



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

POSITION PAPER

BETTER PATENTS, BETTER MEDICINES: RECOMMENDATIONS ON HOW TO IMPROVE THE EUROPEAN PATENT SYSTEM

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1. Introduction

The EGA is the official representative body of the European generic and biosimilar pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector.

The EGA is in favour of a strong patent system with strong patent criteria based on the “inventive step”. The system should ensure that only patents backed by sound evidence are granted, instead of weak patents based upon an inadequate examination. In the past few years, the EGA has observed a deterioration in the scrutiny in patents by the European Patent Office, leading to the grant of many weak patents that are subsequently revoked.

Failures to enforce patent criteria (novelty, inventive step and industrial application) not only damage competition, but can lead to less innovation and to the loss of savings for healthcare systems. Problems occur if “weak” patents prevent competition as such, and ultimately hinder further innovation. When patents are aimed solely at excluding competitors from the markets, patent quality becomes crucial to ensuring the rights of consumers and patients.

In addition to the problem of patent quality, the EGA is also concerned with the current patent litigation system. In our opinion, the users of the system suffer from excessive and abusive litigation and diverging and unbalanced decisions. In this context we believe that an inefficient patent litigation system together with poor patent quality may inadvertently create market power and hinder innovation and access to affordable medicines.

2. Recommendations to improve patent quality:

To overcome the difficulties outlined above, and in order to improve the quality of pharmaceutical patents, the EGA suggests the following modifications to the current granting policy of the European Patent Office (EPO):

- provide adequate resources and continue to encourage the EPO to improve the quality of patents that are granted by applying a consistently high standard of thoroughness in patent examination by well-trained examiners;
- grant patents only for genuine incremental innovation, and not to changes in chemistry or formulation that lack inventive step;
- remove the requirement for EPO examiners to be fluent in three languages in order to allow the selection of examiners from a larger, more technically skilled pool of candidates;
- give incentives to examiners to refuse bad applications in order to increase standards in selecting patents. The current system is biased towards granting, as it is less costly for examiners to grant and there is no reward for refusing a patent. Thus, the reward system for examiners should be rebalanced;



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- require patentees to file high quality applications and introduce the duty of candour to ensure that all information relevant to the patent being examined by the EPO is disclosed by the applicant;
- make the providing of false information to the EPO/National Patent Office an offence against the Community with truly punitive penalties delivered against the abuser (both financial penalties and time limitations on the ability to apply for new patents);
- introduce a mechanism (prosecution history estoppel) whereby patentees are held accountable for statements made during prosecution when a patent is being litigated;
- guarantee that interested parties have sufficient opportunity to alert the EPO about questionable patents within the EPO granting process itself;
- revert the burden of proof: applicants should have to prove and evaluate the alleged technical problem and its alleged solution;
- consider third party observations in detail and within a minimum period of time;
- accelerate the opposition procedure;
- implement an external audit check for patent quality.

3. Recommendation to improve the patent litigation system

The structure established under the European Patent Convention only provides for a common and single European patent application and granting system by the EPO. A European patent is not a unitary patent, but essentially a bundle of national patents. As a result, questions of patent infringement and validity are governed by various national laws and are handled by the national courts operating under different procedural rules. This purely national litigation system results in a complex arena of multiple patent litigation involving high costs, forum shopping and diverging, even contradictory, court decisions. Furthermore the lack of a central judiciary composed of experienced patent judges is regarded as one of the major defects in the current patent system.

In order to overcome these problems, the EGA recommends the following:

- approve the final creation of the Community Patent as a single unitary patent, effective in all Member States, and affordable;
- create a national litigation framework with technically qualified and experienced patent judges who can reach a decision on the merits of a case within a reasonable period of time;
- publish all patent court decisions in an EU register to provide clarity and to increase harmonisation, and to assist in moving towards the creation of a common jurisprudence on European patents;
- reach a consensus on a central patent judiciary in Europe (in this context, the European Union Patent Court project is most welcome);
- avoid interim injunctions by inexperienced judges without a proper assessment of the rights of all the various parties involved;
- require common standards of evidence and a duty on all parties to the litigation to present evidence to the court both for and against awarding a preliminary injunction;



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- involve the health care authorities in patent proceedings, particularly in applications for interim injunctions.

4. Conclusion

In conclusion, it is the assessment of the inventive step that seems, at present, the most problematic area of the patentability requirements. However, it is through changing the awareness of patent examiners and strengthening quality assurance mechanisms at the European Patent Office that the assessment of the inventive step can be improved and made more consistent. If the European Patent Office introduces substantial changes into its granting policy, the quality of the patents will certainly improve. In addition, the negative incidence of poor follow-on patents and of patent thickets¹ will be reduced. In parallel, a consensus for a central patent judiciary in the EU will put an end to high costs, forum shopping, and contradictory court decisions.

Whilst patents are clearly important for encouraging innovation, a fragmented EU patent system that is too permissive in granting patent rights will prevent competition from generic medicines, restrict access to medicines through decreased affordability, and will ultimately discourage real innovation in the pharmaceutical sector.

¹ One of the strategies employed to extend the market monopoly beyond the length of time initially granted by the basic patent is the use of follow-on patents, a practice known as evergreening: originators file numerous follow-on patent applications covering a drug in the hope that at least one of them will be granted and survive a litigation challenge. The consequence of this is often an extensive thicket or cloud of patents around a drug. These follow-on patents stretch the limits of the patentability criteria and disrupt the delicate balance underlying the patent system. An important way of reducing the incidence of poor follow-on patents is for the EPO to continue to improve the quality of the examiners and their training, and to increase the number of more experienced senior examiners. To read more: http://www.egagenerics.com/ega-barriers_rpt.htm