Making Medicines Affordable

MEP Mr. Gianluca Susta
INTA Committee
European Parliament
1049 Bruxelles- Belgium

Brussels, 5th of November 2010

**Ref. EGA comments to the consolidated text on ACTA that reflects changes made during the September 2010 Tokyo round[1].**

Dear Mr. Susta,

I am writing to express the views of the European generic medicines industry concerning the draft ACTA Agreement. The EGA understands and fully supports the basic principles of ACTA, which is the prevention of counterfeiting and piracy. The EGA and its companies and national associations are fully committed to combating counterfeit medicines. EGA is an active and supportive member of both the WHO's IMPACT group and the Council of Europe's Committee of experts on minimizing public health risks posed by counterfeiting of medical products.

However, our industry has serious concerns regarding the current approach when measures to combat counterfeiting and piracy are simply generalized as applicable to all forms of IP rights[2] as is proposed by the European Commission in ACTA. 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.

In this context we would like to ask you to support the **footnote**[3] proposed by the US that excludes patents from the scope of Section 2 on Civil Enforcement. The inclusion of patents in Section 2 could be used to prevent competition. The criminal penalties and preventive measures aimed at counterfeiters can be misused by patent holders to stop legitimate competition from other companies producing similar products, especially where the applicability of patents is complex. In addition, there is a common misconception that if a patent is awarded then it is necessarily valid. This is incorrect and many 'weak' patents later on are revoked. The implications on companies, particularly SMEs, can be punitive 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 due to the delay of generic entry.

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[1] *Informal Predecisional/Deliberative Draft: 2 October 2010*
[2] *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.*
[3] *Footnote {US: For the purpose of this Agreement, Parties agree that patents do not fall within the scope of this Section.}*



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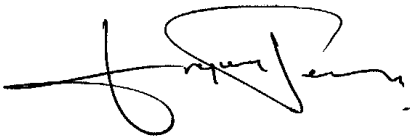
Please also note that the WHO's IMPACT made recommendations on how best to deal with counterfeit pharmaceuticals including stringent regulatory procedures, improved training for customs officers and quality control inspectors, and increased public and health professional awareness. However, IP enforcement was not regarded as the most appropriate measure. A definition of counterfeit was even proposed in the third meeting of IMPACT in Hamamet that excluded patent disputes[4].

In conclusion, the measures proposed in ACTA, which are designed to deal with the criminal activity of counterfeiting and piracy, are not appropriate for patents and would ask you to support their exclusion from the final agreement.

Please do not hesitate to contact us if you need more information on the issue.

Yours sincerely,



Greg Perry
EGA Director General

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*Mr. Carl Schlyter, MEP*

*INTA Committee*
*Mr. Dominique Delaunay, European Parliament*
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[4] *"Violations or disputes concerning patents must not be confused with counterfeiting of medical products". Hamamet IMPACT Third Meeting, 5 December 2008.*



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