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Italian Competition Authority Challenges Patent Measures

Thomas Graf (Cleary Gottlieb Steen & Hamilton LLP) · Monday, January 23rd, 2012

The Italian Competition Authority started the New Year with a bang by imposing a fine of more than EUR 10 million on Pfizer for alleged abuses of the patent system in violation of Article 102 TFEU. The decision is available here.

The Authority's decision goes considerably further than the General Court's AstraZeneca judgment in qualifying patent related conduct as abusive. The Authority does not identify aspects of Pfizer's conduct that went beyond the use of legal instruments provided by the patent system. Instead, the Authority appears to suggest that reliance on such patent instruments can in itself constitute an abuse. This contrasts with AstraZeneca where the conduct at issue was not the use of patent instruments as such, put the provision of misleading information to patent authorities. The approach chosen by the Italian Authority therefore raises important questions about the limits for the application of Article 102 TFEU to patent related conduct.

At the origin of the case was a divisional patent filing that Pharmacia, which was later acquired by Pfizer, made in 2002 for a patent protecting the glaucoma medicine Xalatan. The divisional patent was granted in 2009. This then enabled Pfizer to apply for a supplementary protection certificate ("SPC") in Italy on the basis of the divisional patent, even though Pharmacia had missed the original SPC deadline in Italy for the parent patent. Pfizer's SPC application for the divisional patent did not prolong the SPC period that Pfizer could have obtained under the parent patent. It merely enabled Pfizer to heal the failure to apply in time for an SPC under the parent patent.

Nonetheless, the filing of a divisional patent and Pfizer's reliance on that patent to secure an SPC in Italy seem to have been at the heart of the Italian Authority's objections. It is however unclear what the legal basis for these objections is.

As regards divisional filings, the European Commission expressly recognized in its report on the Pharma Sector Inquiry that divisional patent filings are "a legitimate way to split an initial parent application". The Authority takes issue that Pfizer's divisional patent did not cover any additional innovation and did not lead to the launch of new products. But this misunderstands the nature of divisional patents. Divisional patents by definition cannot exceed the scope of the parent patent. They therefore do not serve to introduce new inventions, but serve procedural purposes (e.g., ensuring unity of invention, accelerating individual patent claims, and addressing formal issues).

The Authority also claims that Pfizer's conduct would have undermined "legitimate expectations" of generic manufacturers as to the duration of patent protection in Italy. This is hard to understand. The mere circumstance that Pfizer missed the deadline for an SPC application for the parent patent

could not have created “legitimate expectations” that it would not introduce an SPC application for its divisional patent. While the Authority suggests in one passage that Pfizer may not have acted in a fully transparent manner, this is not substantiated or explained in any way.

Ultimately, much of the Authority’s case turns on internal communications from the period around 2009 that according to the Authority evidence an intention by Pfizer to delay generic entry. Yet, relying on documents showing an intention to delay generics as a basis for a finding of abuse, especially in connection with an application for an SPC, is highly problematic. This is because the very purpose of an SPC is to extend the original patent period and thereby delay generic entry. It should therefore not be particularly surprising to find internal documents discussing delay of generic entry in connection with an SPC. Nor does this suggest an anti-competitive objective.

What remains then is the fact that by relying on a divisional filing, Pfizer was able to undo its failure of meeting the deadline for an SPC application under the parent patent. In effect, the Italian Authority seems to imply that it is unlawful for a dominant pharma company to rely on divisional patents to meet SPC filing deadlines. But nothing in the relevant EU Regulation precludes such an approach. Nor is there an inherent reason why this should be so, particularly given that an SPC for a divisional patent does not prolong the SPC period that is available under the parent patent.

The intervention of the Italian Authority therefore expands the application of Article 102 TFEU to patent related conduct in a manner that deprives Article 102 TFEU of meaningful limiting principles. It does not identify improper conduct that is distinct from and goes beyond the lawful use of patent instruments provided by the patent system. If the decision were to stand this would therefore considerably increase legal uncertainty and potentially deter the use of legal instruments that EU law has introduced to stimulate innovation. If aspects of the patent system are considered unsatisfactory, the better way to address this is through legislative change, rather than antitrust intervention.

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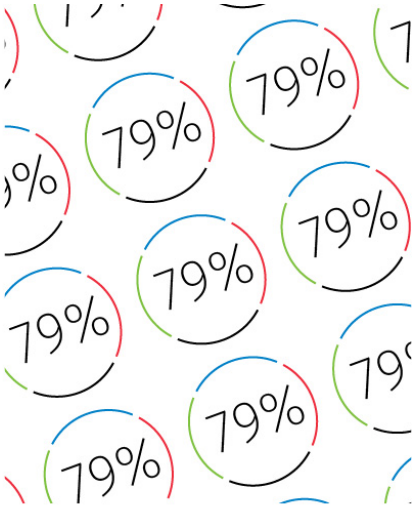

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