WATCH THIS PHARMA SPACE

The European Commission's investigation into the behaviour of companies operating in the pharmaceutical sector in the European Union culminated in the publication of a final report on July 8, 2009. Duncan Curley looks at the implications.

In the face of spiralling European drugs bills, the rationale for the European Commission's initial investigation was to learn more about company practices that cause delays to the market entry of cheaper generic medicines. The commission presented its preliminary report in November 2008. On matters such as patent filing strategies and patent litigation (delaying) tactics, this preliminary report received a largely hostile response from originator pharmaceutical companies. The recommendations proposed in the commission's final report were much less contentious. The commission concluded that there is an urgent need to establish a Community Patent and a unified specialised patent litigation system in Europe. In addition, it welcomed recent initiatives of the European Patent Office (EPO) to accelerate certain of its prosecution procedures and ensure that only high-quality patents are granted.

Where to next for the commission?

The blaze of publicity that accompanied the commission's initial dawn raids for documents and the publication of the preliminary report has faded. There has also been a changing of the guard at DG Competition, with new Commissioner Joaquín Almunia replacing Neelie Kroes, who instigated the sector inquiry during her tenure of the competition portfolio. Although the recommendations in the final report were relatively benign, the pharmaceutical industry has been left in the unsatisfactory position of attempting to anticipate the commission's next move.

Patent settlement agreements

One particular aspect of company behaviour flagged by the inquiry was the question of patent settlement agreements between originator and generic companies. Sometimes, generic companies will mount a challenge to the validity of an originator company's patent rights to try and gain entry to a market before the patent expires. If a drug patent can be successfully challenged and invalidated in a court case, it may open the market up to generic competition. Rather than fight a case to a conclusion, sometimes the originator companies prefer to enter into a settlement agreement with a company that is challenging an important patent, instead of running the risk that a court will invalidate the patent at trial.

The European Commission noted in its final report that the fundamental factor considered by originator companies when deciding whether to enter into a settlement agreement with generic companies is the strength of their position in the case. If an originator company is not confident of winning, it may negotiate a settlement instead.

There are different types of patent settlement agreements, but two possibilities are:

- The originator company pays the generic company a sum of money (or effects some other form of 'value transfer' to the generic company) to withdraw its patent challenge and to remain off the market for a defined period of time
- The originator company gives the generic company permission (a licence) to enter the market, even though its patent is still in force.

For some time, the first kind of these deals has caused controversy in the United States (at the time of writing, a proposed ban on 'pay for delay' settlement deals—which had been backed by the US Federal Trade Commission (FTC)—had just been dropped from President Obama's package of healthcare reforms). It was therefore not surprising that patent settlement agreements were the subject of particular focus by the European Commission, in particular those agreements that involved a payment from the originator company to the generic company (often called a 'reverse payment'), in return for the generic company agreeing to refrain from entering the market. Whilst the FTC's hostility to reverse payment deals has been well documented, the European Commission remains unforthcoming about the compatibility of some of the common means of settling these disputes with the competition rules.

One thing is clear, the commission intends to carefully monitor patent settlements in the pharma sector. In a press release issued in January, the commission followed up its interest in patent settlement agreements during the sector inquiry with further requests to both originator and generic companies to submit copies of all settlements entered into between July 1, 2008 and December 31, 2009. The commission said that it was looking in particular at patent settlement agreements where an originator "pays off" (in the words of Kroes, in the official press release) a generic competitor in return for delayed market entry of a generic drug.

Where is the guidance?

To ignore the force of these words would seem unwise and yet the European Commission has not proposed any substantive guidance or lent any assistance to companies to help them understand how it views these deals. Whilst there is some US antitrust case law on these issues (expressly referred to in the commission's final report), it has been argued that US case law only pertains to behaviour within a very specific US regulatory regime (Hatch-Waxman legislation), which provides a statutory reward for the first generic entrant. There is no such regime in the EU. Although many of the reasons underlying the rationale for settlement by the originator companies in the EU and the US are the same, in the EU, generic companies must compete amongst themselves for first mover advantage. There is no additional reward provided by the EU legislature for the first generic product to reach the market. The incentives to compete and the economic effects of patent settlements are therefore often quite different in the EU and the US.

The guidelines accompanying the European Technology Licensing Block Exemption Regulation offer some guidance, but it really only relates to cross-licensing deals and is arguably too general to be of much assistance. Nevertheless, it is worth noting the warnings in the guidance. For example, where it is clear to the parties to a negotiated agreement that no 'blocking' patent position exists (i.e. both the originator and the generic company believe that the originator's patent is invalid), the consequence is that the "...the settlement is merely a means to restrict competition that existed in the absence of the agreement".

Most commentators would agree that companies in any sector that arrange their contractual affairs based on a patent that they both know to be invalid (a 'sham patent') deserve to feel the full force of the antitrust regulator. Similarly, those companies that mutually agree on contractual restrictions, with the effect of extending the 'exclusionary zone' conferred by a patented monopoly beyond the statutory term, may expect to have their agreement scrutinised very carefully. The real debate—in terms of European competition law analysis—lies not with these kinds of arrangement but with agreements that do not allow generic entry immediately and in an unlimited form, and that are accompanied by a 'value transfer' (such as a payment) from the originator to the generic.

A difficult balance

In assessing the value to society of these kinds of patent settlement agreement, it is difficult to balance the different public interests. It could be argued that originator companies should remain free to take commercial decisions about the strength of their patent rights and to enter into any kind of litigation settlement deal. Settlements should not be discouraged by antitrust regulation. On the other hand, the public purse should be protected against a 'carve-up' of the market between the originator and the generic companies.

The commission has not yet committed itself, but seems instead to have elected to proceed cautiously, by investigating particular aspects of behaviour on a case-by-case basis. One such investigation was announced alongside the publication of the final report. The set of factual circumstances that gave rise to that investigation are known from the UK public record and serve to highlight some of the issues and the kinds of agreement that are of concern.

UK perindopril litigation

The drug product Coversyl® first received marketing authorisation in Europe in the late 1980s. The active pharmaceutical ingredient (API) is well-known as the tertiary butylamine salt of perindopril. The UK patent extension (supplementary protection certificate (SPC)) for Coversyl® expired on June 21, 2003. In anticipation of the expiry of the SPC, Servier filed a number of secondary (or 'follow-on') patent applications, claiming various crystalline forms of perindopril and processes for their manufacture. The granted patents were subsequently the target of litigation challenges brought by generic competitors of Servier in the English Patents Court between 2005 and 2007. Coversyl® had UK sales of approximately £70 million in 2005, which shows the size of the market and the incentive for the generic competition.

It is also important to note that one of the secondary patents relied upon by Servier in the English litigation proceedings had been opposed at the European Patent Office (EPO). The Opposition Division of the EPO decided after oral proceedings on July 27, 2006 to uphold the grant of the patent. There was the possibility of an appeal, but this can take up to three years to be determined. Accordingly, once the grant of the European Patent had been upheld, the companies that wished to launch 'at risk' a generic form of perindopril in national EU markets were well advised to bring separate challenges to the validity of Servier's European patent in the relevant national courts. This is what happened in the UK, with patent challenges brought in 2006 by several UK subsidiaries of generic companies in response to patent infringement lawsuits from Servier.

The settlements

Subsequently, Servier concluded patent settlement agreements with both Slovenia's KRKA and India's Lupin. Some of the terms of the KRKA deal were referred to in a public judgment of the English Court published in October 2008. The essence of the settlement was that KRKA withdrew its challenge to the patent in both the EPO and the UK, and agreed not to sell in the UK in return for permission to market its generic perindopril in certain Central and Eastern European countries.

The deal with Lupin was the subject of a press release, setting out the main terms, which meant Lupin would withdraw its opposition to the

patent in the EPO, as well as the UK validity challenge. In addition, Lupin assigned certain patent rights relating to perindopril to Servier and received a cash payment of €20 million.

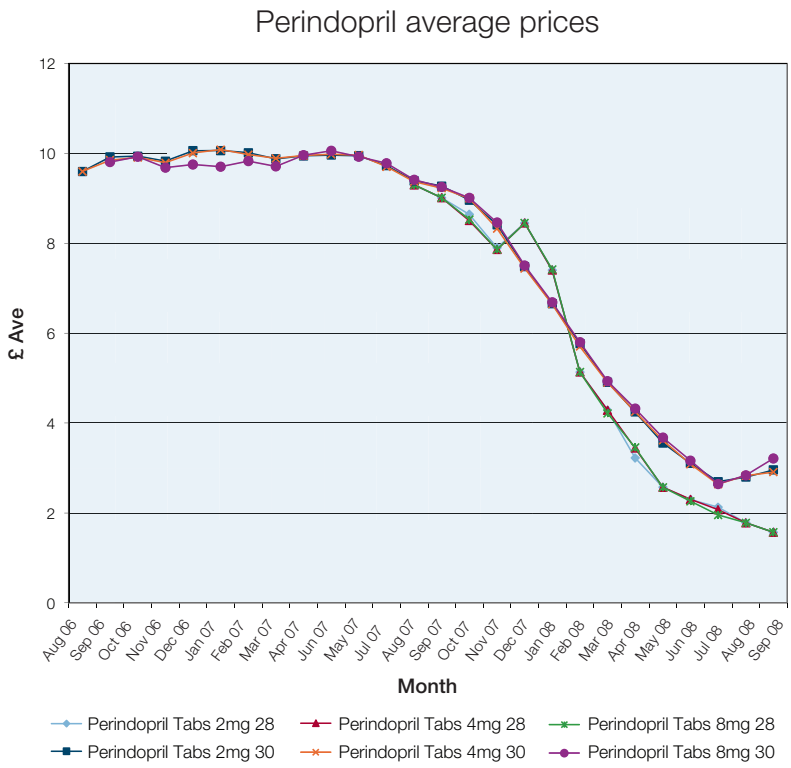
Further deals were done between Servier and other generic companies, and these are also referred to (in anonymised form) in the October 2008 judgment of the English Court. The main terms of one of these other deals were concluded in June 2006. Pursuant to this latter deal, a generic company agreed not to challenge Servier's patent in the UK and not to import or sell generic perindopril, while Servier agreed to provide quantities of perindopril at a guaranteed margin (subject to a floor price) to the company, so that it could sell an 'authorised generic', but Servier also had an option to pay liquidated damages instead of actually effecting supply. This effectively gave Servier the right to exclude its generic competitor from the market. This right was obtained by Servier agreeing to pay the generic company £5 million and a further £500,000 per month, for each month of non-supply to the generic. Servier exercised its option not to supply in August 2006 and continued to do so during the litigation. All told, Servier apparently paid this particular generic company approximately £10 million to stay out of the market.

The end of the party

Apotex was the only generic company to see its validity challenge through to the end. In July 2007, a judgment of the English Patents Court was handed down in Apotex's favour, invalidating the patent in the UK. Three generic companies promptly entered the UK market, even though an appeal by Servier continued for several more months, finally ending in May 2008 with a rejection of Servier's appeal and some damning comments in Lord Justice Jacob's judgment:

"It is the court's job to see that try-ons such as the present patent get nowhere. The only sanction (apart, perhaps, from competition law which thus far has had nothing or virtually nothing to say about unmeritorious patents) may, under the English litigation system, lie in an award of costs on the higher (indemnity) scale if the patent is defended unreasonably."

The graph (courtesy of Wavedata Ltd: www.wavedata.co.uk) show that the price of Servier's Coversyl® remained relatively constant in the UK until the first three generic entrants to the market in July 2007 (the date of the first instance Patents Court decision). The three generics then competed away the price until the final appeal decision in 2008. Thereafter, more generic companies entered the fray and the price dropped further to between approximately £2 and £3 per pack (depending on the strength).



One can appreciate from the graphic that the UK public interest was arguably not served in the period up to July 2007. On one view, until that point in time, the price of Coversyl® was kept higher than it should have been, by virtue of a patent that was later shown to have been invalid and a litigation-and-settlement strategy by Servier (based on that patent) that kept fierce generic competition at bay in the UK market.

On another view—and in Servier's defence—the patent in question had been upheld after an opposition proceeding in the EPO. Servier was then entitled to rely on the patent rights that it had obtained and to defend the generic challenges to its patent.

Conclusions

Prior to the sector inquiry and the commission's individual investigations, it was well known that contractual clauses granting exclusivity and other restrictions on a company's ability to compete have been sensitive topics for European competition regulators, particularly in agreements where the contracting parties have significant market shares. In the specific context of patent settlement agreements, the commission is concerned that they are concluded privately—without proper regard for consumer interest—and it seems determined to test the boundaries of competition law to ensure that consumer welfare is ultimately respected. Although the commission has drawn no conclusions in its final report on individual cases, the series of ongoing investigations demonstrate its view that if companies 'misuse' the patent system and cause harm to consumers, competition law can be used to restore the competitive process. However, until the commission starts concluding its investigations and issuing some decisions (which go on to be tested in the European courts), the full extent of the 'reach' of competition law into the realm of patent settlement agreements remains unknown. This is a debate that continues to unfold and those involved in the European pharma sector should keep a careful watching brief on developments.

Duncan Curley is director of Innovate Legal. He can be contacted at: duncancurley@innovatelegal.co.uk

Duncan Curley

Dr Duncan Curley is the founder and director of the boutique IP law practice, Innovate Legal, based in London. Curley's experience consists predominantly of dispute resolution and patent litigation in the pharmaceutical sector. He is the author of *Extending Rewards for Innovative Drug Development*, a report on supplementary protection certificates published by the Intellectual Property Institute.