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"From *Astra-Zeneca* to *Pfizer*" Stage II: The Italian Administrative Court Reverses the Monopolization Claim Established by the Autorità Garante della Concorrenza e del Mercato

By Stefano Grassani[1]

I. INTRODUCTION

As reported in the July edition of this *Chronicle*, 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]

Pfizer lodged an appeal against the decision before the competent Administrative Court which, with a judgment issued on Sept. 3, 2012, reversed the holding of the IAA and the ensuing fine.

II. A QUICK VIEW OF THE UNDERLYING FACTS

As stated in the above-mentioned *Chronicle* issue, the IAA had found that Pfizer implemented a complex "loss-of-exclusivity" strategy so as to align the duration of its Xalatan's IP rights in Italy where IP protection was due to expire in Sept. 2009, i.e. about 18 months earlier than the rest of Europe (where Pfizer's IP rights over Xalatan were protected until July 2011).

In 2002, Pfizer decided to take steps to remedy this discrepancy, allegedly aware of the fact that loss of exclusivity in Italy would have made early generic entry possible and, moreover, would have inevitably sparked parallel imports from Italy to other countries. Pfizer therefore decided to lodge a request for a divisional patent with the European Patent Office ("EPO"). This

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[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.

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 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.

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.

In 2012, the EPO Board of Appeals—reversing EPO's prior decision of Oct. 2010—found that Pfizer's divisional patent was valid.

III. THE RATIONALE OF THE JUDGMENT ISSUED BY THE ITALIAN ADMINISTRATIVE COURT

In short, the reasoning followed by the Tar Lazio may be summarized as follows.

By filing its applications with the competent regulatory bodies, Pfizer had tried to protect its rights and legitimate interests. Therefore, in order to prove that Pfizer did carry out an abuse of dominant position, the Authority should have proved "a **clear exclusionary intent** in light of a *quid pluris* further to the mere summation of behaviors regarded as legitimate by the relevant administrative and judicial systems."

The Authority would have **not** proved such *quid pluris*. As a matter of fact,

a) **as to the application for a divisional patent and the related "regulatory" proceedings**, the Court held that the IAA, while acknowledging that Pfizer had filed for a divisional patent in 2002, "has not taken into account the circumstances, pleaded by Pfizer, that the divisional patent application had taken place seven years before the foreseen entry of generic manufacturers into the Italian market." In this respect, the Court seemingly regarded as totally irrelevant the fact that the divisional patent application was aimed at being validated only in Italy and did not bring about the marketing of any new and/or improved drug. According to the Court, Pfizer had chosen not to validate its divisional patent elsewhere and such choice "had certainly to be regarded as an entrepreneurial option, the exercise of which may not be regarded, in itself, as having being carried out within a precise exclusionary strategy;"

b) **as to the behaviors carried out by Pfizer in the patent infringement proceedings**, the Court did not consider the conduct as embedding an exclusionary intent. The Court indeed noted that the patent infringement proceedings which arose between Pfizer and the generic companies before a number of Italian courts were in reality initiated by the generic companies themselves, and "in the majority of them Pfizer was a defendant and not a plaintiff." Furthermore, Pfizer appeared in such proceedings and claimed that it had obtained a valid patent. Therefore, litigation could not be held to be vexatious.

That being said, the Court supported the view that the IAA, in reaching its conclusions, had largely based its reasoning on the circumstance that the divisional patent had been initially annulled by the EPO on October 10, 2010, without, however, duly appreciating that, as explained, Pfizer had appealed such ruling before the EPO Board of Appeal and that such an appeal had by its very nature the effect of preventing nullity of the patent until final adjudication of the appeal had intervened. In connection hereof, the Court stressed that:

> the Authority should have evaluated the opportunity to stay the proceedings and wait for the decision on the appeal filed by Pfizer against such annulment. However, the Authority did not do that, thereby reaching conclusions that already at the moment when they were reached, i.e. even if one did not want to take into account the already released decision of the EPO Board of Appeal of May 2012, seemed characterized by their **dependence on non definitive decisions reached aliunde and in addition not even immediately effective** (…). Therefore, the conclusions thereby reached by the Authority look under the present scrutiny affected by the above mentioned lack of investigation and lack of ground argued by Pfizer and are, as such, insufficient to establish the ascertaining of an abuse of dominant position, even more so if the latter allegedly consists of the exercise of conducts carried out to protect rights and legitimate interests.

V. CONCLUSION

The judgment of the Administrative Court looks extremely interesting and potentially (r)evolutionary, as it seems to suggest that proof of an exclusionary intent is required for the purposes of monopolization cases under European antitrust law. As a matter of fact, according to the current case law and contrary to the United States, Article 102 TFUE has been interpreted so that intent is not required for an abuse of dominance to be proven. This standard is well illustrated by Advocate General Masak's recent opinion in the *Astra Zeneca* case[5], where he stated that:

[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 had performed these two actions:

"(47) (…) it follows from the objective nature of the concept of abuse that the misleading nature of representations made to public authorities 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 undertaking in a dominant position **is not required** for the purposes of identifying an abuse of a dominant position …"

(50) "It is settled case-law that the concept of abuse of dominance is an objective concept. I consider therefore that, in the context of an abuse of dominance, in assessing whether a particular course of behavior is misleading, the General Court was not obliged, as claimed by the appellants, to assess AZ's alleged subjective beliefs on an interpretation of law, bona fides or otherwise, but rather to examine their actual conduct. Moreover, the appellants' submission regarding a requirement of proof that AZ knew that it was not entitled to an SPC and was thus acting fraudulently … radically departs from the principle that abuse of dominance is an objective concept."

"(51) (…) the General Court has not, as claimed by the appellants, made it a *per se* abuse for a dominant company to apply for a right it thinks it is entitled to without disclosing the basis for its belief. Rather, the General Court found that an undertaking in a dominant position may not make objectively misleading representations to public authorities to obtain a right, irrespective of whether that undertaking believes it is entitled to that right. Such an approach does not set a low threshold for abuse and **will not** in my view **have a chilling effect on or delay applications for intellectual property rights in Europe** by increasing the regulatory, legal and bureaucratic burden on companies, as claimed by the appellants and also EFPIA, **but rather will curtail abuse of dominance resulting from highly misleading representations made to patent**, or other intellectual property, **authorities**."

- First, given 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, misused 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.