TMPDF
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TMPDF comments on the EGA Review – Patent related barriers to market entry for Generic Medicines in the EU - European Generic Medicines Association - May 2008

GENERAL

TMPDF represents a large group of innovative companies in the UK, from all sectors of industry, which are major users of the patent system, both as owners of patents and as companies affected by the patents of others[1].

The recent EGA review on patent related barriers to market entry makes a substantial number of recommendations concerning the patent system in Europe. Many of these recommendations would, if implemented, have significant effects on patent granting and litigation practices as they apply to every sector of industry, not just the pharmaceutical sector. Because of the general applicability of the recommendations and their controversial nature, TMPDF considers that it should make clear its views on them.

Before considering the individual recommendations, it is emphasised that the Federation is fundamentally opposed to special rules for, or discriminatory treatment against, patent applications in the pharmaceutical (or any other) sector. (This is without prejudice to the award of supplementary protection certificates in respect of granted patents.) The rules and procedures that apply to patent applications in the pharmaceutical sector should be the same as those that apply in all other sectors.

In particular, applications that meet the normal requirements concerning patentability (novelty, inventive step, industrial applicability) and sufficient disclosure should not be denied grant.

ON THE EGA RECOMMENDATIONS:

1. To improve patent quality:

a. *Provide adequate resources and continue to encourage the EPO to improve the quality of patents that are granted by applying a consistently high standard of thoroughness in patent examination by well trained patent examiners;*

We emphasise that the quality of examination in the EPO is very high in the great majority of cases. However, in a small number of technical fields there may be some scope for incremental improvement. For example, in both search and examination, expertise in the relevant subject matter of these particular fields might be improved by additional training. Search might be improved overall if there was somewhat greater attention to Asian language documents and more supervision as regards search strategy. As regards examination, improved case management, more dialogue with the applicant and a somewhat more open approach to the admissibility of clarifying amendments would be helpful in some areas. Procedures should be examined with the aim of avoiding any unnecessary delay. Throughout the search, examination, opposition and appeal stages, somewhat more attention to transparent quality control could be helpful.

[1] List of members attached

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b. *Remove the requirement for EPO examiners to be fluent in three languages in order to allow the selection of examiners from a larger more technically skilled pool of candidates;*

An unbiased study of whether the three language requirement is necessary, given the present language mix of applications, would be worthwhile. It would be important to maintain a requirement that most if not all examiners should be fluent in English, since over 70% of the workload is in English. The study should establish whether a relaxation of the three language requirement would facilitate recruitment in difficult technical areas and help improve the quality of examination.

c. *Require patentees to file high quality applications and introduce the duty of candour to ensure that all information relevant to the patent being examined by the EPO is disclosed by the applicant;*

We are opposed to the imposition of any greater or more detailed requirements upon applicants than already exist through the Convention and its rules (which already require applications to sufficiently disclose a patentable invention). A particular requirement for a "duty of candour" or for an 'information disclosure statement' would increase uncertainty, open the door to litigation over the validity of granted patents which meet all tests of patentability, encourage unwarranted discovery procedures and make litigation longer and more expensive. Such requirements would be minefields for applicants in what is already a difficult and time consuming process.

Accusing applicants of filing applications of inadequate quality, which we assume are those which might eventually fail on patentability or sufficiency grounds, is misconceived. Applicants will draft in a responsible way, since they will have to maintain and defend the granted patent in the future. It is the examiner's duty to confirm that the application complies with the requirements to sufficiently describe and claim a patentable invention.

We consider that the need to provide information concerning experimental conditions and other data, in order to sufficiently disclose the invention, should be no greater than at present, in the pharmaceutical sector or any other. It is well recognised that applicants for patents are not expected to provide competitors with detailed blueprints for the manufacture of particular embodiments.

d. *Introduce a mechanism (prosecution history estoppel) whereby patentees are held accountable for statements made during prosecution when a patent is being litigated;*

We are opposed to the introduction of special provisions concerning prosecution history estoppel. Prosecution history is readily available from the patent office file and may well be referred to in subsequent proceedings. It would be a matter for a court to decide on what weight should be given to it.

We do not accept that there should be subsequent penalties, such as loss of the patent, for misunderstandings that might have occurred during the examination process. Granted patents that meet the legal requirements concerning patentability and sufficiency should be considered valid.

e. *Guarantee that interested parties have sufficient opportunity to alert the EPO about questionable patents within the EPO granting process itself;*

The opportunity for 3rd parties to intervene within the granting process exists under Article 115 EPC, but we consider that procedures could be improved, e.g., by providing for dialogue between the intervener and examiner to ensure that the examiner is fully aware of relevant prior art and understands the intervention. Such a procedure should not be allowed to unduly prolong the prosecution of the application or to become a 'backdoor' opposition.

f. *Accelerate the opposition procedure.*

We consider that procedures should be reviewed with the aim of conducting oppositions more efficiently. However, this should not be at the expense of quality. The quality of opposition division decisions should be examined in the light of findings that about 50%

of those opposition decisions that are appealed are reversed on appeal Further training of examiners dealing with oppositions should be considered.

2. To prevent the creation of patent thickets and reduce the incidence of poor follow-on patents:

We consider that the use of terminology such as 'patent thicket' in a pejorative context and 'poor follow-on patents' to be unfortunate and undesirable. The test of validity for every patent should be the same – does the granted patent meet the normal requirements for patentability and sufficiency?

It is not to be expected that all aspects of a line of research can be covered by a single early patent. Most subsequent work will be concerned with incremental change which, if inventive, should be patentable. The patent system should be neutral in its approach to related patents. The patents follow the research, not vice-versa.

a. *improve the quality of patents as outlined above and apply a rigorous assessment of patentability requirements;*

While we are opposed to some of the measures suggested in section 1, as discussed above, we agree that patentability requirements should be properly assessed.

b *prevent the filing of divisional patents that are essentially identical to the parent application;*

The applicant's filing strategy is a matter for him, provided that it does not result in two sets of claims to the same invention. (It is inevitable from the nature of divisional patents that there will be identical disclosures.) The creation of possibly unnecessary divisional patents is often due to the EPO, which frequently requires applications to be divided against the judgement of applicants.

c *require that patent claims with respect to the pharmacokinetic effect of administering a particular drug be directly linked to the formulation used to achieve that effect;*

This point is not of general application and is primarily a matter for the pharmaceutical sector.

d *limit the scope of second and further medical use patents.*

Again, this seems to be primarily a matter for the pharmaceutical sector.

e *grant patents only to genuine incremental innovation and not to simple changes in chemistry or formulation.*

To repeat again, patents should be granted for invention that meets patentability requirements. Most invention is concerned with incremental change and "simple" changes in chemistry or formulation can be inventive. The scope of the adjective 'simple' is unclear in the context; it is used in an inappropriately pejorative way.

3. To improve the patent litigation system in order to avoid excessive and abusive litigation and diverging and unbalanced decisions:

Again, we are concerned at the use of prejudicial language. In the absence of clear evidence to the contrary, we consider that there is little litigation that could be described as 'excessive' or 'abusive'.

a. *create a national litigation framework with technically qualified and experienced patent judges who can reach a decision on the merits of a case within a reasonable period of time;*

We agree that sound arrangements for litigating patents consistently and uniformly at the national level should be in place, with competent, patent experienced judges reaching decisions within a reasonable time frame. Unfortunately, it may be unlikely that this can be achieved in some EU member states in the near future.

We also consider that all judges dealing with patent cases should have sufficient technical competence to properly understand the majority of cases that are likely to come before them. (There will occasionally be cases of such technical complexity that it will be necessary to have assistance from experts to help with understanding them.)

b. *publish all patent court decisions in an EU register to provide clarity and to increase harmonisation, and to assist in moving towards the creation of a common jurisprudence on European patents;*

We consider that an EU register for national decisions, if properly maintained to show the status of each action, might be of considerable help - not only to highlight inconsistent (and indeed consistent) decisions but also to indicate where litigation is taking place and to facilitate due diligence reporting. There may however be practical problems – do all national administrations publish in a readily available form? Would they all agree to entry on an EU register? And how would the costs of setting up and maintaining the register be paid for?

c. *reach a consensus on one central patent judiciary in Europe;*

Provided that the necessary conditions set out in our previous papers on this subject are complied with (see TMPDF papers at tmpdf.org.uk), we cautiously accept that there should be an EU patent judiciary. However, it is extremely important that the selected judges should be of very high standard, both as regards patent experience and technical expertise, that the EU court as a whole and each individual division should be comprised of an international mix of judges and that the divisions should hear infringement and validity issues together.

It is important that the EU court should be an alternative to, not a replacement for, the national patent/intellectual property courts.

d. *avoid interim injunctions by inexperienced judges without a proper assessment of the rights of all the various parties involved;*

While we are not aware of evidence that injunctions are regularly being granted without regard for the rights of the various parties, we do consider that interim and final injunctions should be carefully considered on an individual basis by experienced patent judges. A particular problem is that the standards for the award of injunctions vary between the different EU states.

e. *require common standards of evidence and a duty on all parties to the litigation to present evidence to the court both for and against awarding a preliminary injunction;*

While common standards of evidence might be helpful, depending of course on what those standards are, it seems unlikely that agreement between EU states on what those standards should be could be achieved in the short term. Different Member States have different procedural traditions that are appropriate to their needs and that deserve respect. Failing an EU agreement, national courts will continue to apply their normal standards.

While there may be a duty in ex-parte proceedings to present the evidence from both sides of an issue, this is irrelevant in inter-partes proceedings, where each side speaks for itself. Indeed, what sanction might be applied against non-disclosure, should the court even be aware of it? It is a matter for the parties to test or contradict the evidence provided by the other side.

f. *seek out a proper balance of convenience by the courts in which inter alia the patentee's ever-greening strategy, the costs to national healthcare authorities, etc., are taken into account;*

The reference to an 'ever-greening strategy', whatever that might be, is prejudicial in the context. Once again, we emphasise that applications for patents that meet patentability and sufficiency requirements should be granted.

While the reference to the costs of national healthcare authorities will be of particular interest to the pharmaceutical sector, the recommendation raises a general matter

concerning costs to public authorities, since the state is a customer of many industries outside the pharmaceutical sector. The possible costs to customers, whether or not they are public authorities, should not influence whether or not a patent or a preliminary injunction should be granted.

g. *involve the health care authorities in patent proceedings, particularly in applications for interim injunctions.*

While the particular involvement of healthcare authorities in patent proceedings concerning pharmaceutical patents is essentially a matter for the pharmaceutical sector to consider, we take the general view that there is no justification for requiring a particular public authority to be involved in patent proceedings in any sector. Public authorities should be on the same footing as any other 3rd party.

As regards the award of interim injunctions, a requirement for healthcare authorities to be involved is a matter particularly for the pharmaceutical sector to consider. It can be observed as a general point however that a company opposed to the award of an interim injunction will presumably call on any available evidence against awarding the injunction, including if appropriate from a public authority. There is no reason for the involvement of the authority to be specifically required. As noted above, the possible costs to customers should not influence whether or not a preliminary injunction should be granted.

4. To overcome some of the other barriers to entry described above:

a. *reject all efforts to introduce patent linkage;*

(Patent linkage applies if a regulatory authority refuses to grant market authorisation to a party not authorised by the patent holder before the relevant patents have expired.)

This point is primarily for the pharmaceutical/agrochemical/biocide sectors to consider.

b. *prevent originators from obtaining patents for and switching the market to 'new' products that offer no substantial therapeutic advantage over the previous product;*

This is primarily a matter for the pharmaceutical sector to consider.

There is however a general point. There is no good reason, if the 'new' patents have been granted properly in accordance with patentability requirements, for preventing their owners from trying to switch the market. That is common practice in all industries. As innovation occurs, innovators often try to persuade their own and competitors' customers to "switch" to the newer innovative products. That will often be the economic rationale for investing in the innovation process. If the new products offer little or no advantage over the old, then the old will be manufactured and sold by competitors. In the case of pharmaceuticals, the health authorities will, presumably, continue to prescribe them.

c. *require patentees to provide sworn statements and supporting evidence for the date of first marketing authorisation in the EEA when applying for an SPC.*

This is primarily a matter for the pharmaceutical and agrochemical sectors to consider.

NOTE: TMPDF represents the views of UK industry in both IPR policy and practice matters within the EU, the UK and internationally. This paper represents the views of the innovative and influential companies which are members of this well-established trade association; see list of members below.

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