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EUROPEAN COMMISSION PHARMACEUTICAL SECTOR INQUIRY PRELIMINARY REPORT - 28 November 2008

COMMENTS FROM THE EPO

PART I: GENERAL COMMENTS

The EPO notes with satisfaction that the European Commission's Preliminary Report supports the patent system and recognises the importance of its function in promoting innovation by allowing the appropriation of inventions, which in turn, promotes healthy competition in the marketplace between pharmaceutical companies, in the interest of society at large.

The EPO's view of an optimal European patent system is that it should deliver high quality patents and conduct all the procedures entrusted to it in a competent, fair, predictable and timely manner. The Office strives to pursue these goals and continually improve its performance so as to maximise its contribution to society.

The EPO is pleased that the Preliminary Report supports its long-held view that patent quality is of paramount importance, and that the evidence gathered reflects that both generic and originator users of the patent system in the pharmaceutical sector share this opinion. This aspect of the Report bolsters some of the Office's current initiatives intending to safeguard or increase the quality of European patents, such as "Raising the Bar" - which focus on the consistent application by the EPO of patentability and other requirements of the EPC. Within this context, it is being queried whether some procedural changes and other adjustments to the European patent system may not be in order.

The Preliminary Report is interesting for the Office as it gives further insight into certain patterns of applicant behaviours which may increase legal uncertainty, some of which are already under careful scrutiny within the EPO. In particular, internal policy discussions are ongoing with respect to a tightening of the rules governing the filing of divisional applications.

Finally, the EPO welcomes the emphasis the report places on the need for the creation of a Community patent and a centralised, specialised European patent judiciary and wholeheartedly endorses the conclusions drawn by the Commission in this respect.

The Preliminary Report on the Pharmaceutical Sector Inquiry is mainly concerned with issues of competition and regulatory law which lie outside the field of patent law and therefore, the area of competence of the EPO. Nevertheless, since the patent system is subjected to particular scrutiny in the Report, it is both appropriate and necessary for the EPO to provide additional information and make observations pertaining to selected technical issues addressed in the Report which are of particular relevance to the Office, its practice or its function.

PART II: SUBSTANTIVE COMMENTS

A. Methodology: counting patents

In § 341 of the report, it is stated that for the 219 INNs forming the focus of the sector inquiry, a figure of nearly 40,000 patents/applications had been granted or were pending in the 27 EU member states, as each European patent validated in one of these states was counted separately, and the number of pending patent applications were multiplied by the number of EU member states designated, then added to national figures on patents and pending applications. Likewise, in § 349, it is stated that "the number of granted patents and pending applications can be as high as 1,300 per INN".

First, we suggest that the terminology should be modified, as these patents are not all granted on the pharmaceutical substance itself, but also on inventions related thereto, *ie* include patents claiming methods, formulations, etc.

Moreover, we question this methodology and its results for two reasons.

We understand that this figure is intended to illustrate vividly the complexities which may arise in terms of both market access and enforcement of patent rights as a result of the fragmentation of the European market, bolstering arguments in favour of the Community patent and a centralised, specialised European patent judiciary.

However, this method of counting patents exaggerates applicable numbers, giving a distorted picture of the functioning of the system, which will affect other important policy issues currently being debated. By definition, an act in a given state will only infringe patents valid for that particular territory, so that even if 27 patents have been granted on a particular INN in the relevant states, *ipso facto*, at least 26 of them will be irrelevant to the case at hand.

Secondly, although this figure is presented in the section on the geographical scope of patenting, given the intuitive connection between granting levels and perceptions of quality, it automatically goes beyond the issue of the fragmentation of the European market and appears to imply a substantive dysfunction of the European patent system in qualitative terms. It is questioned whether this is appropriate. Even if it is not the intention of the Report to criticise the EPO in this manner, this figure could be seized upon for this purpose.

In our view, the more appropriate manner of measuring the potential effect on competitors is to give the aggregate amount of national and European applications pending and patents granted on the INN-related inventions, counted once, along with the average number of designations/validations (14.8 states for the group of INNs studied, according to the data of the Commission, as indicated in § 334).

Another more interesting, accurate and revealing figure would be the average number of European patents granted and European patent applications pending in relation to a single INN (counted once).

B. The “primary patent" / "secondary patent” distinction

We understand that for the purposes of the Pharmaceutical Sector Inquiry, it is useful to distinguish throughout the Report between patents covering inventions consisting in the molecules of new active ingredients, arguably representing what might be labelled a "quantum leap", and those inventions which are the result of subsequent, incremental inventions improving or building thereon - less spectacular perhaps, but nonetheless a cornerstone of the process of innovation.

However, it must be emphasised that the labels “primary patents” and “secondary patents” are not terms of art in the European patent system. Indeed, an invention claimed in a patent application is subjected to the conditions for patentability contained in the EPC and to those alone. Under the EPC, for examination as well as all other purposes, all applications are to be considered equally and fairly. (Arguably, the only possible exception to the principle of equality is the treatment of divisional applications, for which a special regime is foreseen under the EPC regarding only the filing date, the term of the patent, their designations and the subject-matter which they may contain.)

Thus, the suggestion of generic companies that the EPO should subject so-called “secondary patent" applications to a higher level of scrutiny is incompatible with the principles of the EPC, the letter and spirit of which require the EPO to carry out its work in a neutral and predictable manner free of arbitrary considerations, and to subject all inventions to the same standards of patentability under the EPC.

Furthermore, one of the express goals pursued by the patent system is to promote the creation of inventions built on other inventions, as demonstrated by the experimental use exception. Such early enablement of such further follow-on invention also constitutes one of the underpinnings of the mandatory publication of applications 18 months after the filing or earliest priority date. The filing of so-called "secondary patents" is not the exclusive privilege of the holders of so-called "primary patents". Third parties may build upon such knowledge and file for follow-on inventions - in the pharmaceutical sector, both originator and generic companies do so.

Above and beyond these considerations of principle, at a practical level, in most cases, it would be impossible for the EPO to even attempt to classify patent applications into these categories upon filing. The function of the EPO is to assess from a technical standpoint the patentability of inventions for which applications have been filed. Provided the invention falls within the definition of patentable subject-matter, neither the nature of the invention, its importance or usefulness for mankind, its commercial potential or the purpose for which the application has been filed, are relevant to the decision-making process within the European patent granting system, and we strongly suggest that they should remain so.

Finally, the observation in § 891 that “*When the main patent is about to expire […], originator companies may apply for a ‘subsequent’ patent for the same initial molecules, while adding some degree of innovation*” is perhaps no more than an inaccurate formulation, but it must be pointed out that it is at odds with the fundamental principles of patentability contained in the EPC. A subsequent patent may well be granted for an incremental invention *related* to the initial molecules covered by the so-called “primary patent”, but it certainly would not contain a product claim *for the same molecule per se*, as implied in the Report.

C. The role and treatment of third party observations

The EPO wishes to express concern regarding the critical description of the role of third parties during examination, in particular its *ex parte* nature which does not provide for the hearing of witnesses or feedback to third parties (§ 231). There appears to be a broad misconception amongst users of the system regarding the treatment of third party submissions under Art. 115 EPC.

The EPO already takes third party observations fully into account. An examiner will consider such observations *ex officio* pursuant to Art. 114(1) EPC, in accordance with Part E-VI.3 of the Guidelines for Examination in the EPO, and will communicate them to the applicant for comment. In respect of this particular issue, two comments must be made. First, bland allegations do not suffice to constitute an obstacle to grant: appropriate evidence backing up the observation must be adduced. Second, the fact that the third party making a submission is not thereby made a party to the examination proceedings, informed directly of the impact of his submission or given a right to be heard, results from considerations of economy and policy. Opening up any of these avenues could well lead to the development of a new sub-set of gaming strategies on the part of competitors, apart from increasing the workload of the EPO and leading to further delays in grant. It is submitted that the EPC has found a procedural balance in this regard which is defensible and should not lightly be disturbed.

One remaining issue regarding third party observations is why so few of them are filed. Anecdotal evidence suggests that third parties tend to wait for the opposition procedure before bringing cogent evidence of prior art. Particularly in the field of pharmaceuticals, this clearly denotes a strategy on the part of users of the system/ competitors, rather than an ignorance of the existence of this possibility. The EPO would welcome greater use of the mechanism of Art. 115 EPC by third parties, and is currently reflecting on ways to make such filing of third party observations easier and more attractive.

D. Oppositions and appeals at the EPO

The EPO has several areas of concern regarding the report's assessment and conclusions regarding oppositions and appeals at the EPO.

Regarding duration, from the point of view of methodology, it is considered more appropriate to deal with opposition proceedings and appeals to the Boards of Appeal separately. It is suggested in the interest of transparency that separate average figures for each of these procedures as computed by the Commission should also be given in the Report.

The average duration of 3.6 years for both procedures combined (§ 554) is indeed longer than the average duration of patent litigation proceedings in front of the national courts of the 27 EU states in the period examined, at 2.8 years, although there are considerable variations across member states. The comparison between these two types of procedures is an uneasy one. On the one hand, patent litigation proceedings in front of a national court typically pit fewer parties against one another than oppositions, but may need to cover

additional issues of infringement and damages. On the other hand, the opposition and appeal procedures in front of the EPO focus on validity issues alone. However, patent holders often face multiple opponents within a single procedure. Of the oppositions at the EPO for the relevant 73 INNs considered in the section of the Report on oppositions filed by generic companies, over half involved 3 or more opponents, up to a record-level 27 opposing parties. Such a multiplication of submissions necessarily increases the burden on the Opposition Division.

It is also true that dilatory tactics are engaged in by patent holders (both originator and generic companies) as well as, at times, opponents themselves. The EPO tries to curb such tactics where possible, however, several elements make the acceleration of opposition and appeal proceedings a delicate task: the right to be heard and other procedural safeguards which are essential to due process in the context of judicial/quasi-judicial proceedings, the complexities of the material considered and the fact that disregarding cogent evidence which is filed late does not only cause prejudice to the party responsible but also to the public interest.

Still, we recognise that time delays can occur in the combined opposition and appeal procedures and we are striving to improve our performance in this respect.

That the rate of opposition at the EPO in the pharmaceutical sector is higher than the overall rate in all technological sectors is not altogether surprising, as *inter alia* it can be taken as an indication that the market for pharmaceutical inventions is considerably more lucrative than many other sectors, resulting in a higher level of commercial interest in obtaining market access. Moreover, licensing practices in the field of pharmaceuticals may play a role in raising the rate of opposition, in that they may be perhaps comparatively less readily granted by patent holders than in other sectors.

The Report rightly notes that the opposition procedure constitutes a legal mechanism which enhances patent quality. Moreover, both the EPO Opposition Divisions and the Boards of Appeal readily revise EPO decisions where appropriate, as attested by the numbers of opposition and appeal procedures resulting in the revocation of granted patents or adjustments to their scope of protection.

From the perspective of the EPO, it appears a little odd that the terminology employed in the report describes the revocation or amendment of a patent as a “success” and the upholding of a patent as a “defeat”. Moreover, the fact that the upholding of a patent with an amended scope is classified as a “success” for the opponent, may be inaccurate: Surely, a patent holder whose patent survives albeit in amended form could claim with equal right that he has prevailed. The significance of this outcome varies from case to case: the litmus test is whether the patent as upheld continues to provide meaningful protection against competitors or not. Where an amended patent remains a barrier to the entry of a generic company, it is queried how this can be considered a "successful" opposition from the point of view of the opponent.

In all technological sectors, opposition proceedings are considered to be an important quality-enhancing mechanism in that all patent office searches have their limitations. Certain types of prior art– such as public prior use by a third party – may be “unsearchable” as they are not contained in databases and evidence of it may not be found in non-patent literature.

However, in the pharmaceutical sector, oppositions have a further significance, in that EPO examiners cannot conduct experiments to verify applicant allegations. Such laboratory evidence brought forth by opponents is an effective way to counter speculative and/or unduly broad claims, and it is generally not available to examiners during the examination procedure.

E. Defensive patenting and other strategies

The EPO fully agrees that certain types of applicant patenting strategies pursued by pharmaceutical companies (as well as applicants in other sectors) *eg* in terms of defensive patenting or the filing of multiple divisional applications, as described in Section C - 3.1 of the report, may not be in line with the policy objectives of the patent system. However, there is a certain discomfort in classifying behaviours on the basis of the applicant's *intent* in applying for patent rights.

In this regard, it must be emphasised that it is a cardinal principle of European patent law that issues going to the intent of the applicant are irrelevant in terms of obtaining patent rights. The EPC requirements are strictly objective, and therefore predictable and easy to apply, thus enhancing legal certainty. Moreover, whether a patent is applied for in any given case to block the potential development of another invention by third parties rather than to protect the exploitation of the invention as contained in that application by the applicant is a matter which may be difficult to elucidate prior to grant.

The EPO considers that the subjective intent of the applicant in acquiring patent rights for an invention which is patentable should remain irrelevant. Even post-grant, it is suggested that the exercise of such rights pursued along legitimate channels should not be able to be limited solely on the basis of an applicant's subjective intent in choosing to exercise his rights in a particular manner, as long as such behaviour remains in line with prevailing rules of competition law. In some cases, existing national provisions on compulsory licensing in line with the existing international legal framework already provide the metes and bounds of remedies available where the required objective condition of non-use of a patented invention has been established.

In jurisdictions where subjective issues of intent form part of the requirements for patentability or the exercise of rights, these elements are considered to contribute to raising the costs of litigation and to lower the level of legal certainty.

F. Further work

It is hoped that this information will be helpful to the European Commission, and that it will be taken on board in the further conducting of the Pharmaceutical Sector Inquiry.

Of course, the EPO remains at the European Commission's disposal should it require any further clarifications regarding the European patent system.