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I have already reported and commented on the first two phases of Pfizer's adventure as the target of the Italian Antitrust Authority ("IAA") for having allegedly committed abuse of dominant position by judicially enforcing its patent rights against generic latanoprost in the Italian Courts.[2] There is now a little, but maybe meaningful, development in the third (and last) phase of proceedings.

The whole story started in October 2010. It revolved around the fact that Pfizer had obtained a Supplementary Protection Certificate ("SPC") over latanoprost—which, in short, determined the extension in time of Pfizer's patent rights. This event was based on Regulation no. 1768/EEC and was given on the basis of a 2009 grant of a divisional patent (EP '168), which, in turn, derived from a parent patent (EP '417) that had already been granted in 1994, but for which no SPC protection had been requested. Once Pfizer started to enforce such SPC rights against generics launching copy drugs of its latanoprost based product (Xalatan), the IAA decided to open investigations on Pfizer alleging that its overall behavior had resulted in an abuse of dominant position.

In January 2012, the IAA issued its decision, whereby Pfizer was found guilty of such an abuse and ordered to pay some EUR 10.6 million in administrative sanctions to the Italian State. This decision was later reversed in full upon appeal by the competent Regional Administrative Court, by decision of September 2012. The case is now before the Consiglio di Stato, acting as the Supreme Administrative Court, in the last instance. No final decision is expected before the first quarter of 2014, at the earliest. A recent development has, however, already been reported, and it is somewhat worrying.

The January 2012 decision of the IAA, in short, found for the existence of an abuse based on what seemed to me (and not just me) an astonishing misinterpretation of patent law and the rationale of the provisions of the same to which Pfizer had resorted in its route to the obtainment and enforcement of the SPC on latanoprost. The IAA *inter alia* stated that Pfizer's "exclusionary intent" was evidenced by the fact that no new product had been developed or launched based on divisional patent EP '168, as opposed to the invention claimed in the parent patent EP '417. This, according to the IAA, meant that the request—and later grant—of the divisional patent application served as an (undue) means to recover from the fatal mistake of having missed the

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[2] D. Ampollini, *Looking for Sense in the Italian Antitrust Authority Decision in the Pfizer Xalatan Casee,* and *Has the Administrative Court's Reversal of the IAA Decision in Pfizer Got It Right?*, which, respectively, appeared in the July 2012(2), and October 2012(1) issues of the *CPI Antitrust Chronicle*.

deadline to request SPC protection many years ahead, when parent patent EP '417 had been granted and Xalatan had obtained marketing approval.

By noting that no new product had been developed based on the invention claimed in divisional patent EP '168, the IAA in substance appeared to consider EP '168 as a sort of duplication of EP '417, i.e. a mere expedient or artifice having the only purpose of curing a fatal error committed by Pfizer in the past—an error which had caused the market to legitimately expect that latanoprost would go generic at the expiry of EP '417, in 2009, and not at the later expiry of the SPC, in 2011.

It is obvious to all that know even a little of patent law, that the validity (and, even before, the dignity) of a divisional patent is not based on the fact that it will purport the development or launch of a new product. Quite the contrary, a divisional patent by definition concerns an invention that is already contained in the parent patent. In fact, divisional patent EP '168 was eventually found valid in the last instance of EPO opposition proceedings. And, after appeal, the Regional Administrative Court concluded that the IAA decision had to be reversed as Pfizer had simply exercised its rights under patent law, both at an administrative stage (by requesting the divisional patent and later the SPC) and at a judicial stage (by requesting injunctions against generics based on the granted SPC). Further, they concluded that no *quid pluris* (such as the wilful provision of elusive or erroneous information to a patent office as in *AstraZeneca*) had been identified which could support a finding of the existence of an exclusionary behavior.

Against this background, last May the Supreme Administrative Court, which is hearing the further (and last) appeal filed by the IAA against the decision of the Regional Administrative Court, has issued an interlocutory order which, at first sight, may seem to bring the case back to the level of misunderstanding of patent law which already occurred before the IAA, and which one would think (and hope) to have been cured for good by the Regional Administrative Court.

In fact, after an initial hearing on the case, the Court requested the parties to submit:

> detailed and documented clarifications aimed at specifying if divisional patent EP '168 (...) was or was not applied and exploited in practice with the production or commercialisation of new medicinal products or in the improvement of existing ones, or in any alternative activity which is proper of the nature of a pharmaceutical patent and intrinsic of its content according to the Munich Convention, distinct from the activity deriving from the ownership of EP '417 relating to the same active principle and which expired in Italy and Spain on 6 September 2009, later extended until 17 January 2011.

The Supreme Court is, therefore, again posing the question of the purpose of the divisional patent in the framework of the development of a new product and, again, one may be tempted to comment that this question is not pertinent at all. In fact it is not, at least from a patent law perspective. The point is whether the Supreme Administrative Court will be capable of producing a sound reasoning addressing whether such a question, although not pertinent from a patent law perspective, is pertinent from a competition law perspective.

And while I would not rush to a conclusion that the Supreme Administrative Court will reproduce a reasoning similar to that of the IAA, I have to say I am a little bit worried. We may end up with a decision reversing that of the Regional Administrative Court; however, this

decision could hold more water than that of the IAA, and therefore destabilize the industry. Let's see. I will not miss the chance to report on the decision as soon as it comes out.