Aftermath of AstraZeneca and the Pharmaceutical Sector Inquiry: The Big Chill?

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Aftermath of *AstraZeneca* and the Pharmaceutical Sector Inquiry: The Big Chill?

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Introduction

On June 15, 2005, the European Commission decided under art.82 EC that AstraZeneca had abused the dominant position of its drug Losec (omeprazole) on the market for proton-pump inhibitors, which are used to treat ulcers. AstraZeneca was found to have misled national patent offices when applying for supplementary protection certificates (SPCs) based on its patents covering omeprazole and to have selectively deregistered its marketing authorisations for Losec capsules in Denmark, Norway and Sweden in favour of its next-generation Losec MUPS tablets.[1] AstraZeneca appealed against that decision.

On January 15, 2008, the Commission launched an inquiry into the pharmaceutical sector in Europe, starting aggressively with unannounced inspections (dawn raids) at the premises of a number of pharmaceutical companies.[2] On November 28, 2008, the Commission published its preliminary report, which was highly critical of originator companies (that develop and sell new medicines) delaying the entry onto the market of generic companies (that sell medicines equivalent to those new medicines). In particular, the use of intellectual property by originator companies was criticised.

The preliminary report was opened up to a two-month public consultation. Some 75 submissions were received by the Commission, a number of which attacked the findings of the preliminary report and suggested that the approach taken by the Commission could damage innovation in Europe and competitiveness of European companies.

For instance, the European Federation of Pharmaceutical Industries and Associations (EFPIA), which represents originator companies, noted that:

> "The so-called 'toolbox' of originator strategies alleged to delay generic entry is simply a description of lawful commercial activities common to all innovative industries: patent portfolios, patent litigation, settlements, regulatory interventions, and the patenting, development and marketing of next generation products. Calling into question the legality of any of these activities is to invite technological stagnation. It would have a significant and far-reaching chilling effect on innovation, investment and employment across all research based industries on which Europe and the achievement of the Lisbon Agenda depend."[3]

Similarly, the Intellectual Property Institute (IPI), the United Kingdom's leading independent research organisation informing the development of intellectual property law and policy, concluded as follows:

> "[T]he Institute is concerned that the attitude towards the patent system that is apparent from the Report and that appears to have been adopted by the Commission in its preliminary findings in the Pharmaceutical Sector Inquiry may lead to pressure to weaken the patent system not only for pharmaceuticals but for all industry sectors. This would be very damaging to the competitiveness of European companies in global markets. Further, such a move would inevitably make Europe an unattractive option for inward investors in all patent-dependent industries."[4]

On July 8, 2009, the Commission adopted its *Final Report in the Pharmaceutical Sector Inquiry*. This was toned down from the preliminary report, although the Commission still indicated concern over patent-litigation settlements between originator and generic companies and refusals to license unused patents.[5]

On July 1, 2010, the Commission's decision against AstraZeneca was largely upheld by the General Court.[6] This is the subject of a pending appeal to the Court of Justice.[7]

[1] Decision relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3—AstraZeneca) [2006] OJ L332/24.
[2] Documents related to the inquiry can be found at the Commission's website, *http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/* [Accessed September 30, 2011].
[3] EFPIA response (January 30, 2009), para.33.
[4] IPI Response (January 30, 2009), p.12.
[5] European Commission, *Final Report in the Pharmaceutical Sector Inquiry* (July 8, 2009), pp.254–310 and 380–412 respectively.
[6] *AstraZeneca AB v European Commission* (T-321/05) [2010] 5 C.M.L.R. 28. Arnold & Porter (Brussels) LLP represents EFPIA as the intervener in this case. However, the views expressed in this article are strictly the authors' own.
[7] *AstraZeneca v Commission of the European Communities* (C-457/10 P) [2010] OJ C301/18, appeal filed September 16, 2010.

The fundamental question now is whether the sector inquiry and *AstraZeneca* case will lead to a broad change in competition analysis of the pharmaceutical sector, and potentially the "chilling effect" feared by EFPIA and the IPI, or whether their impact is more limited.

As a case study, we consider the investigation by the Italian Antitrust Authority (the IAA) into Pfizer's filings of patents and SPCs to protect its glaucoma drug Xalatan (latanoprost). That investigation was formally opened on October 13, 2010, shortly after the *AstraZeneca* judgment.[8]

Facts of the case

Pfizer's patents, SPCs and marketing authorisations

On September 6, 1989, the Swedish pharmaceutical company Pharmacia AB (acquired by Pfizer in 2003), applied for a European patent for the use of various prostaglandin derivatives, including latanoprost, for the preparation of a treatment for glaucoma or ocular hypertension. The patent was granted by the European Patent Office (EPO) as EP 0,364,417 (EP '417) on February 9, 1994 for a period of 20 years from the date of the application, thus the patent was set to expire on September 6, 2009.

Latanoprost received its first EU marketing authorisation in Sweden on July 18, 1996 and authorisation in other EU countries followed, including Italy on July 24, 1997. Under Regulation 1768/92 art.7,[9] Pharmacia was entitled to apply for SPCs within six months of the marketing authorisation in each country. In order to compensate for the time taken to obtain authorisation, a granted SPC would extend the term of protection in each country to July 17, 2011, 15 years after the first authorisation was granted in the European Union.[10] Pharmacia obtained SPCs in certain countries, including Sweden, but did not do so in Italy where protection was therefore still due to expire on September 6, 2009.[11]

However, prior to grant of EP '417, Pharmacia had filed a divisional patent application[12] at the EPO based on its original patent application.[13] On April 26, 2002, shortly before that first divisional was granted, Pharmacia filed a further three divisional applications.[14] One of those, EP 1,225,168 (EP '168), is the patent now in dispute in Italy.

EP '168 was not examined by the EPO until March 26, 2008, which considered the application was valid in part. Matters then proceeded very quickly. On July 17, 2008, Pfizer responded by deleting from the scope of the patent the part said to be invalid. On August 12, 2008, Breuer & Müller, a firm of European patent attorneys, filed third-party observations in their own name arguing that even the remaining scope was invalid.[15] The EPO sent a copy of the observations to Pfizer but then indicated on November 17, 2008 that they intended to grant the patent, which they did on January 14, 2009.

Like EP '417, EP '168 would expire on September 6, 2009 in Italy. However, on April 30, 2009, Pfizer applied for an SPC on the basis of EP '168 in Italy, and this was granted on June 8, 2009. This extended the protection in Italy until July 17, 2011, the same as SPC protection in other countries in the European Union but under EP '168 rather than EP '417. On July 14, 2009, Pfizer's Italian lawyers wrote to Ratiopharm, a generic pharmaceutical company, requesting confirmation that they would respect Pfizer's rights under the SPC based on EP '168.[16]

On October 12, 2009, Breuer & Müller, now acting for Ratiopharm, filed an opposition at the EPO seeking to have EP '168 revoked and asked that the hearing be accelerated in light of the threats from Pfizer.[17] The opposition was heard on October 5–6, 2010 and the Opposition Division held that the patent should be revoked. However, Pfizer appealed against that decision, meaning the EPO's revocation is suspended pending the outcome of the appeal.

[8] Italian Antitrust Authority Decision 21672 of October 13, 2010.

[9] Regulation 1768/92 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJ L182/1, now codified in Regulation 469/2009 [2009] OJ L152/1.

[10] More recently, paediatric extensions under Regulation 1901/2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 [2006] OJ L378/1 art.36, have now extended this to January 17, 2012.

[11] The authors do not know why no SPC application was filed by Pharmacia in Italy in 1997/1998. However, it seems highly unlikely that this was to lull generic manufacturers into a false sense of security in the hope that Pharmacia would be granted a patent based on a divisional application over a decade later, based on which an SPC application could be filed.

[12] Under art.76 of the European Patent Convention, an applicant can file a divisional patent application which benefits from the filing date of the original application, provided it only covers subject matter which does not extend beyond the content of the earlier application as filed. Under r.25 of the Implementing Regulations then in force, divisional applications could be filed at any time in relation to any pending earlier application. Standard practice at that time was only to file divisional applications only after the EPO had indicated that it intended to grant the parent application, thus allowing the agreed claims to be granted while other claims could continue to be discussed. In the case of EP '417, the EPO indicated that it would grant the patent on March 8, 1993. Under r.36 of the new Implementing Regulations, from October 1, 2010 divisional patents can only be filed within two years of the first substantive communication from the EPO's examination division. For reference, the first substantive communication in relation to EP '417 was despatched on November 28, 1990.

[13] EP 0,569,046, filed on June 15, 1993 and later granted on November 13, 2002.

[14] Pharmacia filed EP 1,224,934 (not granted), EP 1,224,935 (not granted) and EP 1,225,168 (granted on January 14, 2009). Further divisional patent applications were filed later.

[15] As is perfectly permissible in EPO proceedings (cases G-3/97 and G-4/97 [1999] OJ EPO 245 and 270), Breuer & Müller did not indicate whether they were acting for a client or on their own account.

[16] In fact, ongoing litigation between Pfizer and certain generic pharmaceutical companies has resulted in the sale of generic latanoprost as of May 17, 2010. Such sales were then suspended on June 27, 2010 but resumed on July 6, 2010. In addition, by a decision of July 29, 2010, the Italian Supreme Administration Court (Consiglio di Stato) overturned the Lazio Regional Administrative Court and held that generic latanoprost should be added to the Italian state health reimbursement list notwithstanding the ongoing patent dispute (procedure 06066/2010).

[17] A further four opponents also challenged the patent.

The IAA's investigation

Ratiopharm also complained to the IAA and, on October 13, 2010, the IAA launched an investigation into Pfizer's activities in order to determine whether Pfizer had artificially extended the duration of protection for latanoprost in Italy.

Borrowing heavily from the principles developed by the Commission in its pharmaceutical sector inquiry and the General Court in *AstraZeneca*, the IAA indicated that Pfizer's behaviour could be contrary to art.102 of the Treaty on the Functioning of the European Union (TFEU), which replaced art.82 EC in December 2009.

The IAA raised various concerns. First, that Pfizer's EP '168 constituted "double patenting" on the basis that it did not cover a different invention to EP '417. Secondly, that Pfizer had not told the Italian Patent Office that EP '168 was a divisional patent. Thirdly, that the following elements indicated that Pfizer had artificially extended its protection for latanoprost:

- that Pfizer did not launch a new drug following the grant of EP '168, whereas the IAA considered that such a new launch would be normal;
- that Pfizer requested an SPC in Italy several years after it applied for SPCs in other EU countries; and
- that Pfizer did not request SPCs in other countries (in fact, Pfizer took similar action in Spain).

Finally, the IAA noted that the patent had been provisionally revoked by the EPO the week before the IAA launched its investigation.

Referring to the Commission's pharmaceutical sector inquiry, the IAA indicated that the application for multiple divisional patents on the same patent can constitute a defensive technique by originator companies and suggesting that an instrumental use of administrative procedures by a dominant undertaking can constitute an abuse of the dominant position if restrictive of competition.

In the IAA's view, a similar conclusion was reached by the General Court in *AstraZeneca* where it stated that the submission to the public authorities of misleading information liable to lead them into error, in order to obtain IP rights to which the dominant undertaking is not entitled, constitutes a serious restriction of competition. The IAA, again referring to *AstraZeneca*, also indicated that the submission of misleading information must be assessed on the basis of objective factors and that proof of the deliberate nature of the conduct and of the bad faith of the dominant firm is not required for the purposes of identifying an abuse of a dominant position.

The IAA concluded that Pfizer had tried unlawfully to create legal uncertainty as to the date of expiration of its protection for latanoprost, thus discouraging entry by generic firms and increasing their entry costs into the Italian market. The IAA therefore reached the preliminary conclusion that Pfizer's behaviour was contrary to art.102 TFEU.

Pfizer's proposed commitments

Pfizer offered commitments to end the IAA's investigation on April 11, 2011 and modified these on May 11, 2011.

The main commitment offered by Pfizer is that of entering into a royalty-free licence for EP '168 and the SPC in Italy, Spain and Luxembourg with any interested party, and to withdraw its application for a paediatric extension of the SPC. Pfizer also offered to withdraw the actions brought against generic drugs producers who had launched generic latanoprost and to accept the related claims brought against it by generic drugs producers in the Italian courts (with the exception of those relating to the payment of legal and administrative fees). Finally, Pfizer proposed to issue a press release (to be published on its website) to explain latanoprost's properties and to highlight that generic latanoprost was available on the market, and to convey similar information through its pharmaceutical experts.

The proposed commitments were published for a one-month consultation on the IAA's website on May 16, 2011. The IAA's decision on whether to accept the commitments is pending. Pursuant to Italian rules, settlements in antitrust procedures do not require an admission of guilt from the parties involved. Similarly, if the commitments were to be accepted by the IAA, it would not have to adopt a decision detailing why it considered Pfizer's behaviour unlawful as the decision closing the investigation would typically focus on the assessment of the commitments.

Commentary

As described above, the IAA relied to a large extent on the Commission's pharmaceutical sector inquiry and on the General Court's *AstraZeneca* judgment. However, although on a static analysis the IAA's approach allows generic competition for latanoprost sooner in Italy, on a dynamic analysis it represents precisely the kind of chilling effect on innovation suggested by EFPIA and the IPI in their responses to the inquiry.

In the pharmaceutical sector inquiry, the Commission discussed at length the potentially negative effects that can result from a web of divisional patents as they can be used, among other things, to create a situation of legal uncertainty as to the scope and date on which a patent will be granted.[18] However, in the Pfizer case EP '168 was only the second divisional patent based on EP '417. It took the EPO almost six years to provide its first substantive examination after filing of EP '168, to which Pfizer responded in less than four months. The examination report and Pfizer's response were publicly

[18] Final Report in the Pharmaceutical Sector Inquiry, pp.193–201.

available on the EPO's website and Ratiopharm's European patent attorneys were able to file observations less than a month after Pfizer amended its claims (and over a year before the anticipated expiry of EP '417 in Italy). This does not match the concerns of legal uncertainty raised by the Commission in the Inquiry.

This case is also very different from *AstraZeneca*. In that case, AstraZeneca were said to have submitted incorrect information to certain European patent offices in order to obtain or extend SPC protection. Even if that conduct were ultimately found to be abusive by the Court of Justice, there was no similar conduct by Pfizer in the present proceedings. In particular, the SPC Regulation draws no distinction between parent and divisional patents and so there was no reason why Pfizer should have specifically mentioned that the patent was a divisional.

More broadly, the IAA appears to believe that Pfizer has abused the patent system to achieve an unlawful competitive advantage. There appears no solid basis for this belief, as nothing in Pfizer's conduct before the European Patent Office appears out of the ordinary. Pfizer filed divisional applications, amended them as required by the EPO and applied for SPC protection based on the granted patents. It then sought to enforce that protection in order to provide it in Italy with the same term of protection for latanoprost as elsewhere in the European Union.

The exclusive rights provided by patents and SPCs are intended to foster innovation by providing appropriate protection for innovators and thus to avoid the market failure which would occur if pharmaceutical products are exposed to generic competition too soon. If such protection is arbitrarily reduced by competition intervention, incentives to develop new pharmaceuticals will be reduced.

Pfizer appears to have done nothing more than attempt to rely on the patent and SPC system to protect its innovative glaucoma treatment across the European Union for the maximum period allowed by the legislation. However, it has presumably made a commercial calculation to offer commitments rather than fighting a competition investigation in Italy. As a result, it appears unlikely that the IAA will shed any light on the basis for its intervention. This, rather than divisional patent applications, creates real legal uncertainty. We can expect this to lead to further complaints to national competition authorities and, potentially, an increase in antitrust defences to patent enforcement in the pharmaceutical sector and beyond.