COMMENTS

Is Winter Coming? The Competition Chill Continues in *Italian Antitrust Authority v Pfizer (Xalatan)*

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On January 14, 2014, the Italian Consiglio di Stato (the highest administrative court) controversially reinstated a decision of the Italian antitrust authority finding that Pfizer abused a dominant position by obtaining a supplementary protection certificate in Italy on a valid divisional patent for latanoprost (Pfizer's Xalatan brand). That decision raises important and difficult questions on the enforcement practices of certain antitrust authorities in Europe, and should be considered by patent holders both within and outside the pharmaceutical field when planning patent strategy in Europe.

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.

Pharmacia received its first EU marketing authorisation for latanaprost (Xalatan) 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,[1] Pharmacia was entitled to apply for supplementary protection certificates (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 EU.[2] 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.[3]

However, prior to grant of EP '417, Pharmacia had filed a divisional patent application[4] at the EPO based on its original patent application.[5] On April 26, 2002, shortly before that first divisional was granted, Pharmacia filed

* The views expressed in this article are strictly the authors' own and are not necessarily those of their law firm or its clients. An earlier stage in proceedings was considered by Christopher Stothers and Marco Ramondino, "Aftermath of AstraZeneca and the Pharmaceutical Sector Inquiry: The Big Chill?" [2011] E.C.L.R. 591.

[1] Regulation 1768/92 [1992] OJ L182/1, now codified in Regulation 469/2009 [2009] OJ L152/1.

[2] More recently, paediatric extensions under Regulation 1901/2006 [2006] OJ L378/1 art.36 extended this by six months to January 17, 2012.

[3] 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.

[4] 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 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. The Implementing Regulations were amended so that, from October 1, 2010 to March 31, 2014, divisional patents could 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 dispatched on November 28, 1990. However, that time-limit was abolished as of April 1, 2014.

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

a further three divisional applications.[6] One of those, EP 1,225,168 (EP '168), was granted and is the patent now in dispute in Italy.

EP '168 was not examined by the EPO until March 26, 2008, when it considered that 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.[7] 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 EU 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.[8]

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.[9] 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 was suspended pending the outcome of the appeal.

The IAA's decision

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 on 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).

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 from 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: (1) 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; (2) that Pfizer requested an SPC in Italy several years after it applied for SPCs in other EU countries; and (3) that Pfizer did not request SPCs in other countries (in fact, Pfizer took similar action in Spain).[10] 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 suggested 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 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 offered commitments to end the IAA's investigation in April 2011 and modified these in May 2011.

Pfizer offered to enter into a royalty-free licence for EP '168 and the SPC in Italy, Spain and Luxembourg with any interested party, and to withdraw the 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.

[6] 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.

[7] As is perfectly permissible in EPO proceedings (Cases G3/97 and G4/97 [1999] OJ EPO 245 and 270), Breuer & Müller did not indicate whether they were acting for a client or on their own account.

[8] 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 n° 06066/2010).

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

[10] The Spanish competition authority also began investigating the case in December 2012, following the Italian authority's decision, but by resolution on February 13, 2014 refused to open proceedings for abuse of a dominant position.

On January 11, 2012, the IAA, having rejected Pfizer's proposed commitments, issued a decision finding an infringement and imposing an administrative sanction of €10.6 million on Pfizer.

The subsequent appeals

Pfizer appealed to the Regional Administrative Court. Meanwhile, on May 10, 2012 the EPO Technical Board of Appeal allowed the appeal and held EP '168 valid in amended form. On September 3, 2012, the court fully reversed the IAA's decision. It found that Pfizer had done no more than exercise its rights under patent law, both as regards the application for a divisional patent and the subsequent SPC, and as regards the injunctions that it brought against generics. It concluded that no additional elements had been identified to support a finding of abusive conduct.

However, that decision was then further appealed to the Consiglio di Stato (the highest administrative court), which reinstated the IAA's decision on January 14, 2014, making it final and binding. Subsequently, on May 28, 2014, the Italian Ministry of Health announced that it was seeking damages of €14 million (on top of the administrative fine).[11]

Commentary

The Consiglio di Stato appears to have based its conclusion on the following two main arguments:

1. regardless of whether Pfizer obtained its IP rights lawfully (the court regarding the evidence on that as irrelevant), it used them abusively, for a purpose which is inconsistent with that for which these rights are granted, by seeking to exclude competing generics from the market; and
2. this is confirmed by the fact that the divisional patent that Pfizer obtained, and on which the Italian SPC was based, did not lead to the introduction into the market of a new Pfizer product.

It is puzzling that the Consiglio di Stato would find that Pfizer had used its IP rights in a way "inconsistent with the purpose for which they are granted", when the very purpose of IP rights is to exclude competing products, whether they be innovative drugs or generics. There was (rightly) no objection to the fact that EP '417 blocked generic entry in this way until 2009 and the court cannot have been relying merely on internal documents which articulated the purpose of patent and SPC rights. Therefore, it seems that the real concern was based on the second argument.

As for that, those working in the field of patents would be very surprised to hear that divisional patent applications are expected to lead to the introduction of a new product. In order to be valid, divisional applications must be based on the disclosure in the original application from which they are divided, and thus seek to capture another aspect of that invention (which will rarely form the basis for an entirely new product). It would be surprising if that point had not been made in the evidence regarded by the court as irrelevant.

The role of competition law should not be to second-guess the rules and objectives of the IP system, particularly if it seeks to do so while intentionally rejecting the need to understand those rules and objectives.

More broadly, the Consiglio di Stato appears, effectively, to support the IAA's position that Pfizer's IP applications (and potential enforcement) constituted an abuse in and of themselves.

This is not a novel question in European Union competition law. Both the European Union's General Court and its Court of Justice in *AstraZeneca v European Commission*[12] have addressed this very issue. They ruled that the mere fact of applying for an SPC is *not* sufficient to constitute an abuse and that additional elements are required to make an SPC application an infringement of the competition rules under Union law.

More specifically, the General Court ruled that the submission to public authorities of (1) misleading information (2) liable to lead them into error, and (3) therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, is a practice that falls outside the scope of competition on the merits, and that such conduct, when engaged in by a dominant undertaking, is likely to be abusive. In practice, it will depend on the context whether such misleading representations are actually liable to lead the public authorities to the grant the exclusive right applied for—e.g. in view of the limited discretion of public authorities or the absence of any obligation on their part to verify the accuracy or veracity of the information provided.

The General Court found that, on the facts, the European Commission had correctly concluded that AstraZeneca had adopted a consistent course of conduct and that there were numerous items of evidence that support the conclusion that AstraZeneca had deliberately tried to mislead the patent offices. The General Court concluded, therefore, that the misleading representations made by AstraZeneca constituted a practice based exclusively on methods falling outside the scope of competition on the merits and contrary to the regulatory framework establishing SPCs.

The Court of Justice confirmed this interpretation when it ruled that:

> "Contrary to what the appellants submit, that examination by the General Court is not in any way based on the assumption that the practice in question constitutes 'an 'abuse in itself', regardless of its

[11] Ministero della Salute, *Comunicato stampa* n.68 (May 28, 2014), *http://www.salute.gov.it/portale/news/p3_2_4_1_1_stampa.jsp?id=4230* [Accessed August 25, 2014].
[12] *AstraZeneca v Commission* (T-321/05) [2010] E.C.R. II-2805; [2010] 5 C.M.L.R. 28; *AstraZeneca v Commission* (C-457/10 P) [2013] 4 C.M.L.R. 7.

> anti-competitive effect. On the contrary, the General Court expressly pointed out, at paragraph 377 of the judgment under appeal, that representations designed to obtain exclusive rights unlawfully constitute an abuse only if it is established that, in view of the objective context in which they are made, those representations are actually liable to lead the public authorities to grant the exclusive right applied for."[13]

It continued that:

> "AZ's misleading representations actually enabled it to obtain SPCs either to which it was not entitled, as was the case in Germany, in Finland and in Norway, or to which it was entitled only for a shorter period, as was the case in Belgium, in Luxembourg, in the Netherlands and in Austria."[14]

It is unfortunate that the Consiglio di Stato did not seem to have found it necessary to consider the above findings.

In more general terms, we are not aware of a precedent in European Union competition law where the mere application of a divisional patent and/or the application of a subsequent SPC by a dominant undertaking were held to be abusive conduct.

As already said, this case is very different from *AstraZeneca*. AstraZeneca were said to have submitted incorrect information to certain European patent offices in order to obtain or extend SPC protection. 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, there appears to be no basis to hold that Pfizer had abused the patent system to achieve an unlawful competitive advantage. Pfizer filed divisional applications, amended them as required by the EPO and applied for SPC protection once granted. That provided Pfizer in Italy with the same term of protection for latanoprost as elsewhere in the EU. In other words, 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 EU for the maximum period allowed by the legislation.

Nor did the European Commission's Pharmaceutical Sector Inquiry identify a particular issue with the application of divisional patents or SPCs on a stand-alone basis.[15]

In the 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.[16] 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 the filing of EP '168, to which Pfizer responded in less than four months. The examination report and Pfizer's response were publicly 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 Sector Inquiry.

Conclusion

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 were exposed to generic competition too soon. If such protection is arbitrarily reduced by competition intervention, incentives to develop new pharmaceuticals will be reduced. Those concerns were widely raised in response to the Sector Inquiry and, in general, the competition authorities and courts have recognised them—this was even made apparent in the widely criticised *AstraZeneca* case which the Italian authority and courts purported to follow. It is hoped that this decision in Italy will prove to be an aberration, but for the time being patent owners will still need to take appropriate antitrust advice in Europe and ensure that any discussion of patent strategy is written clearly to ensure it cannot be misunderstood by antitrust authorities.

[13] *AstraZeneca v Commission* [2013] 4 C.M.L.R. 7 at [106].
[14] *AstraZeneca v Commission* [2013] 4 C.M.L.R. 7 at [107].
[15] *Pharmaceutical Sector Inquiry, Final Report* (July 8, 2009), *http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/* [Accessed August 25, 2014].
[16] *Pharmaceutical Sector Inquiry* (July 8, 2009), paras 507-546, *http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/* [Accessed August 25, 2014].