burden of proof in patent infringement litigation for the benefit of the holder of a process patent on those conditions specified in subparagraphs (a) - (c) of the said provision.¹

Article 50(1)(a) of the TRIPS states that provisional measures should be available to prevent the infringement of intellectual property rights.²

Certain pharmaceutical producers holding process patents have commenced litigations in Central and Eastern European (CEE) countries, seeking enforcement of automatic injunctive interlocutory measures in alleged infringement cases. These companies argue that the ordering of injunctive interlocutory measures should be indispensable and automatic in process patent infringement procedures, since on the sufficient (lower) degree of certainty, which is required for the ordering of interlocutory measures, the defendant may never be in the position to provide relevant evidence to rebut the presumption provided for the benefit of the plaintiff.

They have attempted to argue their case either by claiming that:

- a) the above two provisions of the TRIPS Agreement should be treated as interdependent or
- b) that such practice is common in the EU

However, as this paper will demonstrate the arguments outlined in a) and b) are unfounded. Consequently, there is no requirement either under international agreements or on common practice of the EU to grant automatic interlocutory injunctions in the course of infringement procedures initiated in relation to process patents directed to the preparation of new products.



2. The position of the EGA

2.1. The purpose of interlocutory injunctions

Under the reversal of the burden of proof obligations, the defendant is obliged to provide evidence that a procedure applied by the defendant to produce an identical product differs from the patented procedure. Interlocutory measures are to provide effective means to combat piracy, since professional infringers seldom remain available to perform or enforce the provisions of the award.

2.2. There is no link between TRIPS Articles 34(1) and 50(1)

However, there is no special link whatsoever between Articles 34(1) and 50(1) of the TRIPS. Such a connection cannot be supported by either the treaty language, or the proposals and working documents, which led to the adoption of the TRIPS Agreement.

In addition, there is no support in the legislative history or in the language of the TRIPS that the ordering of an interlocutory injunction would be indispensable, if the subject matter of the litigation is the alleged infringement of a process patent.

2.3. The rights of defendants are also upheld in TRIPS

Moreover, the principle of fair and equitable procedure is set forth in Article 41(2)³ of the TRIPS and specified in Article 42 (the fourth and fifth sentences)⁴. Thus, the courts should evaluate the evidence provided by all the parties in order to satisfy them with that degree of certainty, which is required to decide on the ordering of interlocutory measures. In the course thereof, reasonable evidence offered by the defendant has to be taken into consideration. The owners of process patents may not automatically be treated differently, as would other owners of IP rights.

Process patent litigations are rather complex matters, where courts may frequently be in need of one or more expert opinions. One significant purpose of interlocutory measures is to grant fast relief. Therefore, if an expert opinion is required, such measures cannot practically be ordered.

2.4. Practice in the EU does not support automatic interlocutory injunctions

Practice within the EU also shows that the assurance of an injunction in case of patent infringement suits for the alleged violation of process patents is not automatic. Courts will always carefully examine whether infringement is sufficiently probable. Thus the Court carefully evaluates whether the process declared by the defendant actually falls under the scope of the plaintiff's patent. In the case of doubt no injunction is issued but the delicate technical question of infringement or not infringement is decided upon in the course of a normal court procedure.



According to the English expert opinion the issuing of an interlocutory injunction depends on "whether the patentee has shown a serious issue to be tried!"⁵

Pursuant to Austrian expert opinion "preliminary injunction will only be granted if a patent is clearly infringed. If difficult questions have to be analysed in order to decide on infringement (usually the private legal opinions filed by the parties come to opposite conclusions) or if the non infringement is obvious and the examination of the request for preliminary injunction would pass the limits of such procedure or if the invalidity of the patent is obvious the Court will not request for injunction."⁶

According to expert opinion in Denmark preliminary injunction relief "may be granted if the patentee can prove or render probable that 1) the actions for which injunctive relief is sought are contrary to the patentee's right, 2) the defendant will carry out such actions and 3) the purpose of the injunction relief would not be served if the patentee had to bring the case before the ordinary courts."⁷

According to expert opinion in Greece "the examination of the two methods is sometimes very complicated and can not be accomplished during the proceedings of the Petition for Injunctions the Court, consisting of one judge, in the case of doubt refers the case for thorough examination to the Three Member Civil Court. In any case, the injunctions are not granted unless the Court is convinced that the defendant is using plaintiff's method for preparing his product."⁸

According to expert opinion in Germany injunctions requested for process patents directed to the preparation of new products courts are very restrained.⁹

Spanish expert opinion is of the view that prior to declaring the requested precautionary measures the Court must examine whether or not the process used by defendant infringes plaintiff's patent.¹⁰

3. Conclusion

On the basis of the evidence presented above, it is clear that courts in CEE countries are not obliged under either international agreements or by example from EU countries, to grant automatic interlocutory injunctions in the course of infringement procedures initiated of process patents directed to the preparation of new products.

¹ **Article 34 - Process Patents: Burden of Proof**

"1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following



circumstances, that any identical product without the consent of the patent owner shall, in the absence of the proof to the contrary, be deemed to have been obtained by the patented process:

- a) if the product obtained by the patented process is new
- b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled

3. In the adduction of the proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account."

² Article 50 (paragraphs 1 and 2)

"1. The judicial authorities shall have the authority to order prompt and effective provisional measures:

- (a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;
- (b) to preserve relevant evidence in regard to the alleged infringement."

2. The judicial authorities shall have the authority to adopt provisional measures *inaudita altera parte* where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed. "

³ Article 41.2

"Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays"

⁴ Article 42 – Fair and Equitable Procedures

"Members shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements." (Our emphasis).

⁵ UK Patent Attorneys Stephenson Harwood

⁶ European Patent and Trade Mark Attorney's Sonn, Pawloy, WeinZinger & Wolfram

⁷ Law firm Kromann Reumert

⁸ European Patent Attorneys Theodorides and Papaconstantinou

⁹ European Patent Attorneys Dr. Stephan G. Beszedes

¹⁰ Luis Torrents Fernández-Mayoralas, Spanish IP lawyer, in En torno al art. 61.2 de la Ley de Patentes. La presunción de que el demandado utiliza el procedimiento patentado cuando la patente reivindica la fabricación de productos o sustancias nuevos y algunos problemas que suscita, published in Estudios sobre Propiedad Industrial, Homenaje a M. Curell Suñol, by Grupo Español de la AIPPI (Spanish Group of AIPPI) in Barcelona in March 2000.