Making Medicines Affordable

MEMO TO THE PANEL

COMMENTS ON THE DRAFT RULES OF PROCEDURE FOR A UNIFIED PATENT COURT

APRIL 2012

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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. Generic medicines currently represent 50% of medicines that are dispensed in the EU while only using 18% of the total pharmaceutical budget. We are an important tool to achieving savings in the health budgets of the Member States.

The EGA comments and proposals are based on Working paper 11813/09 from the Commission Services on the draft Rules of Procedure for a Unified Patent Litigation System - 16 October 2009 - and on the Draft Agreement on a Unified Patent Court and draft Statute, 11 November 2011. Whilst the EGA is generally supportive of the Unified Patent Litigation System, it has a number of concerns about the present draft that it urges the Panel to address in its deliberations on the Rules.

We address this short memo to the Panel to highlight the EGA's main concerns on the current draft of the Rules of Procedure. It is imperative that there is a balance in the Rules of Procedure between the ability of patentees to enforce their rights and the principles of the Internal Market - freedom of movement and competition. This requirement is particularly evident in the pharmaceutical sector, which will be a significant user of the new system. We set out those areas which we think are of utmost importance to our members to enable them to play an important role in reducing the cost of healthcare across Europe. The Pharmaceutical Sector Inquiry Report[1] concluded that *"generic entry does not always take place as early as it potentially could"* and this is particularly pertinent at a time of considerable budgetary constraints to healthcare expenditure. We would hope that the Panel keeps this in mind when drafting the Rules of Procedure.

Our members are, in some cases, right holders and therefore experience litigation processes as both Plaintiffs and Defendants. Accordingly, it should be evident that the comments and suggestions herein are aimed at creating a balanced and equitable system whereby both parties to a patent dispute have the right to be heard on all relevant issues and have their interests protected as appropriate by the Courts.

This submission does not aim to be comprehensive but to offer suggestions regarding the enforcement rules, as they may possibly be adopted for the Unified Patent Litigation System. The EGA is mindful that the system must facilitate strong and effective measures, particularly against trade in falsified medicines. The EGA seeks to ensure fair competition – also at the level of enforcement procedures – between originator and generic pharmaceutical companies, without compromising legitimate enforcement of patent rights. Before dealing with some specific points we first set out a more general comment as to the proposed structure of the new system.

[1] European Commission Pharmaceutical Sector Inquiry- Final Report- 2009 http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

Bifurcated system

Within the framework of the Draft Agreement in many cases there may be two different divisions of the Court dealing with, on the one hand, infringement claims and on the other hand, revocation claims regarding the patent. Any statement for revocation shall have to be filed with the central division (Article 15a(3)), whilst infringement actions shall be brought before a local or regional division (Article 15a(1)). Moreover, when a counterclaim for revocation is instituted in proceedings before a local or regional division, such division shall have discretion to refer the counterclaim to the central division (Article 15a(2)(b)). Only if the local division shall decide to either proceed with both the infringement action and with the counterclaim for revocation or refer the whole case for decision to the central division, shall there be one division ruling on both questions of infringement and (in)validity. The EGA does not consider that a bifurcated system is desirable given (i) the potential for different constructions of patent claims to be asserted by parties or found by respective courts and (ii) the potential for patent owner (or so called "patent trolls") to exploit the system to their benefit at the expense of undertakings attempting to enter the market.

It is imperative that this system does not pave the way for the grant of preliminary or final measures without the Court having duly assessed the validity of the patent. In the EGA's view, the Rules should safeguard that the infringement claim is assessed on the basis of all relevant parameters, including (in)validity of the patent. Therefore, even if the local or regional division ruling on infringement shall not have to make a final decision on the claimed revocation, it should anticipate the central division's ruling in this respect. Where there is a reasonable and realistic chance that the central division revokes the patent, the EGA submits that the Rules should make clear that the decision of the local/regional division is suspended until the central division has rendered judgment.

EGA suggestions regarding enforcement rules

1. There is a need for rules giving guidance on assessing claims for (*ex parte* and *inter partes*) provisional injunctive relief.

In the Draft Agreement, the guidance given to the Court as to the assessment of claims for provisional injunctive relief is very limited. Basically, what derives from Article 37 (1) and (4) Draft Agreement is that in case of imminent infringement or continuing infringement, the Court may hand down interlocutory injunctions, whilst they have the authority (not the duty) to require the applicant to provide any reasonable evidence in order to satisfy themselves with a sufficient degree of certainty that he is the right-holder and that his right is being infringed, or that such infringement is imminent. Paragraph (2) of Article 37 adds thereto that the Court shall have the discretion to weigh up the interests of the parties and in particular to take into account the potential harm for either of the parties

resulting from the granting or the refusal of the injunction. The EGA submits that consideration of these issues should be mandatory.

The provisions on weighing up the parties' interests and demanding reasonable evidence of the infringement create an opening for implementing rules that provide the Court with the tools to adequately assess claims for provisional injunctive relief. In the EGA's view, these tools should in any case concern the material assessment of alleged (threat of) infringement, the possibility to raise, and the material assessment of, a nullity defence, and the demand to take into account the urgency for the provisional relief sought. The latter two issues will be further discussed under 2 and 3.

Further, it follows from Article 37(5) in connection with 35a(4) Draft Agreement that the Court shall ensure that interlocutory injunctions may, if necessary, be taken without the defendant having been heard (*ex parte*), in particular where any delay would cause irreparable harm to the right holder. In such event, the parties shall be so informed without delay after the execution of the measures at the latest. A review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable time after notification of the measures, whether those measures shall be modified, revoked or confirmed.

The EGA considers that the Rules should further specify how a request for an *ex parte* interlocutory injunction should be assessed. An ex parte injunction is a draconian measure which runs contrary to the principle that a party has a right to be heard and as such should be considered an exception rather than the norm. Accordingly, the Rules should set a high threshold for allowing a request for an *ex parte* interlocutory injunction and, after granting provide for a quick review of the case. This will be further discussed under 4, 5 and 6. In the EGA's view, the possibility for an alleged infringer to file a so-called 'protective letter' should be implemented.

The EGA considers that it would be just and equitable that an applicant be required as a matter of course to provide a cross-undertaking in damages when seeking to obtain a preliminary injunction so that if the main proceedings determine that the injunction should not have been granted then a Defendant is assured of being placed in the same position had the injunction not been granted.

2. Nullity defence in preliminary injunction action

Insufficient examination, financial and temporal constraints in Patent Offices may impede a complete accurate assessment of validity and result in low patent quality and the granting of erroneous patents and SPC's. To ensure timely generic market entry, it is paramount that generic companies can defend themselves against poor quality patents, and particularly within interlocutory injunction proceedings. If they cannot do so, generic companies will:

- either have to delay generic market entry until lengthy (and costly) revocation proceedings against the poor quality patents have been completed, possibly until after expiry of the poor quality patents,

- or face an interlocutory injunction on the basis of such poor quality patents if they try to legitimately enter the market after expiry of the originator company's valid (generally primary) patent(s) or SPC(s).

The above constitutes a bar to legitimate trade in the Internal Market. In order to strike the appropriate balance between protection of patent rights and the freedom of competition in the pharmaceutical sector it is therefore of crucial importance that:

- defendants in interlocutory injunction proceedings can raise an invalidity defence (i.e. the asserted patent does not meet the substantive criteria for patentability) in interlocutory injunction proceedings,
- the Court will seriously consider any such invalidity defence in interlocutory injunction proceedings, and
- such an invalidity defence can actually prevent the handing down of an interlocutory injunction.

3. Urgent interest requirement

In weighing up the parties' interests, in the EGA's view, the Court should also take into account whether the right-holder has an urgent interest in obtaining provisional injunctive relief. Typically, such measures are, after all, deemed to serve as a temporary order to cover the period until a decision on the merits is rendered: given the (serious threat of) imminent harm, the patent owner cannot await the outcome of such an action on the merits, and therefore a swift provisional decision is needed. There are good reasons why pursuant to Article 37(5) in connection with 35a(6) Draft Agreement, the patent owner is required to institute an infringement action on the merits within the term stated in that provision.

The demand for urgent interest should, however, be fair, and take due account of the legitimate position of the patent owner. However, patentees should not be allowed to remain passive in the full knowledge of a situation until an urgency arises. A low threshold for urgent interest, or even the absence of an urgency requirement, will have serious negative bearing on the balance between the protection of patent rights and the freedom of competition.

4. Threshold for allowing an *ex parte* interlocutory injunction

As noted above, an ex parte injunction is a very harsh mechanism which runs contrary to basic principles of law in order to provide equitable relief in situations of extreme urgency. In this light, the Rules should provide that the Court will only grant *ex parte* injunctions if it is satisfied that a permanent injunction will be, or at least is **highly likely** to be, granted in full proceedings on the merits, and that the patentee cannot reasonably await the outcome of *inter partes* interlocutory injunction proceedings. Furthermore, the Rules should also incorporate a duty of candour - demanding that an applicant provides all relevant information known to him to the court whether it is positive or negative to its case on the merits or an application for interim relief, including information regarding the

validity of the patent at issue. A failure to meet the duty of candour should also carry a sanction and/or an automatic discharge of the injunction.

5. Quick review of an *ex parte* interlocutory injunction

According to Article 37(5) in connection with 35a(5) Draft Agreement a review, including a right to be heard, shall take place upon request of the parties affected with a view to deciding, within a *reasonable* period after the notification of the measures, whether the measures shall be modified, revoked or confirmed.

In the EGA's view, the rules should specify what a reasonable period is. One must assume that if a patent owner has requested an interlocutory injunction, he is fully prepared to defend his case before a Court, even with the alleged infringer present. After all, the rationale for granting an interlocutory injunction on an *ex parte* base is not that the patent owner had insufficient time to prepare for *inter partes* proceedings, but rather the necessity to obtain an injunction on the shortest possible term. From that perspective, it is only equitable to have the review proceedings conducted on the short term also. By defining a short timeframe for conducting such review proceedings, the rules will also safeguard the interests of the alleged infringer. Of course, the rules should also take into account the calendar of the Court. Furthermore, the review only relates to the interlocutory injunction, meaning that the patent owner will still have ample time to prepare full proceedings on the merits.

6. Threshold for allowing an order to preserve evidence and to inspect property

The measures regarding preserving evidence and inspecting property as laid down in Article 35a Draft Agreement are far-reaching and may facilitate fishing-expeditions and lead to the disclosure of confidential material. As a result the material – possibly commercial (trade) secrets or company know-how – will potentially be disclosed to the requesting party or may even become public. This could cause irreparable harm to the opposing party and could be detrimental to competition[2]. Therefore, the threshold to order the evidential measures should in the EGA's view be high and the provisions should be interpreted restrictively so that the measures are only granted on good grounds. In order to do so sufficient guarantees against unjustified use, e.g. fishing expeditions, should be provided by clearly defining the applicable criteria in the rules.

[2] And – also – render a violation of Articles 8, 16 and/or 17(1) of the Charter of Fundamental Rights of the European Union (2000/C 364/01).

7. Threshold for allowing an order to produce evidence; clarification of criteria

According to Article 35 Draft Agreement, where a party has presented reasonably available evidence sufficient to support its claims and has, in substantiating those claims, specified evidence which lies in the control of the opposing party or a third party, the Court may order that party to produce such evidence. Such an order shall not result in an obligation of self-incrimination. This article thus concerns disclosure of 'specified evidence' which lies in the 'control' of the opposing party, when 'reasonably available evidence' has been presented. These terms require further clarification in the rules, also in the light of the similar concerns expressed in the above paragraph. The EGA recommends a restrictive interpretation of these terms. After all, Article 35 measures should only be granted on good grounds, given that an 'irreparable' situation arises after disclosure (a disclosure cannot be undone) and the detrimental effect it may have on (legitimate) competition[3].

Firstly, as to 'reasonably available evidence', it should be made clear in the rules that on the basis of the evidence presented, the Court is sufficiently convinced that an infringement has taken, or will take place.

Secondly, the term 'specified evidence' implies that a party has the knowledge that such evidence exists and moreover that the party also has knowledge of the content of the document to some extent. The interpretation of the criterion 'specified evidence' has impact on the scope of disclosure and is therefore an important guarantee to prevent fishing expeditions. Simply because the opposing party should be able to argue its position regarding the disclosure of the requested evidence, because the Court should weigh the interests of both parties, the requested evidence should be specified in a way that it is known to the opposing party what evidence is requested. Therefore, this should require the applicant to give a detailed description of the evidence in the control of the opposing party that is necessary for the substantiation of the infringement claim. A general indication of affected patents, or relevant chemical substances should not be sufficient.

Thirdly, the rules should provide further clarification regarding the term 'control'. In this respect it is noted that the term 'control' seems broader than 'in possession'. It is not clear either whether the opposing party can be obliged to undertake reasonable research for the evidence. 'Control', therefore, should not impose an obligation on the opposing party to carry out search activities. Furthermore, it should not cover evidence in the possession of a third party.

Furthermore, it is paramount that a party can only be obliged to disclose evidence - which possibly contains commercial trade secrets or company know-how - if the disclosure is necessary to prove the infringement.

Finally, given that an 'irreparable' situation arises after disclosure, an order for such disclosure should only be given in proceedings on the merits. A mere provisional assessment would provide insufficient guarantees against fishing expeditions and unwarranted disclosure of confidential information.

[3] See also footnote 2.