

The Pharmaceutical Sector Inquiry – Preliminary Report, 28 November 2008

Comments by the Chartered Institute of Patent Attorneys

Introduction

The Chartered Institute of Patent Attorneys (CIPA) is the representative body for patent attorneys in the United Kingdom having a membership of approximately 3,000 individuals including approximately 1,750 registered patent attorneys. The membership can be generally grouped into practitioners from “private practice” (individual private practice firms) and practitioners from in-house patent/legal departments. As a result CIPA’s views represent not only those of patent attorneys but also those of the bodies that patent attorneys represent including multi-nationals, small to medium enterprises, universities and private individuals in all areas of technology. In the context of the Commission’s Pharmaceutical Sector Inquiry, CIPA’s members represent both originator and generic companies, as those terms are used in the Report.

CIPA’s members practise both in front of the UK Intellectual Property Office and the European Patent Office. They also have experience of instructing patent attorneys in other jurisdictions in seeking patent protection for their clients on an international front.

CIPA’s members also have rights to litigate patents in the English Patents County Court and to seek a further qualification which allows them to litigate patents in the English High Court and on appeal.

Background

The Preliminary Report into the Pharmaceutical Sector Inquiry, published on 28 November 2008 (the “Report”) aims to provide the Commission with a factual basis for deciding whether further action is needed¹. In view of the fact that CIPA’s members include patent attorneys who may represent either originator companies or generic companies, and that the Report frequently appears to characterise these two groups as having conflicting views, we shall in the main restrict our comments to the functioning of the patent system.

In particular, we comment on the Chapter C 2, which relates to competition between originator and generic companies and Chapter D 1, which concerns the Commission’s comments on the patent system. We do not condone anti-competitive practices but we are generally concerned at the negative tone taken towards the patent system and the legitimate ways in which it is used.

¹ Executive Summary, page 5

Patents give the holder the right to stop others using the patented invention

In its introduction², the Report notes that: “*Adequate and efficient patent protection is an essential prerequisite for future innovation. It allows companies to recoup investment costs and yield an adequate profit for the risks associated with the innovative process.*” In this regard, the pharmaceutical sector is no different from any other sector of technology. The main function of the patent system is to provide an incentive to innovators to research and develop new products and processes. In return for disclosing to those skilled in the art how to carry out the invention which is the subject of the application for the patent, the patentee is given the right, for a limited period of time (up to 20 years), to prevent others from making commercial use of the invention.

Once the patent has expired, or is no longer in force because it has not been maintained or has been revoked, then anyone is free to use the invention claimed in the patent without reference to the originator.

Loss of Exclusivity

The Report³ defines “Loss of exclusivity” (“LoE”) as “*a situation where a product no longer benefits from an exclusive right, e.g. because of expiry of patent, SPC and data exclusivity (and marketing exclusivity).*” This term is used in particular when assessing the impact of generic entry, where the Report states: that *the savings from generic entry could have been about € 3 billion more, further reducing expenditure for these medicines by more than 5%, if generic entry had taken place without delay.*”⁴

This analysis of cost saving is based on the assumption that generic entry should have been possible immediately following “loss of exclusivity”. This assumption appears mistaken. Most innovative products are protected by more than one patent, whether they are pharmaceuticals or vacuum cleaners.

The expiry of one of the patents covering a product does not mean that competitors are now free to use all of the technology embodied in that product. Rather to use all of the technology, they must either wait until the last to expire of the patents, or design around the remaining patents or attack the validity of the patents.

As the Report has noted, many patentable inventions are made during the life of a drug. Among the first of these inventions is the active principle, which is the very identity of a pharmaceutical product. But there is more to a pharmaceutical product than just the active principle. Over the several years of the R&D programme, the originator must select a particular form of the active principle to incorporate into the product that is to be commercialised (the active substance), investigate its therapeutic applications, improve its commercial production and develop a stable formulation. Many patentable inventions are likely to be made, and applications for patents sought. The patents granted on these applications will expire later than the patent covering the

² Paragraph (4)

³ Page 19, definitions

⁴ Executive summary, page 8

active principle. Frequently, these later patents will also expire after the SPC protecting the active substance and any period of regulatory data protection.

The Community Code defines a generic medicinal product as “*a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.*”⁵

Different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. The generic company must use the same active principle as the originator’s product for his product to be a generic. However, he may be able to change certain aspects of the active principle, in particular its salt form, its specific formulation, how it is delivered and how the active substance is prepared, in an attempt to design around later expiring patents.

Alternatively, the generic company may take the view that one or more of the later patents should not have been granted and can be invalidated. As such, in the pharmaceutical sector, just as in many other technological sectors, there are disputes between originators and competitors, as the competitor attempts to copy as closely as possible the originator’s product, whilst at the same time the originator uses his patents to try and keep the competitor as far away as possible.

The same analysis applies as the originator develops new versions of his product. This is likely to be protected by patents, which overall expire later than the patents covering the initial product. In consequence, generic companies will be able to copy the earlier (and possibly less attractive) product, but will not be able to copy the later product before patent expiry without either designing around to come up with a functional equivalent or attacking the validity of the later patents. Once again this is exactly how the patent system functions in other technological sectors and is not peculiar to pharmaceuticals.

The report states “*To maintain its freedom to operate, it is essential for an originator company to ensure that its research options remain as open as possible, in particular with regard to further development of its own inventions. Filing for broad primary patents and using several secondary patents around an invention is therefore considered instrumental to achieving this goal. As will be shown in chapter C.3.1., companies can however also develop patent strategies that are mainly aimed at foreclosing particular R&D of a competitor.*”⁶

As noted above, the main right given by a patent is the right to prevent competitors from commercialising the patented invention. Certainly, originator companies carry out detailed freedom to operate studies to ensure that they are unlikely to be infringing the valid patent rights of third parties; equally, they will use the patents that result

⁵ Directive 2001/83/EC, Article 10(2)(b)

⁶ Paragraph (117)

from the inventions made during the R&D programme to prevent others having early access to those inventions. This is what patent law provides.

Patent law does not distinguish between ‘primary’ and ‘secondary’ patents

Article 27 of the TRIPs agreement requires that patents be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. No distinction is made in patent law between ‘primary’ and ‘secondary’ patents, although these terms are widely used in the pharmaceutical sector in general and the Report in particular. Nor can there be a different standard for patentability for pharmaceutical inventions – patent law must be applied uniformly across all technologies. Most innovation occurs in a stepwise fashion as a series of developments and innovators must be free to protect inventions as they are made.

On the Granting of Patents at the EPO

According to the Report⁷, a significant number of both generic companies and originator companies call upon the EPO to ensure that patents granted are of high quality and to effectively counter patent strategies that may result in unnecessary delays. The Report goes on to note⁸, that “*it was felt by many respondents that the inventive step requirements for such patent applications were too easily considered as being met*”.

Ensuring High Quality of Patent Grant

Under the heading “Raising the bar on patent quality”⁹, the EPO is taking steps to maintain the quality of the patent granted by the EPO. We generally support those initiatives. However, no patent system can be perfect; it is inevitable that patents will be granted that do not, in the view of the EPO Boards of Appeal or national courts, meet the requirements of patentability. But the patent grant system is an *ex parte* procedure, which has to deal with huge volumes of applications. It is inevitable that when patents are subjected to a far more detailed scrutiny in *inter partes* proceedings a substantial number will be found not to meet the standard. Generic companies will tend to target those patents which they see as not meeting the standards – but this does not mean that the system is inherently weak.

If the bar is set too high, then patents will not be granted for important inventions, and there will be less incentive to innovate; set the bar too low and competitors will still be able to invalidate a patent that should not have been granted, using either the EPO opposition procedure or revocation proceedings in the national courts.

In a footnote¹⁰: the Report states that it is *important that no ... “benefit of the doubt” principle should operate during the examination stage.*”

⁷ Executive Summary, page 15

⁸ Paragraph (1105)

⁹ EPO: 2007 Annual Report

¹⁰ Page 374, Footnote 421

In all proceedings before the EPO, each party normally carries the burden of proving the facts it alleges. The applicant can do this by supplying experimental data or referring to expert evidence. On the other hand, the Examiner is rarely in a position to challenge the patentee, as he can't carry out experiments or commission his own experts. As such it is inevitable that patents will be granted which will later fall in *inter partes* proceedings, simply because there is an opposing party who can bring in evidence.

Delays in the Grant Procedure

Following the filing of a patent application at the EPO –either directly or via the Patent Cooperation Treaty (PCT), the application is subjected to substantive examination. The grant of a patent is not a formality and the task of examining patent applications is undertaken with skill and care by highly qualified and highly professional examiners. However, it is often subjected to delays on the part of the EPO. Normally, the patent applicant is set a 4 month term to respond to communications from the EPO during substantive examination. Although applicants may request a two month extension of time for responding, the principal delay in the rate of examination is the period between the applicant filing a response and the patent examiner issuing a new communication – delays of over a year are quite common.

Obligation to disclose prior art

The Report states in a further footnote¹¹: that “*There is no obligation under current EPO rules for the applicant to disclose the prior art known to it.*” However, Article 124 EPC allows the EPO to invite the applicant to provide information on prior art taken into account in national or regional patent proceedings concerning the same invention. The EPO is now making much more use of these provisions, which must be beneficial in improving the quality of examination. We believe that this is sufficient, particularly in the electronic era when one patent office can easily access the search reports of another. Moves towards work sharing by Patent Offices should lead to greater sharing of information.

Third Party Observations

The Report notes¹² that several generic companies suggested that during the examination of the patent application, the EPO should give greater attention to third party observations. It goes on to say that third party observations were a sign that a patent application had potentially important commercial consequences and that third parties do not, at present, receive any direct feedback from the EPO on whether and how their comments were taken into consideration. Nor can third parties or expert witnesses be heard at the examination stage.

It should be pointed out that the EPO is obliged to communicate any third party observations to the applicant for or proprietor of the patent¹³. Where the observations relate to a pending patent application, the EPO will frequently issue a communication,

¹¹ Page 374, Footnote 420

¹² D 1.4.3, (1117)

¹³ Rule 114 EPC

based on the observations, inviting the applicant to comment. As all correspondence is published on the EPO website, the fate of the observations is clear and the third party is permitted to make further observations if he so wishes. However, greater participation by third parties risks introducing the delays to grant that were common in the pre-grant opposition systems that have been superseded by the EPC.

“Patent Clusters”

The Report states¹⁴ that *“One commonly applied strategy is filing numerous patents for the same medicine (forming so called “patent clusters” or “patent thickets”). Documents gathered in the course of the inquiry confirm that an important objective of this strategy is to delay or block the market entry of generic medicines.”*

Originators file applications for patents to inventions as they arise during the research and development of a drug product. The majority of these will arise during the development of the first launched product. However, product development, as in most technological areas, is a continuous process, and inventions will be made, for which patent protection will be sought at all stage of the life cycle of a product. Provided that the inventions meet the criteria of patentability, then the originator is entitled to exercise his patent right to prevent others from using the invention during the life of the patent.

Opposition numbers and outcomes

The Report¹⁵ states that in the period 2000 – 2007, the opposition rate (i.e. the number of oppositions filed per 100 granted patents) in the closest available proxy for pharmaceuticals (A61K*) is consistently higher than the opposition rate in organic chemistry and all sectors taken together. A61K* refers to the IPC classification A61K from which has been excluded patents classified A61K6 (preparations for dentistry) and A61K7 and 8 (cosmetic and similar toilet preparations).

In A61K* the opposition rate ranged from 7.3% to 11.3%, compared to organic chemistry where it ranged from 3.3% to 4.5% and all sectors where the opposition rate was between 5.2% and 5.8%. First it is misleading to characterise organic chemistry as the closest available proxy; this would appear to be one of those fields excluded in the report from A61K, in particular A61K7 and A61K8, cosmetics, which have a particularly high opposition rate, probably higher than that in A61K*. An alternative proxy would be the class A61, excluding A61K*, which relates generally to medicinal or veterinary sciences; hygiene. This overall class has shown similar increases in patent filings from 2000-2007 compared to A61K*.

Further to characterise the generic companies as prevailing in 75% of the opposition cases¹⁶ *“as the originator company's patent was either revoked or restricted in scope.”* is misleading. An amended patent very often still protects the originator’s commercial product. Without further investigation, it cannot be counted as the generic company being successful. Maintaining the patent as amended might just as well be credited as a success to the originator.

¹⁴ Executive Summary, page 9

¹⁵ Paragraph (552)

¹⁶ Paragraph (570)

Furthermore, the Report's opposition analyses are based on only 52 out of 109 procedures in which a final decision was reached. In such a small sample, statistics of outcomes are of little value. In any event, according to figures published by the EPO in the 2007 Annual Report, which gave the outcome of 2750 oppositions, the opposition was rejected in 31.5% of cases, the patent revoked or amended in 68.5% of the cases – not statistically significant from the 75% figures quoted in the Report.

Duration of Opposition and Appeals Procedures

The Report¹⁷ comments on the duration of opposition and appeals procedures at the EPO, noting at (554) that *“the average duration of the opposition procedure was approximately 3.6 years from the initiation of the procedure until the final ruling (including in the sample final cases with and without appeal).”* The Report goes on to say¹⁸ that *“the sector inquiry also gathered evidence that originator companies whose EPO patents are opposed may, in some instances, prolong the opposition procedure.”*

Informal data gather by CIPA suggests that average duration of opposition procedures, from initiation to final ruling, is in the region of 5 years, and on occasions, particularly where Board of Appeal decides on one issue (for example, sufficiency or added matter) and remits the opposition to the opposition division, to examine the remaining issues (for example, novelty and inventive step), the procedure can take in excess of 10 years. These delays are a consequence of the EPO procedures, in which grounds of opposition are dealt with sequentially, rather than in parallel.

The experience of members of this Institute is that the single biggest factor determining the duration of both opposition and appeal proceedings is the delay in the EPO issuing a summons to oral proceedings. Both opposition and appeal proceedings are essentially carried out in writing. Notice of opposition to the grant of a patent must be given within 9 months of the publication of the mention of grant the patent in the European Patent Bulletin. Although on a small number of patents, a notice of opposition is filed within the first few days of grant, the vast majority of oppositions are filed in the last few days before the expiry of the opposition period.

Thereafter the notice(s) of oppositions, and supporting grounds, are transmitted to the patentee and a period, usually of 4 months, is set by the EPO for the patentee to respond to the opposition and make amendments to the patent. Generally, a two month extension the reply period is available on request by the patentee, but further extensions of time must be justified by the patentee, and are not automatically granted by the Opposition Division. Sometimes either the opposition division or the opponent(s) will make comments on the patentee's reply, but more usually the matter goes quiet until the Opposition Division summons the parties to be heard in oral proceedings held at the EPO. Usually the parties will request that they be heard in oral proceedings, in the event that their request (that the patent be maintained if they are the patentee or that the patent be revoked in its entirety if they are the opponent) is not granted by the Opposition Division. There is a usually a delay of 12-18 months between the initial written responses of the parties and the summons being issued.

¹⁷ C 2.3.1.4, paragraph (554)

¹⁸ Paragraph (555)

Further, parties cannot, under the implementing regulations of the EPC, be given less than two months notice of the date of the oral proceedings. Usually, the hearing is scheduled at least four months from the notification of the summons and often is in the region of 6-9 months after the notification of the summons. The summons may include a provisional, non-binding opinion from the OD of the issues that the parties need to address at the oral proceedings and all parties are set a non-extensible deadline for making final, written submissions, including for the patentee, amendments to the patent, at least one, and generally two, months before the date set for the hearing.

Although the Opposition Division usually will give an oral decision at the hearing, stating whether the opposition(s) are dismissed, the patent is revoked or is to be maintained in an amended form, no appeal can be filed until the OD has notified the parties of its decision in writing. This usually takes at least one month, and often takes from 2 to 6 months from the date of the hearing or even longer.

Any party adversely affected by the decision has a right of appeal to the Board of Appeal. According to the EPC, notice of appeal must be given within 2 months of (written) notification of the OD's decision and the statement of grounds must be filed within 4 months of that notification. Thereafter, the respondent(s) are entitled to reply to the appeals in a period set by the Board of Appeal (usually four months). As with responses in the opposition procedure, the Boards will usually grant a two month extension of time to for filing a reply. The procedure then usually goes quiet, again for a period of 12-18 months or longer, until the parties are summoned to be heard in oral proceedings before the Board of Appeal. Again, the date for the hearing is usually set from 4 to 6 months beyond the date of the summons.

The time periods set by the EPO for the parties to respond to the submissions of the other parties, together with the necessary delays in holding a hearing after issuance of a summons and in rendering the written decision by the OD mean that it is inevitable that even straightforward opposition proceedings, followed by an appeal, are likely to last at least two years. However, the single biggest determinant of the duration of the proceedings is the delay in issuing the summons, once the initial written proceedings have finished in both opposition and appeal proceedings, which usually adds at least two years to the procedure and may well add a great deal more.

We are aware of one example¹⁹ relating to a pharmaceutical patent in which there were 9 opponents, where the appeal was heard 9 months after the filing of the grounds of appeal, with the summons being issued just 6 weeks after the filing of the grounds. The period for the respondents(opponents) to reply ran concurrently, and the board was still able to issue a provisional, non-binding opinion two months before the date of the hearing, inviting parties to make their final written submissions three weeks before the hearing. We would encourage the Boards of Appeal and the Opposition Divisions to act equally fast in other cases in the pharmaceutical sector.

CIPA would welcome an improvement in the timescale of handling the opposition and appeal procedure, although it recognises that the EPO's ability to react may be limited by the availability of suitability qualified staff.

¹⁹ T1772/06

Conclusions

1. Patents are intended to stop competitors using inventions protected by those patents.
2. There is no legal distinction between primary and secondary patents – the only criteria that an invention must satisfy are those of patentability
3. Pharmaceutical products, like products in many other technological fields, may be protected by a number of patents – on expiry of the earliest to expire of the patents, competition is likely to be delayed by the later expiring patents.
4. Much of the delay in EPO opposition and appeal proceedings is due to the slowness on the part of the EPO in issuing summons to oral proceedings.
5. We are generally concerned at the negative tone taken in the Report towards the patent system and the legitimate ways in which it is used.