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## Has the Administrative Court's Reversal of the IAA Decision in *Pfizer* Got It Right?

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## Has the Administrative Court's Reversal of the IAA Decision in *Pfizer* Got It Right?

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In my article, *Looking for Sense in the Italian Antitrust Authority Decision in the Pfizer Xalatan Case*, which appeared in the July (2) issue of the *CPI Antitrust Chronicle*, I discussed the reasons the Italian Antitrust Authority (“IAA”) found Pfizer liable of abuse of dominant position from a patent law perspective. I attempted to reconcile—without succeeding, in fact—the reasoning of the IAA with the meaning and function of the various patent law categories involved. In conclusion, I noted that the real reason, albeit not explicitly stated, behind the decision of the IAA seemed to lie in the fact that divisional patent EP ‘168—which had served as the basic patent for the Italian Xalatan SPC which Pfizer had enforced against various generic companies—had been found invalid in the first instance by the EPO as a result of opposition proceedings.

This may have explained, from a political rather than legal point of view, the finding against Pfizer by the IAA. From all perspectives the finding seemed to be the result of a clear “stretch” of the applicable antitrust provisions, and a disputable interpretation of relevant community law. As I wrote, after having noted that in Italian law there is no such thing as objective liability in cases where patent rights are enforced under patents that are later found invalid, and that the legal test in these cases is such that substantial damages are rarely awarded to a wrongfully enjoined party, I proposed an interpretation of the IAA decision as a (surely not justifiable) example of the (mis)use of competition law by a state agency in an attempt to safeguard the generic industry—and therefore state finances—in view of allegedly unsatisfactory tools in other areas of the law. I then concluded that the interesting thing was that divisional patent EP ‘168 had, however, been found valid in the second (and last) instance by the EPO after the publication of the IAA decision, a pertinent development to consider as the IAA decision was under appeal.

In fact, the IAA decision has now been fully reversed by the Regional Administrative Court sitting in Rome. The reasoning of this latter decision, which was published on September 3, 2012, was on solid ground. The issue of the relevance or not of the validity of Pfizer’s divisional patent remains, however, somewhat unanswered.

The reasoning of the Administrative Court can be summarized by the following passage:

The Authority found for the existence of an abuse of dominant position by correlating several conducts by which, both at an administrative and judicial level, Pfizer enforced its rights and legitimate interests. It is obvious, therefore, that in order to identify an unlawful behavior from a competition law perspective, such conducts must be accompanied by the connotation of a clear exclusionary intent based on a “*quid pluris*” as opposed to the mere summation of behaviors that are lawful according to the administrative and judicial systems respectively.

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Otherwise, one would incur in the misapplication, in an area of law deriving from community legislation, of the community case law (...) as well as in the apparent violation of the principle of legal certainty. Such a “*quid pluris*” the Authority is unable to identify in the case at hand.<sup>2</sup>

In substance the Administrative Court acknowledged that 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), and that no “*quid pluris*” (such as the willful provision of elusive or erroneous information to a patent office as in *Astra Zeneca*) could be identified. Therefore, the Court could not determine the existence of an exclusionary behavior.

As regards Pfizer’s behavior in terms of the judicial strategy, the Administrative Court also pointed out that the decision of the IAA seemed to be in contrast with community case law in *Itt-Promedia*, given that the majority of the judicial proceedings involving the Xalatan SPC had, in fact, been initiated by the generics and not by Pfizer.

After having noted the above, the Administrative Court concluded that the motivation apparatus of the IAA decision seemed to revolve around the EPO’s revocation of divisional patent EP ‘168 in the first instance. This Administrative Court conclusion is analytically supported by the detailed quotation of all points of the IAA decision in which this revocation was mentioned or evoked in support of the overall finding of abuse.<sup>3</sup>

Bringing the logic behind the Administrative Court’s reasoning one step further, one would have expected them to draw the decisive conclusion that the revocation of the divisional patent could have no role in the determination of the “*quid pluris*” necessary to find that Pfizer’s overall conduct had been unlawful from a competition law perspective. This did not, however, happen.

Instead, the Administrative Court pointed to: (i) the fact that the revocation of divisional patent EP ‘168, which was seemingly at the center of the IAA decision, was not final, as it was still subject to appeal, and (ii) the fact that, based on the applicable provisions, the appeal that Pfizer had immediately filed had had the automatic effect of staying the efficacy of the first instance revocation. On this point the Administrative Court stated:

Therefore, after having concluded that the reasoning structure at the basis of the decision focuses on the revocation of the divisional patent by the EPO which occurred in October 2010, it is not illogic to say, as Pfizer did, that the Authority should have considered the opportunity to stay the proceedings until the issue of the decision in appeal. This, however, the Authority did not do. And this led the Authority to reach conclusions which, as early as at the date in which they were reached, i.e. even without considering the later decision of the EPO Board of Appeal of May 2012, were dependent on determinations taken elsewhere which were not final and not even immediately effective, without the Authority, which was surely aware of such a non final character as this was highlighted by Pfizer during the proceedings, taking care of spending any comment in this respect. In this respect, the assessment of the IAA is in the view of this Court affected by

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<sup>2</sup> ¶ 4.1., pages 42 – 43.

<sup>3</sup> ¶ 4.1., pages 44 – 45.

deficiencies in the collection of the necessary evidence as well as from a logic and motivational perspective and are, as such, unable to ground a finding of abuse of dominant position, *a majori* when the specific conduct in question consisted in exercise of rights and legitimate interests.<sup>4</sup>

It seems, therefore, that the Administrative Court suggested that the IAA should have at least stayed the proceedings until the final EPO decision.

It is not incorrect to say, as the Administrative Court in substance did, that if the revocation of divisional patent EP '168 mattered to the decision of the IAA, the IAA was surely wrong in not considering the fact that such a revocation was not final and that, therefore, for this sole reason the IAA decision lacked ground in terms of motivation and logic. Therefore, the above quoted passage does not, in itself, undermine the solidity of the Administrative Court's conclusions.

However, I cannot escape thinking that the Administrative Court's decision was influenced by the fact that divisional patent EP '168 was found valid in appeal by the EPO Board of Appeal. In a way, therefore, it could be said that the Administrative Court decision suffers from the same illness as the IAA decision, i.e. the belief that the finding of validity or invalidity of EP '168 mattered when qualifying Pfizer's behavior as lawful or unlawful from a competition law perspective. This, I am convinced, is wrong. In fact, while I am not informed about the status of the actions between Pfizer and the generics, I would not be surprised to hear that there is at least one, if not many, in which the validity of EP '168 is still under judicial review. So what happens if the Italian designation of EP '168 is later revoked by a national judge?

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<sup>4</sup> ¶ 4.1., pages 46 – 47.