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## Observations on the Preliminary Report drawn up by the Competition DG of the European Commission following its Pharmaceutical Sector Inquiry (Ref. 39514)

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We, Mr. Dominique GUERRE and Mr. Stéphane AGASSE, European Patent Attorneys (EPA) with the European Patent Office (EPO) working for GERMAIN & MAUREAU, an Intellectual Property law firm, submit the following comments on the Preliminary Report drawn up by the Competition DG of the European Commission (EC), and resulting from its pharmaceutical Sector Inquiry.

## **1) Disclaimer**

The comments hereunder do not commit any of the professional organizations to which we belong such as the Institute of Professional Representatives before the European Patent Office (EPI) or the Compagnie Nationale des Conseils en Propriété Industrielle (CNCPI), nor any of the firms or individuals we have professionally served.

For the sake of transparency, we have been intensively working for the observed period 2000-2007 in the sector of generic medicines, in particular on cases relating to many of the active pharmaceutical ingredients (API) identified under the 219 INN's (International Non-proprietary Names) of pages 417-418 of the Preliminary Report. Our work in the field of generic medicines involves making legal opinions about the freedom to operate (FTO) generic medicines in France, the validity/scope of French patent rights, among which European Patents of Originator Companies, as well as closely cooperating with French specialized Industrial Property barristers (Avocats) to challenge in Court the validity of same patent rights, and/or to defend Generic Companies in infringement suits. We have also been very active in opposition proceedings before the EPO against originator European Patents.

We agree that this contribution may be published on the Commission's website, and are ready to be heard if found appropriate by the Commission to supplement our submissions.

## **2) Foreword**

2.1) Consistently with our expertise scope, our comments will be focused:

- on the competition/confrontation between Originator and Generic Companies, and not on the competition between Originator Companies
- and in this competition arena on the IP (Intellectual/Industrial Property) dealings between same companies, to the exclusion of considerations pertaining to the EC and/or national competition law.

2.2) Unless specified otherwise, we will rely hereinafter on the Executive Summary to simplify our references to the Preliminary Report.

2.3) We have read the Executive Summary in its French translation (“Rapport Préliminaire”), and believe that the French translation of “Originator Companies” into “Entreprises Innovantes” (i.e. “Innovative Companies”) is somewhat wrong, if not disparaging Generic Companies.

Generic Companies, in particular their API’s suppliers are engaged in Research and Development (R&D) work, and may provide innovations exactly of the types described in paragraphs (63) to (66), (70) and (74) in pages 422-424 of the Preliminary Report.

Generic Companies need also to recoup their investments, which may be high, if we refer for instance to those required for manufacturing Biosimilars.

Consequently, we would propose to translate “Originator Companies” into French as “Entreprises Princeps”.

2.4) Even if it has become convenient to oppose Generic Companies to Originator Companies, we are not sure that such a distinction has become sufficient to analyze the pharmaceutical sector where major groups usually considered on the Originator side comprise now affiliated or controlled Generic Companies devoted to generic medicines.

### **3) Remarks about the Preliminary Report itself**

Subject to our restriction of paragraph 2.1, the results of our IP practice in the field of generic medicines rejoin the EC Commission findings.

Many of these findings show almost a crisis status of the patent system, at least in the pharmaceutical sector.

### **4) Comments**

#### 4.1) Preliminary comments

At the day-to-day patent practitioner level, the EC Commission findings trigger so many remarks/suggestions that it is out of question to elaborate them without bringing previously some order...

To this end, we will stick to the following Ariane's thread :

(a) These findings should not be used to blame the patent system itself, but some distorted and/or abusive practices of it.

(b) The shortcomings highlighted by the Report result from the unwanted interactive play of the main authorities/bodies concerned with the European Patent system, that are :

- the legislator, among which the EU legislator,
- the various Patent Offices, among which the EPO,
- the European judicial bodies, among which the Court of Justice of the European Communities (ECJ),
- and surprisingly the national public health authorities, among which the regulation authorities,

(c) Consequently, if any remedy is to be sought to the described practices, any and all these authorities are concerned,

(d) Finally, since bringing changes in the EU common statutory law looks sometimes like a hurdle race, we will try to suggest some "short-circuit" means/procedures to achieve the same purposes.

#### 4.2) The European Patent system should remain a privileged instrument to regulate innovation in the medicine market/sector

History of patent law in some European countries shows that the legislator may be tempted to pass law and regulations specific for inventions in life sciences, e.g. in the pharmaceutical sector.

We believe that the principles substantiating European patent law are sufficient and/or adapted to cope with almost all pharmaceutical inventions. Where adaptations to the pharmaceutical sector were required, they have been timely brought and are now available; refer for example to Supplementary Protection Certificates (SPC) (refer to EC regulation n°1768/92).

The pharmaceutical sector should understand and accept what almost all other industrial sectors have already assimilated:

- innovations deserve an efficient and reliable patent protection, to recoup R&D investments and favor hatch of other and new innovations :

⇒ that is the time of exclusive markets

- but once this temporary protection/monopoly has expired, time has come for legal and licit competition :

⇒ that is the time of public domain markets, where the generic industry is permitted and entitled to develop and grow.

#### 4.3) Our comments about substantive patent law

Any patent is in legal essence a licit weapon against competition, and should remain so.

One must accept that Generic Companies are not devoted to medicine forgery, and scrutinize their FTO prior to launching a generic medicine. Conversely, it may be accepted that Originator Companies actually improve an originator medicine and consequently expand and strengthen their patent position around a same INN.

But, at the same time, it must be observed that the patent system might be misused or abused to defeat the breadth and/or occurrence of public domain. Such a patent misuse or “abuse” is currently under trial by the ECJ (T-321/05)

Similarly, concerted patent practices might occur to the same effect, even if no such example in the pharmaceutical sector is currently under the Commission or any European Court investigation.

Across the Atlantic, our US colleagues have an efficient remedy against patent misuse or abuse, that is to deprive the patent owner of his right to enforce his monopoly, without further discussing the validity/scope and/or actual infringement of his patent.

May be, time could have come to introduce such a doctrine in European Patent law and/or jurisprudence.

#### 4.4) Our comments about the patent practice at the EPO

As patent practitioners, we do not know precisely what are “strong” or “weak” patents. We only know patents which are valid or (partly) invalid, and which have a broad or narrow claim coverage. And the “strength” of some patents depends on other extrinsic factors such as, for instance, the market position of the patent owner.

Thus, as practitioners we oppose the quality, so to speak, of a patent to its “strength”.

For sure, the EPO is a key “house-keeper” of the European patent system, and should watch in this respect the quality of the patents it issues. In this respect, it must not be

forgotten that any issued European patent, as any issued national patent, legally enjoys a validity presumption, which may be only rebutted by a third party, before the EPO (one “centralised” opposition) and/or a national Courts (multiple nullity actions).

Efficient working of substantive examination, and the control over it exerted by the Boards of Appeals, and eventually the Enlarged Board of Appeal, within the EPO, determines the quality of the patent titles coming out of this most important organization.

Implicitly, the Commission findings address or touch upon the quality of the issued pharmaceutical patents for the observed period (2000-2007).

We won't take part in this controversial issue. We prefer to concentrate on the following remarks, which could explain why some so-called “secondary” patents have been granted by the EPO and would have not been issued if the EPO had not went off some fundamentals of European Patent law.

#### *4.4.1) Articles 52 and 53 of the European Patent Convention*

Only “technology” creations are within the jurisdiction of patent law, and not other or different creations such as methods for treatment of the human or animal body by surgery or therapy.

The EPO and its various instances should efficaciously resist to accept patentability and grant patents for invention which, although genuinely devised or claimed, amount to cover an innovation which by nature has no vocation for patent protection.

We refer in this respect to the prejudicial question referred to the Enlarged Board of Appeal, under ref. G02/08, regarding medicine administration schemes.

#### *4.4.2) Application of the available EPO case law to some pharmaceutical inventions*

The EPO case law has already extended the possibility for originators to protect some innovations representing a “technical” (as understood by the EPO case law) contribution in the pharmaceutical art. Decision G06/83 issued by the Enlarged Board of Appeal and affirming patentability of the so called “2<sup>nd</sup> or subsequent medical indication” (now enshrined in article 54 EPC 2000) is an example of such patentability extension.

We personally disapprove any attempt to extend now this available case law, and/or exceptions brought in the EPC to non-patentability, to protect pharmaceutical “inventions” which should normally remain out of the patent system.

We refer in this respect to decision T1020/03 which, for the first time, considered an administration scheme of medicines to be a “2<sup>nd</sup> medical indication”, therefore not excluded from patentability.

Exceptions to non-patentability should be construed narrowly.

#### *4.4.3) Inventive step assessment*

Inventive step is a patentability requirement or criterion which does matter for pharmaceutical inventions. If inventive step is appraised too loosely, then there is a room for the so-called “weaked” patents, even if examined and issued by the EPO.

In this respect, we favor a material/concrete and actually documented approach by the various EPO’s bodies, based on what is explicitly disclosed and supported in the original patent specification, that is the Examiner retroactively placing itself in the scientific/technical environment at the priority/filing date.

Purely speculative considerations should not become inventive, simply because ex post facto and later experiments show their effectiveness.

#### *4.4.4) Patent claims commensurate with the extent of the technical contribution actually made by the invention*

All patent practitioners, e.g. patent drafters, are educated to apply for patents having claims bringing a maximum protection coverage, starting from a disclosure which is rather limited in some “instances”. Such a drafting attitude must be accepted in technical fields where extension is plausible or reasonable, based on the common general knowledge in the art at the filing/priority date. In the pharmaceutical field, starting from a limited and disclosed contribution, for instance with very few examples, such an extension is simply hazardous; and, if patentable, patent coverage should almost stick to the documented examples.

#### *4.4.5) The hurdle of divisional patent applications*

In decisions G01/05 and G01/06, the EPO's Enlarged Board of Appeal has approved the practice of filing multiple divisional patent applications, including filing divisional patent applications from a divisional patent application, all using at their respective filing dates the exact same description and the exact same claims as for the root patent application.

Personally, we regret that some legal and/or procedural limits have not been brought to this practice.

We believe that divisional applications should be allowed only for any subject matter extraneous to subject matter already claimed in a parent patent application.

Filing as many divisional patent application(s) as wanted by the applicant, at any time during the pendency of a parent application, generates legal uncertainty and unpredictability for third parties facing the pending patent application(s).

All the above remarks have a same purpose, i.e. to increase the reliability of the European patent system for all parties dealing with it, in the first place patent applicants and owners.

The pharmaceutical community, independently from the classical opposition between Originator and Generic Companies, needs a patent system and thus patents in which they can trust. Meeting this need requires more, better and quicker control in all the EPO's instances dealing with pharmaceutical inventions.

4.5) Some legal remedies are already available in national patent laws, but are insufficiently used by Generic Companies

##### *4.5.1) Declaratory judgments*

Questions of infringement are usually appraised by comparing the allegedly infringing matter with the claimed subject-matter of a patent in suit.

In some instances, there is a shorter and more efficient way to know whether same matter is free to operate, including versus the patent in suit. That is to decide whether same matter pertains to the public domain, in the country of reference, for instance France.

Such a declaratory judgment would have many advantages:

- it may be opposed by the defendant to the later enforcement by the same patentee of further divisional patent(s) of the patent in suit,
- any Court proceedings for such a declaratory judgment may not be stay, because of some procedural steps taken by the patentee, such as a limitation demand for his patent.

Such declaratory judgments are sometimes issued by German Courts, because in Germany disputes about validity and infringement are brought before different tribunals. The same Courts can even extend the German public domain to embodiments non-patentably distinct, e.g. obvious, with respect to those actually disclosed in said public domain.

Such declaratory judgments are shown in the pharmaceutical sector in the jurisprudence of some European countries, for instance, Netherlands (refer to District Court of the Hague, Case number 288241, Cause list number HA ZA 06-1689).

If we refer for instance to France, to favor the development of such declaratory judgments the provisions of Article L615.9 of the French Intellectual Property Code (CPI) should be amended/augmented to:

- expressly apply to any third party wishing to get a declaratory judgment with regard to the French public domain at the relevant date (e.g. the filing date or the priority date of a patent in suit), whether in ex-parte or inter-partes proceedings.
- delete the requirement of the patentee previously notifying his industrial project or plan to the patentee, to be admitted for requesting such a declaratory judgment.

#### *4.5.2) Compulsory licenses*

If we refer to Articles L613.11 to L613.17 of the French Intellectual Property Code (CPI), they provide interested parties, among which national health authorities, with some leverage to urge patent owners, in particular owners of so-called “secondary patents” to grant reasonable licenses of them to competitors lawfully blocked by the same.

In particular, with reference to Article 613.17 of the CPI, French public health authorities may declare a patent for compulsory license eligibility (“licence d’office”), where same patent has been exploited in conditions contrary to public health interest or which have finally been declared as infringing competition law.

#### 4.6) The judicial patent practice by national Courts

##### *4.6.1) The draft European Patent Litigation Agreement (EPLA) and the EPO*

According to the Preliminary Report, much hope is placed by many parties in the Pharmaceutical Sector in the draft EPLA to resolve in particular the question of possibly diverging national decisions, for instance with respect to a same European Patent.

We, of course, share this hope, but there is another matter of interest to be dealt with in the same context: the question of somewhat diverging appraisal methods, and thus with possible different results, about validity of a same patent, between the EPO, in particular its Boards of Appeal, and national Courts. For instance, the EPO's appraisal about inventive step is stuck to the so-called "problem/solution" approach, whereas the judiciary approach of the same question in national Courts might be different; for instance, according to British case law, much weight is given in this respect to Common General Knowledge (CGK) starting from a sole piece of prior art.

Such diverging assessments between the EPO and national Courts would disappear in the long term, only if the Court of Appeal of the European Patent Court, as provided by the EPLA, also acts as an ultimate appealing instance for any final decision made by the EPO, or the European Patent Organization, regarding validity of a European Patent.

Such a judiciary organization does exist in the United States, since the United States Court of Appeal for the Federal Circuits (CAFC) takes appeals from the Board of Patent Appeals and Interferences of the USPTO. This judiciary organization could be adopted at a transnational European level, with much benefit for improving legal certainty in the European Patent system.

##### *4.6.2) The application of European Directive 2004/48/EC*

Generally, the European public has favorably greeted the enactment and transposition into national laws of European Directive 2004/48/EC. But a tight application of this Directive might be simply a disaster for the generic medicines.

This Directive aimed at and provides measures for defeating counterfeiting and piracy (refer for instance to paragraphs (9) and (29) of the recitals). And, indeed the measures

provided by the Directive, such as ex-parte interim injunctions, provide IP owners with new means of effectively enforcing their exclusive rights.

Nevertheless, any patent practitioner in the pharmaceutical sector would easily admit that most infringement occurrences on domestic markets are not counterfeiting and piracy, as in the luxury goods sector, but “normal” or usual controversies about the scope/validity of a patent of interest.

However, the legal measures provided by the Directive are now available to pharmaceutical patent owners, in particular without any distinction between so-called “strong” and “weak” patents; since some national judges requested for such interim injunctions do not previously assess, at least prima facie, the validity and/or infringement of the enforced IP rights.

We pretend that in the pharmaceutical sector a minimum control of the validity/infringement of the enforced IP rights should previously be made by the judge, before granting any of the measures, e.g. interim injunctions, provided by the Directive.

And, if such measures are finally granted to the benefit of the patent owner, the latter should systematically lodge a monetary security actually compensating for the irreparable prejudice generally suffered by the defendant.

#### *4.6.3) Networking the national patent Courts and judges*

The Preliminary Report underlines the drawback of challenging patent rights, even stemming from a same granted European patent, at different national levels, and thus in various jurisdictions, which may lead and actually leads sometimes to national diverging decisions.

Such divergences could be reduced, if:

- the concerned national judges could share their various practices on a regular basis; we know that it has already been made, and we strongly support such initiatives,
- while respecting the statutory independence of each national judge, due attention could be paid in nationally trying a case to any foreign parallel decision, especially where a reasoned foreign judgment is available.

#### 4.7) The patent interference by national health authorities

According to the Report, some regulatory bodies arrogate to themselves the right to control whether the generic product may infringe the Originator Company's patent(s).

Such a patent linkage is simply unlawful under the EU law, as repeated by the Preliminary Report.

But, otherwise expressed, all regulatory bodies must be kept out of private, e.g. civil and commercial dealings, even contentious, in particular patent dealings, between pharmaceutical companies. Such bodies are devoted to safeguarding public health and interest, and not supporting the views of any specific patent holder...

We would add that some national regulations, for instance French regulations, impose on a Generic Company to previously notify the Originator Company of its generic medicine project, so that the Originator Company may timely enforce its patent(s), if deemed appropriate.

Thus, the regulatory bodies should return to their basic missions as defined by national and European Union laws.

#### 4.8) Suggestion of some short-term measures in favour of Generic Entry

##### *4.8.1) Alternative Dispute Resolution (ADR) options*

If the Pharmaceutical Sector, in particular the Generic Companies, allot a significant part of their resources to patent disputes and litigations, this means less resources for improving medicines, that is affording safe, innovative and affordable medicines...

Consequently, all opposed parties in the Pharmaceutical Sector should look at resolving their disputes at other levels than judiciary, for instance by using the capabilities of specific impartial bodies, devoted to IP litigation, such as the WIPO Arbitration and Mediation Center.

Such instances could resolve multi-national patent litigation at a same level, in a fast, efficient and final manner.

*4.8.2) A European Union Directive/Regulation specific for the Generic Medicines is looked for*

We do not believe that many of the shortcomings identified and listed in the Preliminary Report can be remedied in the short-term, if simply waiting for some changes in the pertaining legislations/regulations, whether European Union and/or national.

The generic medicines, for their effective entry in the European market, require without delay a specific, comprehensive, and additional legislative contribution.

In our opinion, there is a need for a further European Union Directive/Regulation, bringing solutions or measures specifically applicable to the generic medicine, and binding upon all parties required for its development, including judiciary and health authorities.

Such a Directive could address the various topics contained in these submissions.

Made in Lyon, on January 30, 2009



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