



Client Alert

Competition Law

10 September 2012

ITALIAN COURT ANNULS PATENT MISUSE DECISION

Decision of the Italian Competition Authority

At the beginning of 2012, the Italian Competition Authority adopted an infringement decision against Pfizer Italia s.r.l., Pfizer Health AB, and Pfizer Inc. ("Pfizer") and imposed a fine of EUR 10.6 million for an abuse of dominant position.

In a decision issued on 8 August 2011, the Italian authority had also rejected commitments suggested by Pfizer.

The decision took issue with Pfizer's request for a divisional patent and of a supplementary protection certificate (SPC), in order to extend patent protection until 2011. The Italian authority alleged that Pfizer, by filing the divisional application, the supplementary protection certificate and the request for pediatric extension, had wilfully put in effect an exclusionary strategy aiming at artificially extending Xalatan patent protection in Italy after the expiry of the main patent in September 2009. Moreover, Pfizer had allegedly brought claims before the courts that, in the authority's view, created an atmosphere of legal uncertainty about the possibility of marketing the new generic drug, thus raising costs for producers of generics. In that sense the Italian decision relied on the precedent set in *AstraZeneca* but, at the same time, went further than that, since there was no allegation here of wilful misrepresentations to the regulatory authorities on the part of Pfizer. Another important factor here was that Pfizer had only filed for what it was entirely entitled to under the applicable EU regulations, i.e. a so-called "pediatric extension", extending the duration of the SPC for 6 more months, as a reward for carrying out tests in order to administer Xalatan to pediatric patients.

Judgment of the TAR Lazio

On 3 September 2012, the Italian Administrative Tribunal ("*Tribunale Amministrativo di Lazio*" - TAR Lazio) quashed the decision of the Italian authority, holding that Pfizer's conduct was legitimate.

The Tribunal severely criticised the authority for not accepting a number of commitments which Pfizer offered during the proceedings, and held that the authority's overall conduct was not justifiable. The reasoning of the authority was based on the consideration that, after the request for a divisional patent, Pfizer did not introduce any new product on the market, but instead filed a supplementary protection certificate application with the Italian Patent Office. According to the Italian Authority, this strategy aimed at prolonging the

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duration of the patent of the drug Xalatan, thus hindering possibilities for competitors to market the generic drug and assess entry costs, which could therefore constitute an abuse of dominant position. The Tribunal, on the other hand, held that the set of commitments proposed by Pfizer had an “*objective substantive consistency*” and were “*likely to diminish the legal uncertainty created by Pfizer’s strategy*”. Therefore, the Tribunal accepted Pfizer’s claim.

The Italian authority’s reasoning was widely criticised because of its far-reaching conclusions and for reading overly extensively the *AstraZeneca* precedent. In *AstraZeneca*, the Commission and the Courts found that the dominant company had used improper means to secure patent protection, to which it was not entitled, by providing misleading information to the patent office. On the other hand, in the case at issue, the Italian authority was unable to identify any such behaviour by Pfizer.

Of particular interest is the part of the judgment which refers to the substance of the abuse of dominance findings and to the authority’s overall theory of harm. In a brief but very powerful couple of paragraphs, the Tribunal held that Pfizer had done nothing more than exercise its rights further to its legitimate interests. It highlighted in particular:

“It is clear that, in order to bring these practices within the scope of the anticompetitive infringement, they must be accompanied by a clear exclusionary intent and an additional anti-competitive element is necessary that goes beyond the existence of a simple group of legitimate actions carried out and brought before the competent administrative and jurisdictional authorities. If it were to be otherwise, this would entail a departure from EU case law to which the parties have referred on many occasions and a flagrant violation of the principle of legal certainty. This additional element was not proven by the Authority in the present case.”

In other words, the Tribunal emphasises that a clear exclusionary intent and other additional elements must exist for there to be an abuse of dominance. This is not inconsistent with the *AstraZeneca* ruling. At the same time, the Tribunal seems to place these kinds of theories of harm under a demanding standard of proof, bearing in mind that they are *prima facie* lawful and that it would be a serious blow to the principle of legal certainty if they could be misconstrued too easily as exclusionary anti-competitive behaviour.

Conclusion

The judgment accepted Pfizer’s complaints and criticised the Italian authority’s decision for lack of sufficient investigation, reasoning and logic. Apart from representing an important victory for Pfizer, it also provides relief to research-based industries which rely on patent protection to bring innovative products and services to consumers.

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