Making Medicines Affordable

BRIEFING PAPER ON THE DRAFT RULES OF PROCEDURE OF THE UNIFIED PATENT COURT- OCTOBER 2012

General Comments

- It is imperative that there is a balance in the Rules between the ability of patentees to enforce their rights and the principles of the Internal Market: freedom of movement and competition.
- This balance is 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.
- 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.
- Both parties to a patent dispute must have the right to be heard on all relevant issues.
- According to the Pharmaceutical Sector Inquiry Report, the mortality rate of pharmaceutical patents in revocation proceedings before national court is 55% (43 of 78 cases).
- Therefore, it is imperative that this system does not facilitate the granting of preliminary or final measures –that delay generic entry- without the Court having duly assessed the validity of the patent.

EGA proposals

1. Mitigating the harshness of bifurcation

The EGA considers that the bifurcated system that is proposed in the draft Agreement on a Unified Patent Court has the potential to produce anti-competitive effects unless sufficient safeguards are built into the Rules. As things stand, the Rules are drafted so as to allow the rights holder to have control over jurisdiction. We consider this to be an unfair imbalance to the system that will have detrimental effects on the generic pharmaceutical industry in particular, and that the system should be neutral rather than weighted towards one litigant.

- Nullity proceedings should be allowed to proceed whilst infringement proceedings are ongoing, rather than being stayed which is the default position under Rule 69.3.

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

- A decision on infringement of the local/regional division should not come into effect until the central division has rendered judgment where there are sound prospects that the central division will revoke the patent.
- A stay of proceedings should only be ordered due to there being an ongoing opposition at the EPO when "a rapid decision may be expected", as required in Article 15a(8) of the Agreement. Currently, Rule 370.1(a) does not mirror this requirement.
- Rule 70.3 provides that a patentee can strip jurisdiction from an applicant for declaratory relief. We consider this to be a biased provision that should be deleted.
- The announcement of the European Council dated 29 June 2012 stated that a defendant to an infringement proceeding should not be able to request a transfer to the central division unless they are domiciled outside of the European Union. We see no rationale for differential treatment that puts European parties at a strategic disadvantage.

2. Need for rules to guide on assessing claims for provisional injunctive relief

The major concerns of our members in respect of the current Rules relate to the grant of provisional injunctive relief. The current Rules allow for injunctive relief to be ordered without sufficient consideration of validity, urgency and the rights of both parties to be heard on relevant issues. In order to restore balance to the Rules, we consider that the Rules should:

- Prescribe that the court must assess validity and that if there is a finding that the patent is likely to be invalid then provisional relief should be refused. Rule 211.2 leaves a wide discretion to the courts, which currently have widely differing practice in relation to this crucial issue.
- Require that the right-holder has an urgent interest in obtaining provisional injunctive relief. Rule 209.2(b) only cites this issue as a discretionary factor.
- Set a high threshold for allowing a request for an *ex parte* interlocutory injunction (which is a draconian measure). This should only occur if it is highly likely that final relief will be obtained by the applicant. After such an order has been granted, the Rules should provide for a quick *inter partes* review of the case.
- Require a duty of candour from an applicant for an *ex parte* injunction – necessitating that all relevant information known to him is disclosed to the court, including as to the validity of the patent. A failure to meet the duty of candour should also carry a sanction and/or an automatic discharge of the injunction.
- Prescribe that an applicant must provide a cross-undertaking in damages in order to obtain provisional injunctive relief, so that if it is determined 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. Current Rule 211.4 only allows security to be ordered, which might not provide sufficient recompense.

3. Threshold for allowing an order to produce evidence: clarification of criteria

The EGA recommends a restrictive interpretation of these provisions given that a disclosure cannot be undone and may have detrimental effect on competition.

- Firstly, as to 'reasonably available and plausible evidence' (as recited in Rule 190.1), it should be specified 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' in Rule 190.1 implies that a party has knowledge of the content of the document. A detailed description should be required 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.
- 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, Rule 190 should provide that the court may take into account the interests and potential losses of third parties when considering the grant of provisional measures.

4. Court experts should be entirely independent

- We note that Rule 185.3 provides that court experts should be independent and impartial. However, in the interests of justice it should be expressly mandated that a court expert should have not have acted as an expert or court appointed expert in any litigation relied on or cited by any party in order to avoid a risk of bias.
- Rule 185.2 allows the parties to make suggestions as to the identity of court experts. However, it is possible for litigants to attain considerable knowledge of proposed court experts and their likely thought processes, preconceptions or even prejudices without having contacted them. We submit that this is not at all satisfactory and that the decision should be taken out of the hands of the parties altogether, in that they should only make submissions in relation to the professional qualifications, specialties and experience of the appropriate candidate and not as to their identity. It is notable that Article 34b(2) of the Agreement requires the court to maintain a list of appropriate court experts and we submit that this resource should be sufficient.

5. Reference to the CJEU

In line with the huge majority of industry we do not with the CJEU to be the ultimate arbiter of issues relating to the unitary patent and consider that Articles 6 to 8 of the proposed Regulation should be deleted, in line with the suggestion of the European Council. Should this lead to constitutional problems then we would suggest that the role is delegated to the Unified Patent Court by the CJEU.