



Making Medicines Affordable

POSITION PAPER

THE EUROPEAN GENERIC MEDICINES ASSOCIATION'S VIEWS ON THE EUROPEAN PATENT LITIGATION AGREEMENT (EPLA)

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1. Introduction

The EGA favours the principle of harmonising court decisions that lies behind the EPLA, but we are not sure if the EPLA is the right instrument to achieve this. As far as the costs of the EPLA are concerned, from the generic medicines industry perspective, legal costs would increase dramatically, thus probably rendering it difficult for any patentee that is not in a sound financial situation to defend its rights

In the EGA's view, the ideal patent system must be clear, transparent, cost-effective, and easy to operate, and feedback from the decisions taken should be used to inform the granting of patents. In addition to this, we would favour implication of national courts which operate at acceptable high international standards with qualified judges.

Our members are of the opinion that the EPLA, if necessary, must be clarified before being acceptable. As now drafted, it is difficult to support.

2. General Arguments in Favour

i) The EPLA will enable central revocation of identical patents. At present, once the nine-month opposition period is terminated, a patent granted by the EPO can only be invalidated by revocation proceedings in each country where the patent is in force. This leads to:

- high litigation/revocation costs for parties involved;
- legal uncertainty because national courts take different views and have different procedural rules;
- sophisticated and obstructive forum shopping to find the most favourable national/regional court;
- different levels of, or heads of, damages;
- on occasions, cross border injunctions;
- costly and complicated professional advice.

ii) Correspondingly, the resources of several national courts can be taken up on infringement and nullity actions on the same European patent.

iii) The present system is a disincentive to take out a European patent and, as such, puts the patent-holder/potential patent-holder at a disadvantage compared to a US counterpart. This frustrates the Lisbon Agenda of seizing the competitiveness initiative from the US.

iv) The fundamental aim and legislative basis of the EU is to form a Single Market, yet there are no centrally-enforceable patents in the EU and no uniform protection. The EPLA is not only a move in this direction, but is the only viable proposal for patent reform on the table.

v) There is an existing body of European patents which needs a cost-effective unitary litigation system, so the EPLA has merit regardless of whether the Community Patent comes into effect. Even if it does, European patents will still exist where for example a patentee wants less than five patents or to cover a non-EU Member State.



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3. General Arguments Against

High Costs:

The EPLA means enormous increase of litigation costs for SMEs, who typically act in their home country only. The situation of the new Member States is even much worse. In Hungary for example the average cost of litigation is about 20,000 EUR instead of the would-be average of 240,000 EUR at the EP Court.

The creation of a new supranational organisation is the main reason of the high costs.

Risk of 'double banking'¹:

Should the EPLA be viewed with distrust, then patentees may decide to double bank or simply to file national patents.

- Examination is worse or non existent in national offices and leads to differing claims scope between European patents and national patents. This leads to additional burden of uncertain risk.
- The enforceability of a national patent, when there is a parallel European patent, is reserved for national law under the EPC. So the EPLA cannot address this issue directly and there will be differences across the EPC contracting states. In most EPC states the national equivalent is allowed to coexist with the European patent, but has no legal effect, unless the European patent is revoked, at which point the national patent can then be asserted through national proceedings.

The self-financial scheme is a problem for the system:

The self-funding proposal is also of major concern: the system is intended to be self-financing so would need to generate revenue rather than concentrate on objectively sound decision-making. This echoes the EPO experience. It could also stimulate more litigation, rather than better quality consistent outcomes. The only solution is to charge enormous court fees. In addition, the court is likely to be an expensive office to maintain due to the language requirements - especially at the central court.

Courts do not usually have to drum up their own business, or finance their own expansion and investment. The main advantage to this approach is that the organisation can be well-resourced through its own efforts, but the organisational focus is then on financial planning and business expansion. That can work when demand is high, but when demand falls or changes, the focus is then on retrenchment with personnel and investment in innovation being the first areas under pressure. The critical nature and difficulties of planning ahead mean maintaining a well-resourced and influential planning function within the organisation.

None of this helps to retain the focus of the organisation on the core objective of the scheme: the fair dispensing of justice. Cost-effectiveness is vital, but being responsible for raising one's own revenue is an illusory independence.

¹ To 'double bank' is to file a national patent application in an European Patent Convention country and an identical, or near identical, patent application at the European Patent Office, or as a PCT application designating the EPO.



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Predominant role of the European Patent Office:

The EPLA preserves the institutional role of the European Patent Office/European Patent Convention which are not EU regulatory bodies and do not have frameworks which conform to EU specifications. Although said to be an alternative to the Community Patent, the EU will have less input and control than with the Community Patent.

One of the consequences is that the proposed European Patent Judiciary would lack independent judges and democratic control.

Judges will be appointed and supervised by the Administrative Committee which also sets the budget, and comprises representatives of the participant countries. This is not an EU body or regulated by it. The new Court of Appeal itself is the advisory council. It also retains within itself the right of judicial review of an appeal decision. So we have serious doubts about the degree of independence of the judges.

In addition to this, more details are required on the nature of the 1st instance regional divisions. If the present national courts are used, will they function as now or under a modified procedure with judges selected by the Administrative Committee? Will those judges be selected from the national judges? How much influence will the EPO have in the selection of judges?

The level of competence of the judges is unclear:

Patent cases are a complex mix of law and technology, and need somewhat different procedures from pure law cases. Judges will therefore need clear guidance, time to acquire expertise, time to listen to the complexities of the case, and competence to decide expeditiously but effectively. They would also have to understand issues of validity as well as infringement (the proposed European Patent Court under the CP proposals had also evoked concern for its level of competence).

Procedures and ability will still vary between national courts due to different legal traditions and the EPLA will not change this. A national court which can act as a regional EPLA court will inevitably have a different procedure depending upon whether the patent at issue is a national or an European Patent. This will lead to the need for further expert litigation skills and knowledge.

According to the EPO's commentary on the EPLA, decisions will be made by panels of three or five judges, one of which will be "technically qualified" and "two legally qualified". It is unclear what this means, particularly in the context of the EPO's role and the need for judges who are familiar with patent law and validity.

Forum shopping will not disappear

If infringement is being dealt with by one court, including the grant of injunctions, logically the issue of validity has to be dealt with in the same way. The patentee is therefore risking all patents in Member States at the same time. An inexperienced court could be capricious or could misapply the law, leading to the revocation of



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European-wide protection which then would have to be appealed. Certain European courts have substantial patent experience, and some have none. Even experienced courts have different characters, with some being more user-friendly for SMEs. Forum-shopping should therefore be allowed, which still occurs within the US federal court system.

The new Court of First Instance will have regional divisions set up in Member States, including up to three in larger states. De facto, courts will be set up in some states which do not already have patent courts operating to the best EU standards. According to the Agreement itself, the patentee will have the choice of proceedings in the regional division where it is domiciled or where the infringement allegedly occurred, so there will still be an element of forum shopping.

If a generic has a pan-European launch, then the patentee appears to be free to choose which country he brings an action in under the EPLA. Therefore, generics may only decide to first launch in countries where they like the local EPLA court.

Danger of bottle necks

It is unlikely that a central EPLA appeal court could handle all appeals from across all EPC Member States, at least initially, and significant delays in Second Instance could be anticipated.

Detailed Court Procedures are inexistent:

There are no draft Procedure Rules for the EPC to operate the EPLA (other than on basic matters such as the need for case-management and oral hearings). For example, the Agreement only refers to the “production” of documents and the “hearing” of witnesses form of pleadings and there is no information concerning:

- extent of disclosure and discovery;
- whether proper cross-examination of witnesses will be permitted (as opposed to the more discursive approach in opposition proceedings where cross-examination is discouraged);
- the court’s remit may exclude issues which then have to be adjudicated upon in parallel national proceedings, leading to further expense and time.

Loss of flexibility

After a seven-year transitional period, the EPLA will be a mandatory system with no option to use national court procedures if preferred or if considered more suitable.

4. Specific consequences for generic medicines producers

The biggest advantage of the EPLA could be its biggest disadvantage to generic medicines: a sound revocation decision in the EPC will lead, in a single action, to revocation in all relevant markets. An unsound decision will fail to achieve that, and will require appeal within the EPLA structure to the EPC’s Court of Appeal.



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Considering that the decision of the courts affects all Member States, there is a concern that if a company brings a badly prepared case forward and loses, it means all the Member States are affected and the market is closed for everyone. This raises the question of whether it will be possible to join existing actions in order to ensure as good as possible a case is put forward.

Moreover, the logic is that an injunction can be granted in one action for all relevant markets, so if it is a poor decision based, for example, on the standard of proof required by the 2004/48/EC Directive on enforcement of Intellectual Property Rights by civil measures, the generic “infringer” will be seriously disadvantaged. It is of course correct that the Directive was designed for transposition into national laws so is not directly applicable to the EPLA, but some of the wording on remedies is similar. There is a list of interim measures against an infringer contained in Part IV of the Draft EPLA Agreement which is also similar to the Directive, but in fairness, the Agreement appears to be tougher on the need for the discharge of an injunction where substantive proceedings are not commenced, and on safeguards against abuse of procedure. However, there is no reference to standard of proof, and there is also some confusion in that national courts retain the power to make these same orders on EPC matters. The latter would of course let in the element of variability which the EPLA is said to obviate.

5. Recommendations

i) In support of comments by Sharon Bowles, MEP at the Plenary Session of the European Parliament of 28 September 2006, the EGA recommends for the EPLA to minimise court fees as much as possible, rather than force litigants to bear all costs of judges’ salaries and the establishment cost of the appeal court. The entire proposed system of self financing should be revised.

ii) There is a need for detailed Procedure Rules, which should be transparent, easy to operate and that give due weight to the needs of both parties, including those with smaller resources than their opponents. Their aim is to achieve a fair result, but one which is also cost-effective and as expeditious as possible in complex matters.

iii) The role of the EPO in the EPC operating the EPLA highlights the absolute requirement for experienced, independent and well-trained patent judges, not simply in making decisions, but in training the next intake of judges and devising appropriate quality standards and procedural rule-revision. No-one is suggesting a monopoly of those Member States which already have well-respected patent courts, but there has to be an effective and transparent system for transference of skills and expertise to judges from Member States without that advantage. Alongside that is a quality assurance system which focuses on “Getting it Right First Time” - simply because in a unitary system, not achieving that has dangerous consequences for injured parties. It also does not promote respect for, or confidence in, the scheme, which in this case is meant to be a superior substitute for national proceedings of variable quality and value.

iv) We recommend full case management from the EPLA, with compulsory preliminary hearings to set a timetable, with target dates for the hearing and decision.



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v) We recommend clarity: all EPLA cases, including 1st instance, should have a simple and transparent Register of Proceedings that is open to the public. All decisions should be published. There should be public access to court submissions, which should only be denied for reasons of confidentiality.

vi) We would prefer if the national courts are not phased out after the seven-year transitional period.

vii) The European Patent Office has a crucial role within the EPLA, so for this reason its activities should be reviewed in the following way:

- There is a need for **higher standards in the selectivity of patents**. This could be obtained for example by giving incentives to examiners to refuse bad applications. The current system is biased towards granting, as it is more costly for examiners to grant than to refuse while they get no reward. There is a need to rebalance the reward system of examiners.
- **A separation of powers** would increase the independence of examiners consistent with the goal of improving patent quality
- Pressure on examiners (coming from patent attorneys, from the large number of applications, from applicants and from senior managers) should be mitigated.
- An **external audit check for patent quality** should be put in place.

6. Conclusion

If the patent system is to change, and there is no reason to oppose sensible change, the solution has to be demonstrably better than the situation it replaces. The draft EPLA Agreement and its commentaries clearly show the influence and power of the EPO, but are short on the important detail of how the scheme will work for practitioners and users.

The EPLA cost-base is unsuitable; its independence not guaranteed despite pious words in the preamble; its procedural rules are almost non-existent; and its quality of judiciary and decision-making are not provided for. That is not to say that these matters cannot be addressed, but it should not be left to guesswork when being asked to express support for radical reform. Without specific, well thought-out proposals and guarantees, the result may be another EPO Opposition procedure by another name, or a patchwork of regional/national divisions with contrasting styles and standards.

Finally, in the EGA's view a harmonised approach on patent litigation would only make sense if the civil procedure laws of the different EU states were similar, and if all the court systems in the EU had similar resources available, which is not the case right now. The main reason why we get different court decisions on the same issue is because civil procedural measures are different. As there is no harmonisation of legal procedures in Member States, rulings under the EPLA may simply add another layer of rules on how claims should be construed, and of tests for assessing patentability and infringement.



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Therefore, the crucial point would be to harmonise patent procedural law in order to obtain uniform procedural rules. This could be reached for example through an EC Directive.

If the EPLA in its current form is pursued further, we will have a very efficient system in place which might serve well to large multinational corporations that have English, French or German as their language. We doubt however that it will serve well the interest of all patentees, or the interest of all citizens and business of the EU Member States.