



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

POSITION PAPER

THE EUROPEAN UNION PATENT COURT

MARCH 2009



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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.

Patents play an important role in modern society. In order to encourage the creation, dissemination and efficient exploitation of technology, patents provide inventors with a limited term of legal monopoly on their invention. Generic medicines play an equally important role in promoting pharmaceutical innovation and ensuring the affordability and sustainability of European healthcare systems. In this regard, immediate market access of generic medicines after patent expiry is of crucial interest to society, and any hurdle to this access should be eliminated.

The underlying structure of the European Patent Convention (EPC) only provides for a common and single European patent application and granting system by the European Patent Office. Once granted, a European patent is not a unitary patent, but is essentially a bundle of national patents. As a result, questions of patent infringement and validity are governed by various national laws and are dealt with by the national courts under different procedural rules. There are no provisions in the EPC for a court with powers to settle patent disputes at European level. This purely national litigation system results in multiple patent suits involving high costs and complexity, forum shopping and uncertainty. As significant differences exist between the various national court systems and the way the courts handle patent cases, diverging and even contradictory decisions on the substance of cases are frequent. Many of these courts are not even equipped to hear patent cases due to a lack of training and experience. In addition, the application of the law varies widely, depending on the specific judge dealing with the case.

On 29 April 2004 the Directive 2004/48/EC of the European Parliament and of the Council on the enforcement of intellectual property rights (the 'IP Enforcement Directive') was approved with the aim to harmonise the various legislative systems so as to ensure a high, equivalent and homogeneous level of protection of intellectual property rights in the internal market. The IP Enforcement Directive, however, does not create a central judiciary composed of experienced judges properly equipped to deal with questions of validity and infringement on a pan-European basis. Patent enforcement remains a matter of national law and national courts. It is therefore very difficult for a generic medicines company to develop a European launch strategy. The only remaining option is very often to litigate on the same patent(s) and the same issue(s) in numerous countries, with no assurance that the same decision will be reached in each jurisdiction.

In this context, an effective solution would be the creation of a central European patent court that would deal with questions of invalidity and infringement at a pan-European level. Therefore, the EGA welcomes the initiative of the European Commission to create a European Union Patent Court, and would like to suggest some amendments to the proposed draft agreement. These amendments are aimed at improving the text as a whole and at contributing to create a more efficient system for the future.



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2. EXECUTIVE SUMMARY

The European Union Patent Court will ensure harmonisation of patent rights throughout its Member States, both in view of the scope of protection as well as in view of validity. However, it is important that the European Union Patent Court integrates experienced patent judges and supports and strengthens only valid patent rights and justified claims.

Also, due care of the public interest must be taken into consideration. This point is crucial in the case of the pharmaceutical industry since a decision regarding a patent covering a medicine will have great financial impact, not only on the companies involved, but also on consumers and the Member States.

In order to balance the rights of the patentee and the public interest, and in order to prevent abuse of patent rights, the EGA has suggested the above mentioned amendments to the present draft agreement on the European Patent Court. The following points are particularly important to the EGA:

- **Art. 7:** Composition of panels: a technically qualified judge should always be present; this should also be the case with panels of the local/regional divisions.
- **Art. 14e:** Introduction of the Bolar provision and the anti-patent linkage provision.
- **Art. 15a:** Validity and infringement of a patent should always be dealt with in the same proceedings at the same division, rather than in separate proceedings.
- **Art. 27(5):** In infringement actions filed by the holder of a licence, the patentee should always be part of the infringement proceedings or automatically become part of the infringement proceedings in case of a counterclaim for revocation in order to avoid separate proceedings.
- **Art. 33:** Means of evidence. Three points are important to the EGA here: a) the limitation to discovery; b) the adequate examination and cross-examination of witnesses at a hearing; and c) parties should be able to appoint their own experts.
- **Art. 35a:** Order to preserve evidence and to inspect property: the applicant should have to pay a security to ensure compensation for any prejudice suffered by the defendant.
- **Art. 37:** The EGA suggests adding two new provisions:
 - Sentence 2 in (2): *“the interest of other affected parties such as the public or the administration, not party in the litigation, should also be taken into account when deciding on provisional measures”*.
 - Provision (6) for damages to be paid by the patentee in case of an unjustified preliminary injunction.
- **Art. 37a(2):** Re-phrase this provision which now states that the injunction shall be subject to periodical penalty payments; it should be changed so that the penalty payments are due in case of non-compliance with the injunction.
- **Art. 41:** Damages or profits should be paid to the alleged infringer who was enjoined in 1st instance after which the 1st instance decision was revoked in appeal or where the patent was subsequently revoked.
- **Art. 58:** The opt-out provisions shall be deleted in order to have a common system for all patents, whether strong or weak.



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3. SUGGESTED AMENDMENTS TO THE DRAFT AGREEMENT

Article 5 | The Court of First Instance

(1) The Court of First Instance shall comprise a central division as well as local and regional divisions.

EGA Comment:

A dual system where the validity of a patent is dealt with by a central division and the infringement of the same patent is dealt with by local/regional divisions is clearly detrimental to the generic medicines industry.

As it is well known, validity is the main issue in many cases, and this tendency is expected to increase in the years to come in light of EPO practice (ie, an increase in granting secondary pharmaceutical patents). With a dual system, a very high risk exists of being subject to preliminary injunctions and infringement decisions whilst a decision on validity is pending before the (overloaded) central court. This would amount to a systematic delay to the entrance of generics onto the market.

Moreover, it is contrary to legal certainty that the patent be construed by different divisions for validity and infringement: the patent's scope could be different for validity than it is for infringement, which is not acceptable.

The EGA is therefore strongly against this dual system and suggests that both issues – infringement and validity – must always be dealt with by the same division. This can be done by either changing Art. 15a (Jurisdiction in respect of infringement and validity) or by not providing for a central division, but only for local/regional divisions with competencies for both validity and infringement.

Article 6

Composition of panels of the Court of First Instance

(2) Any panel of a local division shall sit in a composition of two permanent judges, who shall be nationals of the Contracting Party hosting the division concerned, and one judge from the Pool of Judges.

(4) Any panel of a regional division shall sit in a composition of two permanent judges chosen from a regional list of judges, who shall be nationals of the Contracting Parties concerned, and one judge from the Pool of Judges who shall not be a national of the Contracting Parties concerned.

(5) Without prejudice to paragraphs 2 and 4, any local or regional division may request, where appropriate, and after having heard the parties, the President of the Court to allocate from the Pool of Judges a technically qualified judge with qualifications and experience in the field of technology concerned. In cases where such a technically qualified judge is allocated, no further technically qualified judge has to be allocated under Article 15a, paragraph 2(a).



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EGA Comment:

In the current draft, the presence of a technically qualified judge is optional for local and regional divisions. As patents are a complex technical subject, this means that cases or preliminary injunctions might be decided without the proper technical criteria or insight, mainly because the technical judge may only be requested after hearing the parties. As a result, “ex parte” injunctions could be granted without a technically qualified judge having analysed the case. As many cases relate to infringement under the doctrine of equivalents, the technical complexity of the cases is great. The presence of a technically qualified judge in local/regional courts should be compulsory to achieve better final and provisional court decisions. We therefore suggest adding in paragraphs 2 and 4, that a technically qualified judge should also be on the panel, and, furthermore, that paragraph 5 is deleted.

EGA Proposal:

6(2) Any panel of a local division shall sit in a composition of two permanent Judges, who shall be nationals of the Contracting Party hosting the division concerned, and one technically qualified Judge with qualifications and experience in the field of technology concerned from the Pool of Judges.

6(4) Any panel of a regional division shall sit in a composition of two permanent Judges chosen from a regional list of Judges, who shall be nationals of the Contracting Parties concerned, and one technically qualified Judge with qualifications and experience in the field of technology concerned from the Pool of Judges who shall not be a national of the Contracting Parties concerned.

Delete paragraph 5

Article 9

The Advisory Committee

(2) The Advisory Committee shall comprise patent judges and practitioners in patent law and patent litigation with the highest recognised competence. They shall be appointed, in accordance with the procedure laid down the Statute, for a term of six years. They may be re-appointed.

EGA Comment:

The Advisory Committee has a very powerful function: it establishes a list of candidates to be appointed as judges of the Court. It is crucial that this Advisory Committee is absolutely neutral and should not be influenced. This is not guaranteed in the present draft. Practitioners in patent law, e.g. patent attorneys and lawyers, represent companies and there is a risk that these practitioners will choose judges for the list of candidates who suit them and their clients. The EGA suggests that in order to limit the risk of certain industries influencing the appointment of judges, the Advisory Committee be comprised only of judges. These are more likely to be neutral.

EGA Proposal:

(2) The Advisory Committee shall comprise patent judges ~~and practitioners in patent law and patent litigation with the highest recognised competence~~ (DELETE). They shall be appointed, in accordance with the procedure laid down the Statute, for a term of six years. They may be re-appointed.



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CHAPTER IIIA - SUBSTANTIVE LAW

Article 14a

Substantive patent law

For the purpose of litigation under this Agreement the Court shall base its decisions on:

- (a) this Agreement
- (b) Council Regulation (EC) No ... on the Community patent;
- (c) the European Patent Convention;
- (d) national law which has been adopted by the Contracting Parties to implement Article 65, Article 67, paragraphs 2 and 3 and Article 70, paragraphs 3 and 4, of the European Patent Convention;
- (e) any further provision of Community law and national law implementing Community law, as well as international agreements, applicable to patents, including Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

EGA Comment:

The various laws on which the Court will base its decisions are listed in article 14a. In line with the proposed Bolar provision in article 14e, EGA proposes the addition of Directive 2004/27/EC relating to medicinal products for human use.

EGA Proposal:

To add

NEW- 14a(i) Directive 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use.

Article 14e

Limitations to the effects of the European patent

The rights conferred by the European patent shall not extend to:

- (a) acts done privately and for non-commercial purposes;
- (b) acts done for experimental purposes relating to the subject-matter of the patented invention;
- (c) acts carried out solely for the purpose of conducting tests and trials in accordance with Article 13 of Directive 2001/82/EC¹ or Article 10 of Directive 2001/83/EC² in respect of any patent covering the reference product within the meaning of the said Directives;

¹ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, OJ L 311, 28.11.2001, p. 1.

² Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.



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EGA Comment:

The “Bolar” provision allows all development, testing and experimental work required for the registration of a generic and biosimilar medicine to take place during the patent period of the original product. The purpose of such a provision is to ensure that generic medicines are on the market immediately after patent expiry so as to improve access and encourage competition. The Bolar, as currently drafted in the EU Patent Court in Art. 14e(c), may lead to legal uncertainty due to its poor wording. However, the version proposed by the EGA is more complete and covers **the consequential practical requirements**. In 2003 the Council and the Commission in a Note from the Secretariat to the Permanent Representatives Committee, considered that *“the submission and subsequent evaluation of an application for a marketing authorization as well as the granting of an authorization are considered as administrative acts and consequently as falling out of the scope of patent protection.”*

Patent Linkage: the introduction of patent linkage presents the single biggest barrier to generic competition. Patent linkage is a regulatory scheme which prohibits the granting of market authorisation or price and reimbursement status to a generic medicine until all patents have expired, or until it has been determined that no patents are being infringed, or are invalid or unenforceable. This practice forces the scientific pharmaceutical experts at the medicines agencies and the price & reimbursement authorities to make necessarily ill-informed judgements on complex patent issues that normally can only be determined in specialised courts. Patent linkage is inconsistent with European law and must not be allowed to become ensconced in practice.

EGA Proposal:

~~DELETE article 14e(c) acts carried out solely for the purpose of conducting tests and trials in accordance with Article 13 of Directive 2001/82/EC³ or Article 10 of Directive 2001/83/EC⁴ in respect of any patent covering the reference product within the meaning of the said Directives;~~ and add a NEW ARTICLE:

14e bis NEW. *The necessary studies and trials with a view to the application of a marketing authorization in any Contracting Party, Member State or in third countries for a medicinal product and the consequential practical requirements, including the ones related to the active pharmaceutical ingredient, as well as the submission and subsequent evaluation of such an application for a marketing authorization and the granting of the authorization, shall not be regarded as contrary to patent rights or to supplementary protection certificates, in accordance with art.10.6 of Directive 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.*

³ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, OJ L 311, 28.11.2001, p. 1.

⁴ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.



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Article 14f

Right based on prior use of the invention

Any person, who, if a national patent had been granted in respect of an invention, would have had, in a Contracting Party, a right based on prior use of that invention or a right of personal possession of that invention, shall enjoy, in that Contracting Party, the same rights in respect of a European patent for the same invention.

EGA Comment

1. The addition of the following paragraphs is suggested in order to provide for a pan-European prior-use regulation which is not limited to a particular country. The wording below has been taken from UK Patent law.
2. Additionally, the possibility of including a definition of “effective and serious preparations” (present in the following paragraph) should be considered. It seems that most national laws don’t mention which acts are considered an effective and serious preparation. This is left to the discretion of the Courts, and at least in Spain there is no uniform criteria in this respect; consequently, generic medicines have suffered from diverging and unfair decisions.

EGA Proposal to add:

14f (2) Where a European patent is granted after the date referred to in Article 59 or a Community patent is granted for an invention, a person who in any Contracting Party before the priority date of the invention does in good faith an act which would constitute an infringement of the patent if it were in force, or makes in good faith effective and serious preparations to do such an act, shall have the rights conferred by paragraph (3) below.

14f(3) Any such person shall have the right:

(a) to continue to do or, as the case may be, to do that act himself; and

(b) if it was done or preparations had been made to do it in the course of a business, to assign the right to do it or to transmit that right on his death or, in the case of a body corporate on its dissolution, to any person who acquires that part of the business in the course of which the act was done or preparations had been made to do it, or to authorise it to be done by any partners of his for the time being in that business;

and the doing of that act by virtue of this paragraph shall not amount to an infringement of the patent concerned.

14f (4) The rights mentioned in [subsection \(3\)](#) above shall not include the right to grant a licence to any person to do an act so mentioned.

14f (5) Where a patented product is disposed of by any person to another in exercise of a right conferred by [paragraph \(3\)](#) above, that other and any person claiming through him shall be entitled to deal with the product in the same way as if it had been disposed of by a sole registered proprietor.



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Article 15 Competence

(1) The Court shall have exclusive competence in respect of:

- (a) actions for actual or threatened infringements and related defences, including counterclaims concerning licences, or for a declaration of non-infringement;
- (b) actions or counterclaims for revocation;
- (c) actions for damages or compensation derived from the provisional protection conferred by a published patent application;
- (d) actions relating to the use of the invention prior to the granting of the patent or to the right based on prior use of the patent;
- (e) actions for the grant or revocation of compulsory licences in respect of Community patents;
- (f) actions on compensation for licences within the meaning of [Article 20, paragraph 1] of Council Regulation (EC) No. ... on the Community patent;
- (g) actions relating to the grant or refusal of supplementary protection certificates issued for Community patents.

EGA comment:

1. The EGA further proposes that the EU Patent Court should also have competence to deal with unfair competition cases when brought up in patent infringement cases. It is common that in patent infringement cases one of the defences brought forward by the defendants is unfair competition issues. It makes sense to combine these arguments with the patent related issues and to deal with them in one proceeding to ensure quick and efficient proceedings.
2. Furthermore, to make a reference to “threatened” infringements generates legal uncertainty and is clearly detrimental to the generics industry. It also favours forum shopping. The EGA therefore proposes to delete the word “*threatened*” or to change it into “imminent” which is more concrete. This proposal for changing the word “threatened” applies to any use citing this term.

EGA proposal:

(1) The Court shall have exclusive competence in respect of:

- (a) actions for actual or ~~threatened~~ (DELETE) infringements and related defences, including counterclaims concerning licences, or for a declaration of non-infringement;



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Article 15a

Jurisdiction in respect of infringement and validity

(1) Actions for actual or threatened infringement, actions for damages or compensation, actions relating to the use of the invention prior to the granting of the patent or to the right based on prior use of the patent actions for the grant or revocation of compulsory licences and on compensation for licences, actions relating to the grant or refusal of supplementary protection certificates, and actions for provisional and protective measures or injunctions shall be brought before:

(a) the local division hosted by the Contracting Party where the actual or threatened infringement has occurred or may occur, or the regional division in which this Contracting Party participates; or

(b) the local division hosted by the Contracting Party where the defendant is domiciled, or the regional division in which this Contracting Party participates.

If the Contracting Party concerned does not host a local division and does not participate in a regional division, actions shall be brought before the central division.

(2) Where a counterclaim for revocation is brought in the case of an action for infringement, the local or regional division concerned shall, after having heard the parties, have the discretion to either:

(a) proceed with both the infringement action and with the counterclaim for revocation and request the President of the Court to allocate from the Pool of Judges a technically qualified judge with qualifications and experience in the field of technology concerned;

(b) refer the counterclaim for decision to the central division and suspend or proceed with the infringement proceedings; or

(c) with agreement of the parties, refer the case for decision to the central division.

(3) Direct actions for revocation or actions for declaration of non-infringement shall be brought before the central division. Such action may only be initiated if no action for infringement has been initiated between the same parties relating to the same patent before a local or a regional division.

(4) If an action for revocation is pending before the central division, an action for infringement between the same parties on the same patent may be initiated at any division, subject to paragraph 1. The local or regional division concerned shall have the discretion to proceed in accordance with paragraph 2.

(5) An action for declaration of non-infringement pending before the central division shall be terminated once an infringement action between the same parties related to the same patent is initiated within three months before a local or regional division.

(6) Parties may agree to bring an action before the division of their choice, including the central division.

(7) The action referred to in paragraph 3 can be brought without the plaintiff having to initiate an opposition procedure before the European Patent Office. In the case of pending opposition proceedings before the European Patent Office any party to an action before the Court shall inform the Court when it has requested accelerated proceedings before the European Patent Office. The Court may stay its proceedings when a rapid decision may be expected from the European Patent Office.



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EGA Comment:

The relationship between oppositions and post grant amendments with the European Patent Office (EPO) and invalidity proceedings with the EU Patent Court should be clarified: for example, what happens with an action or counterclaim for revocation if an opposition is pending before the EPO? What happens if the decision in the revocation proceedings differs from the decision in the opposition proceedings or the post grant amendment? What happens if a decision is taken at the EU Patent Court that the European Patent is limited or revoked?

The EGA proposes a clarification on the aspect relating to post grant amendments at the EPO: according to the European Patent Convention (EPC), a patentee is allowed to amend the claims of a granted European patent, ie, the “post grant amendments” at the EPO. These should not be possible in respect of any countries relevant to a patent for which the validity is challenged in the EU Patent Court. Amendment has to be sought only at the Court. In the event of an amended set of claims being held valid and infringed by the Court, the patentee must then seek post grant amendment at the EPO, otherwise the entire patent shall be declared invalid and no relief shall be granted under any claims held valid and infringed by the Court.

1. As already mentioned above under Art. 5, the EGA strongly suggests not to separate infringement actions and actions relating to the validity of a patent. Issues relating to the validity are practically always raised in infringement proceedings and, in order to avoid forum shopping, different interpretations of the patent in infringement and validity proceedings, unfair preliminary injunctions taken without regard of the invalidity case and, in order to avoid lengthy proceedings, these proceedings should be dealt with by the same division and a dual system of separate infringement and invalidity proceedings must be avoided, see below suggested changes.
2. Furthermore, invalidity actions and actions for the declaration of non-infringement should be included. This provision allows an opportunity for forum shopping to the party filing the action. This should be open also to the party seeking to invalidate a patent.

EGA Proposal:

(1) Actions for actual or threatened infringement, actions for damages or compensation, actions relating to the use of the invention prior to the granting of the patent or to the right based on prior use of the patent, **actions for the revocation of patents or supplementary protection certificates**, actions for the grant or revocation of compulsory licences and on compensation for licences, actions relating to the grant or refusal of supplementary protection certificates, and actions for provisional and protective measures or injunctions shall be brought before:

(a) the local division hosted by the Contracting Party where the actual or threatened infringement has occurred or may occur, or the regional division in which this Contracting Party participates; or

(b) the local division hosted by the Contracting Party where the defendant is domiciled, or the regional division in which this Contracting Party participates; or

(c) in the case of a revocation action, if the defendant (patentee) is not domiciled in any Contracting Party, the action should be brought before the local division hosted



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by the Contracting Party where the plaintiff is domiciled, or the regional division in which this Contracting Party participates.

(2) Where a counterclaim for revocation is brought in the case of an action for infringement, the local or regional division concerned shall, after having heard the parties, have the discretion to either:

(a) proceed with both the infringement action and with the counterclaim for revocation ~~and request the President of the Court to allocate from the Pool of Judges a technically qualified judge with qualifications and experience in the field of technology concerned; (DELETE) (according to the change proposed by the EGA, every division shall comprise a technically qualified judge)~~

(b) ~~refer the counterclaim for decision to the central division and proceed with the infringement proceedings; (DELETE) or~~

(c) with agreement of the parties, refer the case for decision to the central division.

Proposed change: **15a(4) *If an action for revocation is pending before the central division, an action for infringement between the same parties on the same patent may be initiated only at the central division.***

Art. 15a(5) allows forum shopping for the patentee and should not be allowed. The EGA proposes to delete this paragraph 5 or to amend it so that the subsequent infringement action is filed also at the central division.

Article 27 Parties

(1) Any natural or legal person, or any body equivalent to a legal person entitled to initiate proceedings in accordance with the applicable law of the Contracting Party concerned, shall have access to the Court in order to initiate actions, to defend itself against actions, or to seek application of the procedures and remedies provided for in this Agreement and in the Rules of Procedure.

(2) The holder of an exclusive licence in respect of a patent shall be entitled to initiate proceedings before the Court in the same way as the proprietor of a patent, provided that the proprietor is given prior notice, unless the licensing agreement provides otherwise.

(3) The holder of a non-exclusive licence shall not be entitled to initiate proceedings before the Court, unless the patent proprietor is given prior notice and in so far as expressly permitted by the licence agreement.

(4) In proceedings initiated by any licence holder, the patent proprietor shall be entitled to join them as a party.

(5) The validity of a patent cannot be contested in infringement proceedings initiated by the holder of a licence where the proprietor of the patent does not take part in the proceedings. The party in infringement proceedings wanting to contest the validity of a patent shall have to initiate proceedings against the proprietor.

(6) Any other natural or legal person, or any body equivalent to a legal person entitled to initiate proceedings in accordance with the applicable law of the Contracting Party concerned, who is directly and individually concerned by a patent, may initiate proceedings in accordance with the Rules of Procedure.



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EGA Comments:

1. For reasons of legal certainty, exclusive and non-exclusive licences should be recorded ones.
2. Regarding paragraph 4, it should be clarified that the patentee and other licensees will not be able to initiate further infringement proceedings (*lis pendens* and *res iudicata*).
3. Paragraph 2 allows for licensees (of exclusive licences) to initiate patent infringement proceedings. However, according to paragraph 5, revocation actions cannot be brought up in proceedings where the patentee does not take part. In such cases, the alleged infringer must initiate new proceedings against the patentee. However, most infringement actions will include revocation proceedings. Therefore, there may be abuse (payment of additional fees), and for this reason the EGA suggests that the patentee must always be part of the infringement proceedings or automatically become part of the infringement proceedings in case of a counterclaim for revocation.
4. It should be specified that any person who is concerned by a patent shall have access to the Court in order to initiate invalidity actions or actions for the declaration of non-infringement.

Article 29

Language of proceedings at the Court of First Instance

(1) The language of proceedings before any local or regional division shall be the official European Union language(s) of the Member State or the official language(s) of other Contracting States hosting the relevant division, or the official language(s) designated by Contracting States sharing a regional division.

(2) Notwithstanding paragraph 1, Contracting States may designate one or more of the official languages of the European Patent Office as the language of proceedings of their local or regional division.

(3) Parties may agree on the use of the language in which the patent was granted as language of proceedings, subject to approval by the competent division. If the division concerned does not approve their choice, the parties may request that the case be referred to the central division.

(4) [At the request of one of the parties and after having heard the other parties] / [With the agreement of the parties] the competent local or regional division may, on grounds of convenience and fairness, decide on the use of the language in which the patent was granted as language of proceedings.

(5) The language of proceedings at the central division is the language in which the patent concerned was granted.



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EGA Comment:

If the language of proceedings at the Court of First Instance and the Court of Appeal is the language of the division and the parties cannot agree to use the language in which the patent concerned was granted, then the division shall provide, on request of one of the parties, interpretation of the proceedings into the language in which the patent concerned was granted. The costs for the interpretation shall be borne by the division.

Art. 29(4) now includes the possibility that the language is changed “at the request of one of the parties and after having heard the other parties”. The language should only be changed with the agreement of ALL parties.

Article 33

Means of evidence

(2) The Rules of Procedure shall govern the procedure for taking such evidence. Questioning of witnesses and experts shall be under the control of the Court and be limited to what is necessary.

EGA Comment

The EGA would like to make some recommendations on the Rules of Procedure that will govern the procedure for taking evidence according to paragraph 2).

1. The rules must provide a framework for limitations to discovery.
2. Adequate examination and cross-examination of witnesses at hearings is essential.
3. Hearings should not be short nor result in an inaccurate decision because the true facts are not determined through adequate examination of the witnesses. Parties should be able to appoint their own experts who should both advise the Court and be available for examination and cross-examination on the issues in dispute. The EGA recommends avoiding the model of the EPO-type of one day hearing without examination.

Article 34

Reversal of burden of proof

(1) If the subject-matter of a patent is a process for obtaining a new product, the identical product when produced without the consent of the proprietor shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process.

(2) The same shall apply if there is a substantial likelihood that the identical product was made by the process and the proprietor of the patent has been unable, despite reasonable efforts, to determine the process actually used.

(3) In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and trade secrets shall be taken into account.



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EGA Comment:

1. In para 1, the EGA suggests including the term “substance” in addition to the term “product”.
2. Paragraph 2 is likely to be abused and is not common in all the current laws of Contracting Parties. The EGA considers that this article is not necessary due to the existence of Art. 35(1) which states that the Court may order a party to produce evidence under certain circumstances. Therefore, we suggest deleting paragraph 2.
3. Additionally, the EGA suggests introducing a new paragraph 4. The purpose of this amendment is to avoid cases, of which there are many examples, where it is very difficult, due to missing information, to show that the patent was invalid. If such evidence could have been required from the patent owner or from other authorities/third parties, the case would have been much easier. For these reasons, patent challengers should have the same facilities as the ones provided to patent proprietors in point 2. We are against the fact that procedural rules allow an invalid right to be defended and consider that the right of a patentee to gather information to assess infringement is sufficiently provided for under Article 35(1).

EGA Proposal

1. 34(1) If the subject-matter of a patent is a process for obtaining a new product or substance, the identical product or substance when produced without the consent of the proprietor shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process.

2. **DELETE: article 34 par(2)**

3. ***New paragraph 34(4) In actions or counterclaims for revocation of patents or Supplementary Protection Certificates (SPCs), where the proprietor of the patent/SPC and/or any other third parties have evidence which is not available to the party pursuing the revocation and this evidence is prima facie relevant for the assessment of the patentability of the patent/SPC, the Court shall request that party or parties to provide this evidence.***

Article 35a

Order to preserve evidence and to inspect property

(1) The Court may, even before the commencement of proceedings on the merits of the case, on application by a party who has presented reasonably available evidence to support the claim that the patent right has been infringed or is about to be infringed, order prompt and effective provisional measures to preserve relevant evidence in respect of the alleged infringement.

(2) Such measures may include the detailed description, with or without the taking of samples, or the physical seizure of the infringing goods, and, in appropriate cases, of the materials and implements used in the production and/or distribution of these goods and the documents relating thereto.

(2a) The inspection of the premises shall be conducted by a person appointed by the Court in accordance with the Rules of Procedure.



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(3) At the inspection of the premises the requesting party shall not be present itself but may be represented by an independent professional practitioner whose name has to be specified in the Court's order.

(4) The measures shall be taken, if necessary without the other party having been heard, in particular where any delay is likely to cause irreparable harm to the proprietor of the patent, or where there is a demonstrable risk of evidence being destroyed.

(5) Where measures to preserve evidence are adopted without the other party having been heard, the parties affected shall be given notice, without delay and at the latest immediately after the execution of the measures. 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.

(6) The Court shall ensure that the measures to preserve evidence are revoked or otherwise cease to have effect, upon request of the defendant, without prejudice to the damages which may be claimed, if the applicant does not initiate, within a period not exceeding 20 working days or 31 calendar days, whichever is the longer, proceedings leading to a decision on the merits of the case before the Court.

(7) Where the measures to preserve evidence are revoked, or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of the patent right, the Court may order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by those measures.

EGA Comment:

The person requesting such measures to preserve evidence should be obliged to properly justify why the evidence is at risk and needs to be preserved. This should be specified for example in the Rules of Procedure.

1. Regarding para 2, a full physical seizure of the goods, materials, etc. is in fact a preliminary injunction, taking a sample of the possibly infringing goods must be sufficient.
2. Regarding para 3, the EGA understands that the "independent professional practitioner" should be a neutral person provided by the court, and should not be a representative of the requesting party. If the "independent professional practitioner" is a representative of the requesting party, then confidential information obtained during the inspection of the premises could be misused. It is important to protect confidential information of the alleged infringer and to avoid abuses of the law to illegally obtain information. The EGA suggests to either delete the phrase as shown above or to specify that the independent professional practitioner did and will not represent the requesting party in this case.
3. The EGA proposes to enter a new para (5a): A bond should be placed in advance by the applicant before proceeding with the measures in order to cover expenses and avoid abuse. If no action is filed afterwards without proper justification, the applicant should lose the bond in favour of the other party.
4. In para. 7, the word "may" should be changed to "shall". See also below Art. 37 (6).



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EGA Proposal:

Proposal 1. (2) Such measures may include the detailed description, with or without the taking of samples, or the physical seizure of **only that amount of** the infringing goods **necessary to preserve evidence**, and, in appropriate cases, the materials and implements used in the production and/or distribution of these goods and the documents relating thereto.

Proposal 2. (3) At the inspection of the premises the requesting party shall not be present ~~itself but may be represented by an independent professional practitioner whose name has to be specified in the Court's order.~~ (DELETE)

Proposal 3. (5a) **NEW** The Court shall order that the measures to preserve evidence are subject to the lodging by the applicant of adequate security or an equivalent assurance intended to ensure compensation for any prejudice suffered by the defendant as provided for in paragraph 7.

Proposal 4. 35a (7) Where the measures to preserve evidence are revoked, or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of the patent right, the Court **shall** order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by those measures.

Article 36

Court experts

(1) Without prejudice to the possibility for the parties to produce expert evidence, the Court may at any time appoint court experts in order to provide expertise for specific aspects of the case.

EGA Comment:

This should be also upon request of one of the parties.

(4) Expert advice given to the Court shall be made available to the parties who shall have the possibility to comment on the advice given.

EGA Comment:

Cross-examination should be possible.

Article 37

Provisional and protective measures

(1) The Court may grant injunctions against an alleged infringer or against a third party whose intermediary services are used by the alleged infringer, on a provisional basis, intended to prevent any impending infringement, to forbid the continuation of the alleged infringement or to make such continuation subject to the lodging of guarantees.

(2) 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.

(3) The Court may also order the seizure or delivery up of the goods suspected of infringing a patent right so as to prevent their entry into or movement within the channels of commerce. If the injured party demonstrates circumstances likely to endanger the



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recovery of damages, the Court may order the precautionary seizure of the movable and immovable property of the alleged infringer, including the blocking of his/her bank accounts and other assets.

(4) The Court may, in respect of the measures referred to in paragraphs 1 and 3, require the applicant to provide any reasonable evidence in order to satisfy itself with a sufficient degree of certainty that the applicant is the right-holder and that the applicant's right is being infringed, or that such infringement is imminent.

(5) Article 35a, paragraphs 4 to 7 shall apply by analogy to the measures referred to in this Article.

EGA Comment:

Preliminary injunctions are currently abused by large companies and are often used to unjustly block other (generic medicines) companies from entering the market. Even if later compensation is provided for when the infringement was held not to occur or the patent was held invalid, the generic company does not come back to the state it would have had if the preliminary injunction had not been granted. Therefore, it is crucial that safeguards against misuse of provisional methods be introduced.

“The potential harm” mentioned in Art. 37(2) is a subjective parameter which could benefit one side, more often the patentee. The Court should assess invalidity (if raised by the defendant), infringement and urgency. The court should only grant a preliminary injunction if, after having heard the defendant, the patent appears presumably valid and infringed, and a real situation of urgency is justified.

1. In addition, the EGA suggests entering a second sentence in paragraph 2 in order to take the interest of consumers and/or healthcare funds or governments into consideration and to weigh up the bigger earnings of innovators (patent owners) vs. generic companies (defendants). Otherwise, preliminary injunctions may be granted too often.
2. The conditions set by paragraph 4 should be met to avoid abuses on the grant of provisional measures. Instead of “may”, the EGA suggests using the word “shall”.
3. The EGA suggests adding an additional paragraph 6 to stop current abuse of the allowance of preliminary measures as a blocking strategy, when the applicant of such measures knows that the claim is unjustified. The aim of this amendment is to take into account unfair profits made by the party requesting the abusive preliminary measures. Furthermore, it would be fair and balanced to apply the same criteria to requests for damages and to requests for compensations to unfair provisional measures. Abuses are due precisely to the fact that the requesting party usually earns much more money by obtaining unfair provisional measures and afterwards minimally compensating the affected party which could hardly justify its losses by not having been present on the market, than by accepting the presence of the party on the market and having to compete at lower prices. This leads to provisional measures being asked as a litigation strategy and, quite frequently, the sole objective of the litigation is to achieve these lucrative provisional measures. This is particularly the case in the pharmaceutical industry for markets such as the UK, which are tender driven: if a generic company is awarded a tender contract in the UK, launches the product, and is then enjoined, the tender penalties can be very large for periods of about 1 year (which is a typical tender contract period). The penalties are large because the generic medicines company will likely have to buy supplies at innovator prices to satisfy the tender contract.



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EGA Proposal:

Proposal 1. 37(2) 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 interest of other affected parties such as the public or the administration, not party in the litigation, should also be taken into account.**

Proposal 2. 37(4) The Court ***shall***, in respect of the measures referred to in paragraphs 1, 2 and 3, require the applicant to provide reasonable evidence in order to satisfy itself with a sufficient degree of certainty that the applicant is the right-holder and that the applicant's right is being infringed, or that such infringement is imminent.

Proposal 3. ***37(6) new To calculate compensations according to point (5) when applying Article 35a(7), the criteria established in Article 41(3)(a) to set the damages shall apply mutatis mutandis and the Court shall take into account all appropriate aspects, such as the negative economic consequences, including lost profits, which the party subject to the provisional measures has suffered, any unfair profits made by the party requesting the provisional measures and, in appropriate cases, elements other than economic factors, such as the moral prejudice caused to the party subject to the provisional measures.***

Article 37a

Permanent injunctions

(1) Where a decision is taken finding an infringement of a patent, the Court may grant an injunction aimed at prohibiting the continuation of the infringement. The Court may also grant such injunctions against an intermediary whose services are being used by a third party to infringe a patent right.

(2) Where appropriate, such injunction shall be subject to a periodic penalty payment payable to the Court with a view to ensuring compliance.

EGA Comment

Art. 37a(2) should be re-phrased in accordance with the IP Enforcement Directive 2004/48/EC. The penalty payment should be imposed only when the alleged infringer does not comply with the injunction. According to the current phrasing, the periodic penalty payment shall be paid in addition to the injunction.

EGA Proposal

37a(2). Where appropriate, **non-compliance with** such an injunction shall be subject to a periodic penalty payment payable to the Court with a view to ensuring compliance.

Article 38a

Decision on invalidity of a patent

(1) The Court shall decide on the validity of a patent on the basis of a direct action for revocation or a counterclaim for invalidity.



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EGA Comment:

The defendant should be able to raise invalidity also as a defence only (inter partes), without necessarily filing an invalidity counterclaim seeking the cancellation of the patent (erga omnes).

Article 39

Power to order the communication of information

(1) The Court may, in response to a justified and proportionate request of the plaintiff and in accordance with the Rules of Procedure, order an alleged infringer of the patent to inform the plaintiff of:

- (a) the origin and distribution channels of the infringing goods or processes;
- (b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the goods in question; and
- (c) the identity of any third person involved in the production or distribution of infringing goods or in the use of an infringing process.

EGA Comment:

Art. 39 is likely to be abused. More warranties for the alleged infringer are desirable. An order of communication of information should be issued only after the (positive) decision on infringement has been taken. If not, confidential information could (and will be) accessible by any patent holder even before the court has decided on infringement. This should not be possible. The EGA proposes the following amendments:

EGA Proposal:

39(1) The Court may, in response to a justified and proportionate request of the claimant and in accordance with the Rules of Procedure and after infringement has been ascertained by the Court, order a party ~~(allegedly)~~ **(DELETE)** infringing the patent to inform the claimant of:

Article 41

Award of damages

(1) The Court may, at the request of the injured party, order the infringer who knowingly, or with reasonable grounds to know, engaged in a patent infringing activity, to pay the injured party damages appropriate to the prejudice actually suffered as a result of the infringement.

(2) The injured party shall, to the extent possible, be restored in the position it would have been in if no infringement had taken place. The infringer shall not benefit from the infringement. However, damages shall not be punitive.

(3) When the Court sets the damages:

(a) it shall take into account all appropriate aspects, such as the negative economic consequences, including lost profits, which the injured party has suffered, any unfair profits made by the infringer and, in appropriate cases, elements other than economic factors, such as the moral prejudice caused to the injured party by the infringement; or



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(b) as an alternative to (a), it may, in appropriate cases, set the damages as a lump sum on the basis of elements such as at least the amount of the royalties or fees which would have been due if the infringer had requested authorisation to use the patent in question.

(4) Where the infringer did not knowingly or with reasonable grounds to know engage in infringing activity, the Court may order the recovery of profits or the payment of compensation.

EGA Comment:

1. In para (1), the EGA proposes to delete the phrase “or with reasonable grounds to know” because it would be a fairer warranty for the alleged infringer if it only said “knowingly”.
2. The payment according to paragraph 4 is not different from the payment according to paragraph 1 in the case of “knowingly infringing”. To limit it to the profits of the infringer or to a compensation in the amount of royalties would be fairer. Damages should be deleted.
3. In addition to damages or compensations being paid by the infringer to the patentee, damages or compensations should also be paid to the alleged infringer who was enjoined in 1st instance after which the 1st instance decision was revoked in appeal or where the patent was subsequently revoked. These damages could be calculated in accordance to Art. 41 (see also Art. 37 where new paragraph 6 was suggested in order to stop abuses of preliminary injunctions). The payment of such damages is considered essential to prevent abuse of the Patent Court by the patentee. As mentioned for Art. 37, a decision enjoining a pharmaceutical (generic) company can cause huge damages (particularly in tender driven markets). It should make clear that the injured/enjoined party should be restored as much as possible to the position it would have enjoyed had no infringement taken place.

EGA Proposal:

Proposal 1. 41(1) The Court may, at the request of the injured party, order the infringer who knowingly, ~~or with reasonable grounds to know (DELETE)~~, engaged in a patent infringing activity, to pay the injured party damages appropriate to the prejudice actually suffered as a result of the infringement.

Proposal 2. 41(4) Where the infringers did not knowingly, or with reasonable grounds to know, engage in infringing activity, the Court may order the recovery of profits or the payment of a compensation in the amount of royalties ~~or the payment of damages (DELETE)~~.



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Article 42

Legal costs

(1) Reasonable and proportionate legal costs and other expenses incurred by the successful party shall, as a general rule, be borne by the unsuccessful party, unless equity requires otherwise.

EGA Comment:

The EGA suggests that costs be set to the amount of 80% of the reasonable and proportionate legal costs, following the line of the UK system. This would benefit the smaller litigants.

EGA Proposal:

42(1) **80% of the** reasonable and proportionate legal costs and other expenses incurred by the successful party shall, as a general rule, be borne by the unsuccessful party, unless equity requires otherwise.

Article 44a

Period of limitation

The EGA proposes the following insertion:

Art.44a. Proceedings relating to use, to the right based on prior use, to infringement and to damages referred to in the this Chapter may be initiated until five years from the date on which the requesting party became, or had reasonable grounds to become, aware of the facts justifying the proceedings. ***After that date, the above referred proceedings cannot be initiated.***

Article 45

Appeal

EGA Comment:

1. An appeal should also be possible against orders according to Art. 38 (corrective measures in infringement proceedings) and Art. 41 (award of damages). The EGA suggests adding these.
2. The EGA suggests that, instead of having to file an appeal within 15 days after notification of an order, the term should be extended to 30 days.

EGA Proposal:

45(1) An appeal against a decision of the Court of First Instance may be brought before the Court of Appeal by any party which has been unsuccessful, in whole or in part, in its submissions. An appeal may be brought against a final decision of the Court of First Instance or against an order referred to in Articles 35, 35a, 35b, 37, **38**, 39 or **41**.

45(2) An appeal may be brought within two months of the notification of a final decision of the Court of First Instance or within ~~fifteen~~ **(DELETE)** *thirty* calendar days of the notification of an order referred to in paragraph 1.



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Article 54

Publication of decisions

The Court may order, at the request of the applicant and at the expense of the infringer, appropriate measures for the dissemination of the information concerning the decision, including displaying the decision and publishing it in full or in part in public media.

EGA Comment:

In the opinion of the EGA, the original drafting of this article is clearly unbalanced in favour of patent/SPC proprietors.

1. The EGA suggests instead the following wording in order that also the alleged infringer can publish a decision which is in his favour (regarding non-infringement or invalidity of the patent) which is possible in various Member States.
2. Further, the applicant should properly justify why publication is necessary in the concrete case.

EGA proposal:

54 (new). *The Court may order, at the request of the successful party and at the expense of the losing party, appropriate measures for the dissemination of the information concerning the decision, including displaying the decision and publishing it in full or in part in public media.*

Article 58

Transitional period

(4) Unless proceedings have already been initiated before the Court, holders of European patents granted prior to the date referred to in Article 59 shall have the possibility to opt out from the application of Article 3. To this end they shall notify their opt-out to the Registry by the latest one month before expiry of the transitional period.

EGA Comment:

The original drafting of that article is unbalanced in favour of patent/SPC proprietors. What is proposed allows patent proprietors to use the new system at their discretion. If they have a strong "old" patent, they can benefit from the extensive and powerful means for fighting infringers of the Agreement (by not opting it out). If their patent is weak and they fear either revocation actions or counterclaims for revocation, they can "opt out" the patents granted before the date. According to Article 59, they would be out of the scope of the Agreement and hence free from a centralized route for revocation. This constitutes a discriminative treatment in favour of patent holders. The benefits of a centralized path for revocation should be available from the first day for all EP patents, as weak patents are an unfair obstacle to competition in the EU and what should be rewarded is true innovation, not unfair rights.

EGA proposal: **DELETE 58(4)**



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Draft Statute of the European Union Patent Court

CHAPTER I - JUDGES

Article 3 Appointment of judges

(1) Pursuant to the procedure set out in Article 11 of the Agreement, judges shall be appointed by the Mixed Committee acting by common accord on the basis of proposals from the Advisory Committee and, as far as nationals of the Member States of the European Union are concerned, from the Council.

See comments above concerning the Advisory Committee.

Preliminary List of Topics to Include in the Rules of Procedure of the European Union Patent Court

II. Procedure

EGA Comment:
ALL OF THIS SHOULD BE PART OF THE AGREEMENT, AND NOT PART OF THE RULES OF PROCEDURE OF THE COURT.

1. Written procedure
2. Interim procedure
3. Oral procedure
4. Electronic procedures
5. Obtaining evidence
6. Provisional and permanent injunctions
7. Settlement
8. Stay of proceedings
9. Expedited proceedings
10. Discontinuance of proceedings
11. Decisions
12. Legal costs
13. Legal aid
14. Serving of documents
15. Time limits