Making Medicines Affordable

POSITION PAPER

RESPONSE TO THE EUROPEAN COMMISSION'S QUESTIONNAIRE ON THE PATENT SYSTEM IN EUROPE

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1. Section I - Basic principles and features of the patent system

The idea behind the patent system is that it should be used by businesses and research organisations to support innovation, growth and quality of life for the benefit of all in society. Essentially the temporary rights conferred by a patent allow a company a breathing-space in the market to recoup investment in the research and development which led to the patented invention. It also allows research organisations having no exploitation activities to derive benefits from the results of their R&D activities. But for the patent system to be attractive to its users and for the patent system to retain the support of all sections of society it needs to have the following features:

- clear substantive rules on what can and cannot be covered by patents, balancing the interests of the right holders with the overall objectives of the patent system
- transparent, cost effective and accessible processes for obtaining a patent
- predictable, rapid and inexpensive resolution of disputes between right holders and other parties
- due regard for other public policy interests such as competition (anti-trust), ethics, environment, healthcare, access to information, so as to be effective and credible within society.

1.1. Do you agree that these are the basic features required of the patent system?

Yes.

1.2. Are there other features that you consider important?

a) Expertise of patent examiners in specific areas such as pharmaceutical patents would be very desirable.

b) In the case of pharmaceuticals, while considering the patent application, examiners should take non-patent literature into account such as regulatory guidelines which have an impact on many pharmaceutical patents.

c) Litigation scheme: it would be desirable to have a thorough, fair and rapid court system for infringement and revocation actions with a judiciary that is scientifically literate with regards to pharmaceuticals.

d) Litigation and enforcement should be swift, efficient, transparent and judicious with the optimal mix of technical and legal measures.

e) As regards competition protection, particular attention should be paid to preventing and combating anti-competitive practices, especially those involving abuse of dominant position (Art. 82 of the EC Treaty).

1.3. How can the Community better take into account the broader public interest in developing its policy on patents?

Role of the Patent offices:

Patent offices need more time to examine patents, and should not require examiners to grant patents in order to obtain their objectives and thus receive bonuses. A thorough, fair and rapid review of patents by patent offices based upon experimental results as well as prior art is necessary. The system should ensure that only patents backed by sound evidence (similar to marketing authorisations) are granted, instead of weak patents based upon an inadequate examination. Poor patent quality and legal standards may inadvertently create market power and reduce innovation.

- *We suggest that patent offices of the Member States reward examiners for those patents that survive legal action and penalise for those that are revoked.*
- *The provision of false information to the EPO/National Patent Office should be made an offence against the Community with truly punitive penalties delivered against the abuser (both financial and time limitations on the ability to apply for new patents).*

Role of generic medicines/public interest:

The European generic medicines industry is beneficial to national healthcare systems by providing high-quality affordable medicines to millions of Europeans as well as encouraging valuable competitiveness and innovation in the pharmaceutical sector. The patent system must not be used to restrict competition from generic medicines by granting weak patents.

Role of Member State National Health authorities:

- *It is necessary to be aware that it is the Member State National Health authorities that are actually paying for medicines that are protected by weak or false patents.*

2. Section II – The Community patent as a priority for the EU

The Commission's proposals for a Community patent have been on the table since 2000 and reached an important milestone with the adoption of the Council's common political approach in March 2003
[http://register.consilium.eu.int/pdf/en/03/st07/st07159en03.pdf; see also http://europa.eu.int/comm/internal_market/en/indprop/patent/docs/2003-03-patentcosts_ en.pdf].
The disagreement over the precise legal effect of translations is one reason why final agreement on the Community patent regulation has not yet been achieved. The Community patent delivers value-added for European industry as part of the Lisbon agenda. It offers a unitary, affordable and competitive patent and greater legal certainty through a unified Community jurisdiction. It also contributes to a stronger EU position in external for a and would provide for Community accession to the European Patent Convention (EPC). Calculations based on the common political approach suggest a Community patent would be available for the whole of the EU at about the same cost as patent protection under the existing European Patent system for only five states.

Question

2.1 By comparison with the common political approach, are there any alternatives or additional features that you believe an effective Community patent system should offer?

The Community patent system could be a valuable tool for the European generic medicines industry, but only if enacted and supported by a Community Patent Court dealing with infringement/revocation actions against Community patents.

Moreover, it is essential that this centralised court be comprised of integrate competent judges who are experts in patent law and knowledgeable in the field of science, as well as specialised attorneys.

3. Section III – The European Patent System and in particular the European Patent Litigation Agreement

Since 1999, States party to the European Patent Convention (EPC), including States which are members of the EU, have been working on an agreement on the litigation of European patents (EPLA). The EPLA would be an *optional* litigation system common to those EPC States that choose to adhere to it.
The EPLA would set up a European Patent Court which would have *jurisdiction* over the validity and infringements of European patents (including actions for a declaration of non infringement, actions or counterclaims for revocation, and actions for damages or compensation derived from the provisional protection conferred by a published European patent application). National courts would retain jurisdiction to order provisional and protective measures, and in respect of the provisional seizure of goods as security.
For more information see:
[http://www.europeanpatentoffice.org/epo/epla/pdf/agreement_draft.pdf].
Some of the states party to the EPC have also been tackling the patent cost issues through the London Protocol which would simplify the existing language requirements for participating states. It is an important project that would render the European patent more attractive.
The European Community is not a party to the European Patent Convention. However there is Community law which covers some of the same areas as the draft Litigation Agreement, particularly the "Brussels" Regulation on Recognition and Enforcement of Judgments (Council Regulation no 44/2001) and the Directive on enforcement of intellectual property rights through civil procedures (Directive 2004/48/EC). [http://europa.eu.int/eurlex/pri/en/oj/dat/2004/l_195/l_19520040602en00160025.pdf] It appears that there are three issues to be addressed before EU Member States may become party to the draft Litigation

Agreement:

1. The text of the Agreement has to be brought into line with the Community legislation in this field.
2. The relationship with the EC Court of Justice must be clarified.
3. The question of the grant of a negotiating mandate to the Commission by the Council of the EU in order to take part in negotiations on the Agreement, with a view to its possible conclusion by the Community and its Member States, needs to be addressed.

Questions:

3.1 <u>What advantages and disadvantages do you think that pan-European litigation arrangements as set out in the draft EPLA would have for those who use and are affected by patents?</u>

Advantages:

- *The current judicial system for the review of infringement cases is not uniform across the Community and in some jurisdictions patents are upheld whilst in others patents are revoked, usually on the same grounds. In addition to this, the costs of fighting actions in 25 jurisdictions are quite significant. Generic medicines companies usually cannot afford to fight such actions across Europe and in legal systems which are "foreign". Only the originator companies can afford such a response.*

- *The costs of enforcing IP and challenging infringement through litigation in the current system are prohibitively high, especially for small and medium-sized enterprises.*

- *If a centralised Patent Court handling post-grant litigation is introduced, the burden of litigation in each Member State as well as the prohibitive cost of litigation, which sometimes cause the development of generic products to be abandoned, will disappear. The problem of non-harmonised or divergent rulings by multiple national courts in various countries will also disappear.*

- *If the centralised Court declares a patent invalid, the generic industry will be able to market the product simultaneously in all the Member States of the European Patent Convention where the patent has been revoked.*

- *The unitary body must have a check system in order to ensure uniformity, quality and transparency in decision making.*

Disadvantages:

*If the centralised Court declares a patent valid or infringed, it creates a **single** decision on a patent, as well as a precedent for another decision in the same line. Following the decision, the market of all the Member States involved will be simultaneously closed to the medicinal generic product. This situation could be extremely problematic if the decision was taken by a Court with no experience regarding pharmaceutical patents.*

3.2 Given the possible coexistence of three patent systems in Europe (the national, the Community and the European patent), what in your view would be the ideal patent litigation scheme in Europe?

a) We could be in favour of a Community Patent Litigation system that would set up a Community Patent Court with jurisdiction on the validity and infringement of Community patents. This Court would be comprised of specialised judges and attorneys and should be protected from the influence of national courts. If the Community Patent is adopted, we believe that the European Patent System should be abandoned in order to avoid further bureaucracy and confusion.

If the European Patent system disappears and is replaced by a Community Patent system, the EU would have to sign bilateral agreements with the countries that were contracting states of the European Patent Convention and are not EU members (such as Monaco, Liechtenstein, Iceland, Switzerland, Bulgaria, Rumania and Turkey), so that these countries are not excluded.

To summarise, the idea would be to persuade non-EU countries to join a unitary system extended to them from its Community base.

The major issues to be resolved in order to make the system effective would be:

- *Choice of language(s) to be used in the scheme.*
- *Lack of specialised judiciary.*
- *Time taken to resolve infringement actions.*
- *The unitary body in charge of patent litigation must have a system of checks and balances in order to ensure uniformity, quality and transparency in decision making.*
- *Criminalisation of civil IP disputes as proposed by the recent proposal of an EC Directive on enforcement of intellectual property rights through criminal measures.*

b) With regard to the national patents litigation scheme, only the national courts should be involved in revocation/infringement proceedings.

4. Section 4 –Approximation and mutual recognition of national patents

The proposed regulation on the Community patent is based on Article 308 of the EC Treaty, which requires consultation of the European Parliament and unanimity in the Council. It has been suggested that the substantive patent system might be improved through an approximation (harmonisation) instrument based on Article 95, which involves the Council and the European Parliament in the co-decision procedure with the Council acting by qualified majority. One or more of the following approaches, some of them suggested by members of the European Parliament, might be considered:

(1) Bringing the main patentability criteria of the European Patent Convention into Community law so that national courts can refer questions of interpretation to the European Court of Justice. This could include the general criteria of novelty, inventive step and industrial applicability, together with exceptions for particular subject matter and specific sectoral rules where these add value.
(2) More limited harmonisation picking up issues which are not specifically covered by the European Patent Convention.
(3) Mutual recognition by patent offices of patents granted by another EU Member State, possibly linked to an agreed quality standards framework, or "validation" by the European Patent Office, and provided the patent document is available in the original language and another language commonly used in business.
To make the case for approximation and use of Article 95, there needs to be evidence of an economic impact arising from differences in national laws or practice, which lead to barriers in the free movement of goods or services between states or distortions of competition.

Questions:

4.1. <u>What aspects of patent law do you feel give rise to barriers to free movement or distortion of competition because of differences in law or its application in practice between Member States?</u>

The main problems that affect the European generic medicines industry are:

- ***Disharmony of the judicial system*** *in the review of infringement cases in the Member States:*

As an example: whereas in the UK the validity of the patent is assessed at the same (specialised) court, the German court has no competence to take it into account and will only take a look at the infringement issue. The validity of the patent is investigated in a totally different procedure at the German patent office, resulting in different timelines and great uncertainty. As a consequence, two companies allegedly infringing the same (European) patent, but in different countries, might face two completely different court procedures with different outcomes. Based on the strength in the particular market and the decision made, a company might be enabled (or disabled) to enter other markets.

- ***Differences of access to preliminary injunctions***. *In some countries, preliminary injunctions are too easily obtained with little recourse to real value damages if found incorrectly applied. In other countries, this is not the case because the burden of proof is higher. This situation creates market distortions as in some countries generic products enter the market with no problems whilst in others they might be blocked or delayed by the injunction. A higher burden of proof must be applied throughout the EU regarding preliminary injunctions.*

- ***The granting of overly broad patent protection***, *together with restrictive or restricted licensing of IP, can impede the development of the next generation of generic products and reduce competition.*

- *The practice of obtaining patents defensively also appears to be widespread in some industries, where rights holders have no intention to develop marketable products or to license the IP to others, but simply wish to prevent others from undertaking research and development in similar areas. Others may hold defensive patents and seek to generate revenue not by commercializing them, but by seeking out potential infringers and proposing licensing agreements to them under threat of litigation. While such practices are legal, they may hinder innovation if the original patent was dubious or too broad in scope, and impose barriers to market entry for those who have legitimate generic products but are unable to risk litigation.*

4.2. To what extent is your business affected by such differences?

- *For European generic pharmaceutical companies selling to other companies in several Member States, the impact of the different patent and legal systems is significant. As these companies sell to other companies in Member States that have different patent and legal regimes, they have to incur extra costs to get advice on intellectual property rules. Because of the significant costs of the legal advice necessary to understand the legal requirements in the different countries, small and medium-sized enterprises are sometimes blocked.*

- *The costs of enforcing IP and challenging infringement through litigation under the current system are prohibitively high, especially for small and medium-sized enterprises.*

4.3. What are your views on the value-added and feasibility of the different options (1) – (3) outlined above?

If a system of mutual recognition of patents by national patent offices throughout the EU is introduced, the Community Patent will no longer be necessary.

5. Section 5 – General

On a scale of one to ten (10 is crucial, 1 is negligible):

5.1. How important is the patent system in Europe compared to other areas of legislation affecting your business?

Score 10 crucial

5.2. Compared to the other areas of intellectual property such as trade marks, designs, plant variety rights, copyright and related rights, how important is the patent system in Europe?

Score 10 crucial

5.3. How important to you is the patent system in Europe compared to the patent system worldwide?

Score 10 crucial

5.4 Are there other issues than those in this paper you feel the Commission should address in relation to the patent system?

*a) The use of **evergreening**/life cycle management strategies by originator pharmaceutical companies.*

Both the patent system and pricing and reimbursement system allow and encourage evergreening. Whilst these practices are not illegal, they do act as barriers to access to generic medicines and competition. They also provide for "false" innovation. It is important to distinguish between genuine incremental innovation and mere changes in chemistry/formulation, which are developed to block competition.

*b) Growing threat of **patent linkage**:*

By patent linkage we understand linking the marketing approval or any other procedure related to price, reimbursement and substitution for generics to the patent status of the reference product. Patent Linkage aims to delay approval / reimbursement / substitution / marketing of generics even if quality, safety and efficacy have been proven. Patent linkage is an integral part of 'evergreening' strategies to delay generic competition and monitor the generic business strategy. They are a clear abuse of the EU regulatory system, and are purposefully confused with US practices which have no application to the EU system.
The reason why originator companies wish to enforce patent linkage is to ensure that National Authorities become indirect 'enforcers' of patents. This would avoid litigation through the courts of justice to enforce their patent and thus avoid public scrutiny and questioning of the patent's validity before it is enforced. Patent enforcement would thus be carried out behind close doors by National Authorities, making it easy to implement and uphold frivolous patents.

It should be stressed that two distinct areas of competence have existed in the past and currently exist in the context of the new legal environment. These two areas of competence are:

1) *Patent Offices assess and grant patents. The Patent Offices have no power and competence to assess quality, safety and efficacy of medicines or agree on price and reimbursement;*
2) *National Authorities assess quality, safety and efficacy of medicines and agree on price and reimbursement. The National Authorities have no power and competence to assess the status or judge the validity of patents of medicines.*

*c) **Restrictive legislation**.*

Some future EC proposals that affect the patent system might create unjustified barriers to generic competition.

1. Directive 2004/48/EC on measures and procedures to ensure the enforcement of intellectual property rights has several major flaws:

- *The Directive provides for draconian provisions allowing temporary injunctions on a low level of proof, seizure of goods, blocking of bank accounts, etc.*
- *The Directive fails to provide adequate safeguards to protect innocent defendants from abusive litigation. The Directive could "be used to try to keep unwelcome competitors out of the market or to hamper legitimate competition".*
- *The Directive abolishes the distinction between piracy/counterfeiting and alleged infringement of patent right. This would equate to all alleged patent infringers being treated the same as criminals, pirates/counterfeiters.*

2. Criminalisation of Intellectual Property patent disputes through the new EC's proposal for a Directive on criminal measures to enforce IP rights.

The EGA welcomes the European Commission's initiative to propose a Directive aimed at providing Member States with measures and remedies to deal effectively with counterfeiting and piracy activities, which are often carried out by criminal organisations.

However, our industry has serious concerns regarding the current Directive's approach of simply generalising measures to combat counterfeiting and piracy as applicable to all forms of IP rights. In particular, employing a single approach is not justified for patents. In fact, abolishing the distinction between piracy/counterfeiting and alleged infringement of patent rights sets a dangerous precedent which equates all alleged patent infringements with criminal activity such as piracy/counterfeiting. It should be pointed out that article 61 of the TRIPS agreement (upon which the proposed Directive is said to be based) distinguishes between trademarks, counterfeiting and copyright piracy on the one hand, and other IP rights disputes on the other. This division should be maintained in the present Directive. Patents should be excluded from the scope.

In addition to this, the EGA has major concerns that the criminal measures provided to enforce Intellectual Property rights will be misapplied and misused by IP holders against legitimate competition in the areas of patents. It should be noted that Directive 2004/48/EC recognised this possible abuse and, in article 3.3, stated that 'the measures, procedures and remedies shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse'.

3. Six months 'paediatric' extension of the Supplementary Protection Certificate provided by the new EC Regulation on medicinal products for paediatric use, which will be approved at the end of 2006.

CONCLUSION

Whilst patents are clearly important for encouraging innovation, an unattractive EU patent system encouraging its misuseby including:

- easily granted patent rights
- frivolous litigation through generous injunction systems,
- criminalization of patent disputes
- patent linkage

will prevent generic competition and consequently:

- restrict access/affordability
- discourage real innovation.

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6. Contact details

1) Are you replying as a citizen / individual or on behalf of an organisation?

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