These issues are likely to arise more frequently in the future as companies seek to align their intellectual property portfolios with their long-term strategic objectives.

Antitrust in the Pharmaceutical Sector in the EU

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On July 8, 2009 the European Commission adopted its Final Report in its competition (antitrust) inquiry into the pharmaceutical sector.[72] Almost three years later, this article considers the subsequent antitrust developments in this sector in the EU, with a focus on two major decisions adverse to AstraZeneca and Pfizer, which are both under appeal.

During the course of the aggressive inquiry, which began on January 15, 2008, concerns were raised that excessive antitrust scrutiny of patents "*would have a significant and far-reaching chilling effect on innovation, investment and employment across all research based industries on which Europe…depends*",[73] "*would be very damaging to competitiveness of European companies in global markets*"[74] and "*would inevitably make Europe an unattractive option for inward investors in all patent-dependent industries*".[75]

The Final Report indicated particular concern in relation to settlements between innovative pharmaceutical companies and generics (similar issues have been considered in the United States[76]) and also said that "*defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a license on unused patents will remain under scrutiny in particular in situations where innovation was effectively blocked*".

Reports on pharmaceutical settlements

Since the publication of the Final Report, the Commission has produced two reports monitoring pharmaceutical settlements (to the end of 2009 and 2010) and is currently working on a third report (to the end of 2011).

In the second report, published on July 6, 2011, the Commission welcomed a significant drop in so-called "pay-for-delay" settlements (which involve payment by the innovator to the generic in return for a limit of generic entry).

[72] The Final Report, and various documents relating to the inquiry, can be found on the website for the inquiry at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html. Discussion of the inquiry can be found in The AIPLA Antitrust News, May 2009, pp7-13 and October 2009, pp6-11.

[73] Submission of the European Federation of Pharmaceutical Industries and Associations (EFIPA) in response to the Preliminary Report, January 30, 2009, para 33.

[74] Submission of the Intellectual Property Institute (IPI) in response to the Preliminary Report, January 30, 2009, p12.

[75] Ibid.

[76] See most recently *FTC v Watson Pharmaceuticals*, April 25, 2012 (11th Cir.), rejecting the FTC's appeal against the dismissal of its complaint against a "pay for delay" settlement on the basis of failure to allege that the settlements exceeded the scope of the patent in question.

Ongoing and closed investigations

The Commission has opened investigations against various innovative pharmaceutical companies including Servier in relation to perindopril (July 2, 2009), Lundbeck in relation to citalopram (January 7, 2010), Cephalon in relation to modafinil (April 19, 2011) and Johnson & Johnson in relation to fentanyl (October 18, 2011).
The Commission opened but then closed investigations against AstraZeneca (March 1, 2012) and GlaxoSmithKline (March 2, 2012). It has also closed an existing investigation against Boehringer Ingelheim (July 6, 2011).

AstraZeneca - omeprazole

In the period since the pharmaceutical inquiry, the Commission has successfully defended its existing antitrust decision against AstraZeneca for abuse of a dominant position in relation to omeprazole at first instance. The decision on the further appeal by AstraZeneca is now due soon.
In this case, the Commission decided on June 15, 2005 that AstraZeneca had abused its dominant position by (a) making misrepresentations to national patent offices when applying for Supplementary Protection Certificate protection (patent term extension), thus lengthening the term of protection and (b) seeking to deregister the marketing authorization for omeprazole capsules in certain EEA Member States when launching omeprazole tablets, thus reducing the risk of parallel imports and generic competition.

AstraZeneca appealed to the General Court against the findings of dominant position and of abuse. However, those appeals were largely rejected on July 1, 2010.[77]

The judgment of the General Court was then appealed by AstraZeneca to the European Court of Justice.[78] The hearing took place on January 12, 2012 and the (non-binding) Opinion of Advocate General Mazák is due on May 15, 2012. The final judgment of the Court can be expected later in 2012 or early 2013.

Pfizer - latanoprost

National competition regulators have also been considering the pharmaceutical sector. On January 11, 2012, the Italian competition authority made a controversial decision against Pfizer for abuse of a dominant position in relation to latanoprost.
In this case, Pfizer's predecessor Pharmacia had applied for European patent EP 0,364,417 covering the use of latanoprost for the treatment of glaucoma. Once it was granted, Supplementary Protection Certificates (SPCs) providing patent term extension were obtained in certain countries in the EU but not for some reason in Italy and Spain (most likely administrative oversight). However, prior to grant Pharmacia had filed a divisional patent application, and a subsequent divisional of that (EP 1,225,168) was filed on April 26, 2002 but first examined by the EPO only on March 26, 2008 and then granted on January 14, 2009. On the basis of that divisional patent, Pfizer filed and obtained an SPC in Italy, so as to have the same duration of protection there as in the rest of the EU.

[77] Case T-321/05 [2010] ECR II-02805. The General Court was previously known as the Court of First Instance.
[78] Case C-457/10 P, filed on September 16, 2010. Arnold & Porter (Brussels) LLP represents EFPIA as the intervener in this case, although the views expressed in this article are strictly the author's own.

However, following an Opposition filed by generic competitors (Ratiopharm and others), the divisional patent was revoked at first instance by the Opposition Division of the European Patent Office on October 6, 2010. One week later, and following a complaint by Ratiopharm, the Italian competition authority launched an investigation on October 13, 2010.

Despite extensive commitments offered by Pfizer in 2011, under which it would provide royalty-free licences under the divisional patent and SPC, the Italian competition authority proceeded to its decision on January 11, 2012. The authority relied heavily on the General Court's judgment in *AstraZeneca* in finding an abuse of a dominant position by Pfizer and imposing a fine of €10.7 million. In a long decision which contains several misunderstandings of basic patent practice, the Italian authority found particular anti-competitive conduct in the filing of the divisional patent application, the failure to launch a new product based on the divisional which the authority thought would have been "normal", the limitation of the SPC applications to countries where Pfizer did not already have an SPC and Pfizer's subsequent reliance on the patent in litigation. It is difficult to see what, if anything, is exceptional about Pfizer's conduct.

Pfizer has appealed both against the revocation of the divisional patent by the Opposition Division (appeal T 2402/10, which will be heard on May 10-11, 2012) and the decision of the Italian competition authority, which is likely to take significantly longer.

Conclusions

The developments following the pharmaceutical sector inquiry should be of interest to anyone who files, obtains or asserts patents in the EU. Although the focus has been on that particular sector to date, many of the principles will apply equally to other sectors.

At present, where an undertaking has a dominant position in a particular market, its conduct in relation to patents in the EU is likely to be subject to a higher standard than otherwise (*AstraZeneca*). Of even greater concern is the suggestion that filing, obtaining and granting patents can be anticompetitive even in the absence of any suggestion of a reduced standard of conduct (*Pfizer*). These developments are notable at a time where the courts in the United States have limited the scope of inequitable conduct as a basis for non-enforceability of patents.[79]

In addition, these cases serve as an important reminder that document management is not only relevant in relation to possible discovery obligations in the United States. Both decisions relied heavily on internal communications where blunt commercial discussions were viewed suspiciously by the antitrust regulators. In particular, it should be remembered that communications of in-house counsel, and even external counsel not qualified in the EU, may not be accorded privilege and could be seized and relied upon by EU antitrust authorities.[80]

[79] *Becton Dickinson v Therasense*, May 25, 2011 (Fed. Cir. en banc).

[80] Case C-550/07 P *Akzo Nobel v Commission* [2010] ECR I-0000 (September 14, 2010) following Case 155/79 *AM & S Europe v Commission* [1982] ECR 1575, paras 25-27.