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EUROPEAN GENERIC MEDICINES ASSOCIATION

POSITION PAPER

**EGA COMMENTS ON HOW TO IMPROVE THE EFFICIENCY OF EUROPE'S
PATENT SYSTEM**

SACEPO COMMITTEE ANNUAL MEETING

JULY 2010

EGA COMMENTS ON HOW TO IMPROVE THE EFFICIENCY OF EUROPE'S PATENT SYSTEM

1. KEY MESSAGES:

- The EGA seeks to continue constructive dialogue with the European Patent Office (the EPO). Our mutual goal is to improve the efficiency of Europe's patent system in line with the EPO's own initiative to "raise the bar".
- The EPO must look to:
 - improve the quality of patents and applications through continuous improvement of its examination procedure;
 - accelerate examination proceedings; and
 - streamline and speed up opposition proceedings.
- The EGA also supports the introduction of an "Information Disclosure Statement", to improve the European examination procedure by creating a repository of the most relevant prior art with minimal addition effort required by the examiner.
- The EGA welcomes the new EPO rules that limit opportunities of filing divisional applications but remains concerned about the possibility of evading these rules and supports further reform in this area.

2. EXAMINATION OF APPLICATIONS

- a) The EPO should give the **right incentives** to examiners to help them reject weak patents. While we acknowledge the point system currently used by the EPO is already weighted in this direction, there are still not sufficient incentives for examiners to refuse patent applications, as significantly more work is required to refuse a patent than to grant it. However, the EGA welcomes the fact that recent and stricter case law of the Board of Appeal has been introduced into the Guidelines for Examination, giving more power to examiners to reject applications.
- b) The examination process must be structured to promote careful and in-depth examination. One measure to do this may be a **second search**, specifically in those cases where the patentee responds to the first examination report indicating the prior art documents cited by the examiner are not relevant. With the patentee's own explanation of the "invention" in greater details, the examiner can perform a more focused and better search. This additional information about the invention would clearly enhance the quality of the examiner's search and ultimately result in better quality patents, with the appropriate scope of protection. The IDS (discussed below) is another way to achieve this objective as it can help the examiner understand the invention at an earlier stage.
- c) There is also a need for **behavioural reforms** to discourage abuse of the patent system such as poor quality applications and "strategic" patenting. An example of strategic patenting is the abuse of divisionals that the EPO has recently tried to limit by



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introducing rules preventing the filing of divisional applications that are identical to the parent. The EPO should identify further instances of abuse, such as patent for polymorphs or common salt forms, and try to find a remedy to stop abuses for example, by requiring applicants to explain how this new form is different from previous forms, and not the inevitable result of prior art production methods. For example, the claimed crystal polymorph is a crystal form that is the natural or inevitable result when a particular prior art method of making the compound is used. This would not necessarily be publicly known, as the crystal form may not have been assessed or published. In conclusion, the EPO should have a procedure to acknowledge “problematic patents” (such as polymorphs) and exercise its rights under Articles 114 and 124 in this regard.

- d) While we welcome the EPO’s recent reforms, further work is necessary in order to ensure the proper use of **divisional applications**. First, the time limit for filing mandatory divisional applications should be reduced to 2 months to avoid “creative” use of this mechanism. Secondly, the Enlarged Board of Appeal should clarify the EPO stance on prohibition of double patenting (T 307/03). Finally, prosecution of divisionals should be accelerated to avoid potential misuse of them i.e. having a pending application with overly broad claims “hanging over” the development of other competing products for an undefined period. The EPO should considering using Article 114 EPC¹ to take the initiative to improve the examination of these pending divisionals, particularly where the parent application or any related patent is either under opposition, or where litigation is underway regarding that “patent family”.
- e) **Time limits** for examination should not be so long. Applicant’s reply should be received in 2-3 months, not 4 months, and the current almost automatic extension of 2 months should only be granted if justified by, for example, carrying out experiments which take a long time to do.
- f) The examiner should be required to take **third party observations** (Art. 115² EPC) into consideration during the examination as this is the only opportunity to bring new prior art to the attention of the examiner before grant, particularly “unsearchable” prior art such as prior use and repetition of prior art experiments, which is otherwise unavailable to examiners. Third party observations allow the examiner to get a balanced overview of objective factors affecting patentability - e.g. repetition of prior art (novelty); repetition of processes in the patent (sufficiency). The examiners must demonstrate that they have taken all third party observations into account by expressly responding to the points raised in their examination report. Properly considering third party observations could be an opportunity to reject weaker patents and reduce the number of oppositions.

¹ **Art. 114 Examination by the European Patent Office of its own motion** (1) In proceedings before it, the European Patent Office shall examine the facts of its own motion; it shall not be restricted in this examination to the facts, evidence and arguments provided by the parties and the relief sought. (2) The European Patent Office may disregard facts or evidence which are not submitted in due time by the parties concerned.

² **Art. 115- Observations by third parties** (1) Following the publication of the European patent application, any person may present observations concerning the patentability of the invention in respect of which the application has been filed. Such observations must be filed in writing and must include a statement of the grounds on which they are based. That person shall not be a party to the proceedings before the European Patent Office. (2) The observations referred to in paragraph 1 shall be communicated to the applicant or proprietor of the patent who may comment on them.

- g) The EPO should also consider reviewing the application of its rules regarding **abuse of procedure** available through Article 125 EPC³ in relation to governing the conduct of both applicants and opponents before the EPO.
- h) As part of the social contract that justifies the monopoly rights granted by a patent, the patentee must disclose its invention to the community. In other words, the concept of **sufficient disclosure** should not be reduced to a formal “are all the features of the claim mentioned?”. The disclosure must provide sufficient knowledge to the community that they can understand and reproduce the invention that has been granted a monopoly. This concept would also make clear that the claims of a European patent must not simply claim a task but a real solution to a real problem.

3. OPPOSITION PROCEDURES

- a) Opposition procedures should become a **priority** for the EPO, reflected in a number of changes. We welcome the initiative of the Chemistry division in this respect and would support any efforts to formalise this prioritisation within guidelines or agreed EPO procedures.
- b) First, opposition proceedings must be **streamlined** as they currently regularly take longer than the initial examination period. As a first step, the EPO must again be more rigorous in rejecting applications for extension of time that have no merit - applicants must show these extensions are genuinely justified.
- c) Secondly, the **time for filing oppositions** should be extended, potentially to 6 years. The EPO process enables patentees to obtain patents in numerous markets throughout Europe via one mechanism. In the absence of a European patent court, the EPO opposition procedure is the only opportunity for third parties to revoke those patents through one mechanism. As a European patent is granted and can be enforced in any one of the Member States during this extended opposition period, there is no serious prejudice to the patent owner.

In order to speed up the opposition process generally and reduce any uncertainty during this extended period, once a first opposition is initiated, further potential opponents have only a limited period, say 4 months from the date of that first opposition, to file their own opposition. After that period, no further oppositions will be accepted in relation to that patent. It is the EGA’s proposal that this contraction of the timeline should occur even without the extended opposition period.

For example, the notice that a patent is granted is published on 1 January 2010. The period to oppose would remain open until 1 January 2016. However, Company A files an opposition immediately after the date of grant of the patent on 10 January 2010. Other

³ *Art. 125- Reference to general principles: In the absence of procedural provisions in this Convention, the European Patent Office shall take into account the principles of procedural law generally recognised in the Contracting States.*



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opponents will have 4 months to file their own opposition i.e. until 10 April 2010. If they do not file by that date, no further oppositions will be accepted even though the original opposition period has not yet expired.

We acknowledge that this proposal could only be introduced by an amendment to the European Patent Convention.

- d) Thirdly, the opposition division should be procedurally required to **decide on all issues** raised in an opposition, rather than closing the opposition as soon as the patent is found invalid on any one ground. A good example may be where the patent is found invalid on the basis of added matter, but no decision is taken on the novelty or inventiveness of the patent. The patentee can then immediately appeal that decision, creating a delay in the opposition procedure until the appeal is heard. If the appeal is successful, the rest of the issues will be remanded to the Opposition Division. This could in theory happen a number of times until all issues of the original opposition are heard. The opposition division clearly has the discretion to find on all issues, as was the case on one of the alendronate divisionals.

The impact of this problem is exacerbated by the order in which opposition arguments are presented and heard, i.e. starting with technical grounds of opposition that are often only available in the context of an opposition hearing but not national courts (such as added matter objections) before addressing the substantive grounds of novelty and inventive step.

- e) Finally, the patentee should be strongly discouraged from **reformulating** the problem-solution-approach any time they choose to do so. This is a practical means to keep the bar high at opposition procedures and further to properly value the work done by the EPO in the examination process.

4. INFORMATION DISCLOSURE STATEMENT (IDS)

- a) The EGA proposes that the EPO introduce an **IDS** - but not the additional “inequitable conduct” prohibition seen in the US - in order to “raise the bar”. The applicant is best placed to understand all of the most relevant prior art in relation to its invention, and should be required to assist and educate the EPO by providing a list of those references at an early stage. Indeed, the applicant is already required to provide this information to a number of other patent offices around the world. As such, requiring an IDS in Europe will not greatly inconvenience applicants and will assist in the granting of better quality European patents. It is intended to aid the examiners in their work and to improve the quality of their search and their understanding of the invention.
- b) It is not the EGA’s proposal to introduce any penalties in relation to the implementation of the IDS. We intend this to be a tool, not a weapon, which will serve to improve patent quality and require the patentee to better define its invention.