CPI COMPETITION POLICY INTERNATIONAL

CPI Antitrust Chronicle
July 2012 (2)

From *Astra-Zeneca* to *Pfizer*: When Protection of Originators' Patents Ceases to be a "Right" and Becomes an Abuse of Dominance

Stefano Grassani
Pavia e Ansaldo

From *Astra-Zeneca* to *Pfizer*: When Protection of Originators' Patents Ceases to be a "Right" and Becomes an Abuse of Dominance

By Stefano Grassani[1]

I. INTRODUCTION

On Jan. 11, 2012, the Italian Antitrust Authority ("IAA") found Pfizer Inc. and its Swedish and Italian subsidiaries guilty of abuse of dominant position pursuant to Article 102 of the Treaty on the Functioning of the European Union ("TFUE").[2] The IAA alleged that these subsidiaries jointly engaged in unlawful exclusionary conducts so as to unlawfully extend IP exclusive rights over Pfizer's *Xalatan* blockbuster drug,[3] deterring or, in any event, delaying entry of generic competition on the Italian market. A fine in excess of US$ 11 million was levied on Pfizer.[4]

The decision has drawn widespread attention among practitioners and pharma companies, as it questions the antitrust legitimacy of regulatory tactics which may be lawful under IP laws, but could be said to raise obstacles to competitors and, therefore, trigger antitrust scrutiny. It has even been argued that, with this ruling, the IAA has gone considerably further than the already quite pervasive standard of abuse of dominance set by the 2010 EU General Court's judgment in *Astra Zeneca*.[5]

---

[1] Head Antitrust Practice, Pavia e Ansaldo, Milan-Italy.

[2] In the European Union, Article 102 TFUE broadly replicates Section 2 of the Sherman Act.

[3] *Xalatan* (active principle: *laanoprost*) is an eye-drop drug that reduces pressure in the eye by increasing the amount of fluid that drains from the eye. Xalatan is used to treat certain types of glaucoma and other causes of high pressure inside the eye.

[4] The text of the decision may be downloaded at http://www.agcm.it/concorrenza/intese-e-abusi/open/41256297003874BD/9AEB2CC6CAB65EA2C1257996003333CD.html. Unfortunately, only an Italian version is available. An English press release may be retrieved on the website of the IAA, at http://www.agcm.it/en/newsroom/press-releases/1986-pfizer-sanctioned-with-106-million-euro-fine-for-abuse-of-dominant-position.html.

[5] Commission Decision of 15 June 2005 (Case COMP/A.37.507/F3 – AstraZeneca), upheld by the EU General Court in 2010 and currently pending before the European Court of Justice. The *Astra Zeneca* case is the first one where the EU Commission found an abuse of dominance in the pharmaceutical industry. In 2005, the EU Commission fined Anglo-Swedish drug manufacturer AstraZeneca EUR 60 million (about $72 million) for allegedly misusing the patent system and the procedures for marketing pharmaceuticals to block or delay market entry for generic competitors to its ulcer drug *Losec*. The Commission decided that AstraZeneca's actions constituted serious abuses of its dominant market position in violation of Article 102 TFUE. According to the EU Commission, from 1993 to 2000 AstraZeneca attempted to block or delay market access for generic versions of Losec and to prevent parallel imports of Losec. AstraZeneca did these two actions:

While I respectfully disagree that the IAA's decision in *Pfizer* departs from the existing EU case law, it is certainly a very interesting ruling, with far-reaching implications. Moreover, the fact that it was issued by a national competition agency confirms that the decentralization of European antitrust law brought about by Regulation 1 of 2003 is indeed a reality, to the point where national agencies do not refrain from dealing with sensitive and critical matters—such as the interplay between IP and antitrust law—which one would assume the EU Commission would be primarily addressing.

Therefore, notwithstanding the fact that an appeal has been lodged by Pfizer before the Italian lower administrative court, and that a judgment is expected by the end of this year at the latest, the decision of the IAA in and of itself is worth of consideration.

II. A QUICK VIEW OF THE UNDERLYING FACTS

At the origin of the case is a complex "loss-of-exclusivity" strategy implemented by Pfizer in order to align the duration of its Xalatan's IP rights in Italy. Most likely as an undesired result of omissions inadvertently occurred at the time of the first marketing of Xalatan in Europe, Pfizer had not initially sought the granting of a supplementary protection certificate ("SPC") in Italy, with the consequence that IP protection over Xalatan was due to expire in Sept. 2009 in Italy, whereas in the rest of Europe Pfizer's IP rights over Xalatan were protected until July 2011.

In 2002, Pfizer decided to take steps to remedy this discrepancy, perfectly aware of the fact that loss of exclusivity in Italy would make early generic entry possible and, moreover, would inevitably sparks parallel imports from Italy to other countries.[6] Through its "Loss-of-Exclusivity Group," Pfizer therefore decided to lodge a request for a divisional patent with the European Patent Office ("EPO"). This divisional patent encompassed in its claims the active principle *latanoprost,* which was used for the production of Xalatan.

In January 2009, the EPO granted the divisional patent to Pfizer, subject to certain amendments to its claims, aimed at preventing the risk of double patenting of the latanoprost molecule. Notwithstanding these changes, Pfizer stipulated that the divisional patent covered latanoprost and, therefore, enabled it to apply for an SPC related to the Xalatan in Italy; an argument which Pfizer successfully made before the Italian authorities soon after having

---

- First, giving misleading information to several national patent offices in the European Union, resulting in AstraZeneca gaining extended patent protection for Losec through supplementary protection certificates ("SPCs"). In this specific case, the patent offices essentially relied on information supplied by AstraZeneca and they were not obliged—as in normal patent assessments—to consider whether the products were innovative. AstraZeneca's misleading conduct amounted to an abuse in Belgium, Denmark, Germany, the Netherlands, Norway, and the United Kingdom;
- Second, misusing rules and procedures applied by the national medicines agencies which issue market authorizations for medicines by selectively deregistering the market authorizations for Losec capsules in Denmark, Norway, and Sweden with the intent of blocking or delaying entry by generic firms and parallel traders. At the time, generic products could only be marketed and parallel importers only obtain import licenses if there was an existing reference market authorization for the original corresponding product (Losec).

For a cursory look of the decision, *see* Fagerlund & Rasmussen, *AstraZeneca: the first abuse case in the pharmaceutical sector*, at http://ec.europa.eu/competition/publications/cpn/cpn2005_3.pdf.

[6] Given that *Xalatan* had been originally developed by Pharmacia, some of the initial steps had been taken by Pharmacia, which was later acquired by Pfizer. For sake of simplicity, reference shall be made only to Pfizer.

obtained the divisional patent by the EPO. With the granting of the Italian SPC on the divisional patent in June 2009, Pfizer was able to close the IP gap between Italy and the rest of Europe, stretching patent protection for Xalatan in Italy to July 2011, in line with the rest of Europe.

The move caught generic companies by surprise (among them, Ratiopharm) which were ready or had planned to enter the market in Sept. 2009. Pfizer took legal steps to prevent them from entering the market in 2009, claiming Xalatan patent protection had been extended. Litigation ensued before both the EPO appeal board and Italian civil courts. In this context, a complaint was ultimately lodged with the IAA.

In October 2010, the EPO ruled that Pfizer's divisional patent was null. Soon thereafter, the IAA opened an antitrust investigation against Pfizer for abuse of dominance under Article 102 TFUE. The theory of harm was that Pfizer, deemed to be dominant on the market for advanced anti-glaucoma drugs, had abused its position to the detriment of competitors and, ultimately, consumers.

Before the IAA, Pfizer argued that it had no intent to foreclose competition, but simply to heal the failure to apply in time for an SPC under the original parent patent, and was not placing itself in any better situation than it would have been had it sought an SPC in the first place.

III. THE IAA'S FINDINGS

Relying on the evidence found in the course of the proceedings, which included proof of knowledge by Pfizer of the instrumental use of the IP regulatory regimes so as to align Xalatan's patent protection throughout Europe, IAA concluded that an infringement to Article 102 TFUE had been committed and, as said, severely fined Pfizer.

First of all, the IAA considered that Pfizer did not seek a divisional patent as a reward to any new invention, application, or innovative therapeutic use of its patented *latanoprost* molecule. According to the IAA, it was proven that the divisional patent applied for and obtained by Pfizer with the EPO had no other purpose than that of enabling Pfizer to immediately request, in Italy, an SPC from which Pfizer was time-barred from seeking, thus unduly extending patent protection for the Xalatant in Italy by almost two years. This artificial "creation" of a divisional patent was, therefore, a remedial scheme merely aimed at allowing for the release of an SPC which, under EU regulatory provisions, Pfizer was no longer entitled to in Italy.

Secondly, the IAA also took into account that no product was meant to be released by Pfizer based upon the divisional patent requested. Furthermore, the divisional patent was "validated" by Pfizer only in Italy, where—as a result of its own inaction—there was a gap in Pfizer's IP rights. No use was made of the divisional patent in the rest of Europe where, as explained, extended patent protection was already safeguarded.

IV. THE IAA'S REASONINGS

Against such a factual scenario (something Pfizer did not dispute before the IAA), it is now interesting to examine the legal reasoning pursued by the IAA, which very closely reflected the standard and principles embedded in the *Astra Zeneca* precedent:

1. As the EU General Court stated in *Astra Zeneca* (as well as in a number of other cases), the use of IP regulatory provisions simply to prevent competition, with no beneficial

effect or innovation being promoted, may amount to an abuse of dominance under European antitrust law. The type of competition that is to be promoted and protected under EU antitrust rules is competition "on the merits." This implies that IP rights, and the monopoly associated therewith, are warranted when the dominant company has engaged in a truly rewarding activity: a new product has been launched; a new drug has been discovered; a new process has been deployed; or, at the very least, the IP right has been somewhat linked to consumers' welfare. If IP rights become the tool for market entrenchment, and the holder has a dominant position, the misuse of the patent regime is not efficiency-driven and, consequently, may infringe antitrust law.

2. The IAA confirmed the principle, according to EU case law, that an abuse of dominance does not require intent to exist or to be proven. As Advocate General Masak recently held in the pending appeal of *Astra Zeneca* before the European Court of Justice:

> It is settled case-law that the concept of abuse of dominance is an objective concept. (…) the appellants' submission regarding a requirement of proof that AZ knew that it was not entitled to an SPC and was thus acting fraudulently, in my view, radically departs from the principle that abuse of dominance is an objective concept;[7]

3. The fact that a conduct may be legal or that a patent is lawfully granted under IP law does not preempt the enforcement of antitrust law, as the two sets of rules are independent and pursue different objectives:

> Where behaviour falls within the scope of the competition rules, those rules apply irrespective of whether that behaviour may also be caught by other rules, of national origin or otherwise, which pursue separate objectives. Similarly, the existence of remedies specific to the patent system is not capable of altering the conditions of application of the prohibitions laid down in competition law and, in particular, of requiring, in cases of behaviour such as that at issue in the present case, proof of the anticompetitive effects produced by such behavior.[8]

Therefore, the fact that Pfizer's conduct merely tried to recoup the same protection that it would have had if it had not "forgotten" to demand an SPC in Italy did not seem to work as a valid justification in the eyes of the IAA. As a matter of fact, EU rules on the granting of SPCs make the release of supplementary certificates contingent, *inter alia*, upon certain procedural time limits. If a company fails to comply with such limits and misses the deadline, the SPC cannot be granted and the company loses patent protection at the expiry of the basic patent life.

In light of the above, the IAA concluded that competition on the merits should be construed so as to prevent a dominant company from indirectly and subtly seeking for such additional patent protection by resorting to tactics which, ultimately, have a purely foreclosing object, regardless of whether such tactics are formally lawful under IP law.

[7] Opinion of Advocate General Masak delivered on May 15, 2012, *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62010CC0457:EN:HTML.

[8] IAA's decision at ¶181, citing ¶ 366 of the EU General Court's judgment in *Astra Zeneca*.

V. CONCLUSION

Needless to say, some of these concepts may raise an eyebrow. The notion of "objective" abuse and the possibility that defensive IP strategies may be found to amount to monopolization conducts (far beyond the theory of misuse of powers as known in the United States) are certainly bold holdings, well suited for criticisms for their "chilling innovation" spill-over effects. Yet, in Europe, this is for the time being good law.