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Pfizer ordered to pay Euro 10.6 million for abuse of dominant position by the Italian Antitrust Authority

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By decision of 11 January 2012 Pfizer was found liable of abuse of dominant position by the Italian Antitrust Authority and ordered to pay 10.6 million euro. My previous posts on this case can be found here, here and here. In substance AGCM (the Italian antitrust Authority) has now decided that Pfizer abused its dominant position for having unlawfully delayed the entry into the market of generics of its product Xalatan, by means of a complex strategy in which Pfizer would have artificially prolonged the protection afforded by its patent rights and initiated legal actions aimed at impeding the activity of generic competitors more than at protecting its valid rights. Last spring, Pfizer had offered undertakings under Article 14ter Law 287/1990 with a view to having the procedure cease and avoiding the application of the sanctions that may have derived therefrom. Said undertakings in fact looked quite substantial. It was difficult to think what else Pfizer could have offered in order to avoid the continuation of the proceedings. AGM has however rejected those undertakings (the reasons are unknown) and preferred going forward with the procedure. In particular, AGCM has now concluded that – based on an inquiry which seems to have been rather detailed, involving in particular the examination of various email correspondence incurred between Pfizer Inc and its local subsidiaries – Pfizer has wilfully carried out an excluding strategy consisting in: *"1) the artificial extension of Xalatan patent protection in Italy after the expiry of the main patent in September 2009, including: a) the application and grant of divisional patent EP '168; b) the validation of the divisional patent only in Italy and other countries where the expiry of the patent protection on Xalatan – provided by EP' 417 – was due on 6 September 2009 (editor's note: where Pfizer had not timely filed for an SPC based of EP '417); c) the application for and the obtainment of an SPC in Italy aimed at adjusting the duration of the patent protection in our country with respect to that existing in the rest of Europe (July 2011); d) the application for paediatric extension; and 2) the commencement of a litigation aimed at discouraging or increasing the costs of the sale of latanoprost generic products or directly preventing their marketing, including: a) sending cease and desist letters to generic companies warning them against the marketing of latanoprost generic before the new expiry date of July 2011; b) pressure on AIFA with a view to preventing the grant of MAs to generic companies as well as their inclusion in the Transparency List; c) filing of high damage claims"*. The decision is subject to appeal within a 60-day deadline before the Administrative Court in Rome. I do not know whether Pfizer has already appealed but no doubt they will. This is indeed a decision which will be extensively commented in the IP Community. Here are my first thoughts. The decision pays a lot of attention to the contents of email communications exchanged within Pfizer which would inter alia show how Pfizer's decision to file the divisional patent application would be just that of obtaining an SPC with an

expiry date equal to that of the Xalatan patent protection in other countries, when Pfizer was aware of the limited chances of success of the litigation that would have been later initiated thereupon. If I am not mistaken, the awareness of the existence of *"limited chances of success"* of patent litigation is an element which the European Commission also pointed at in the 2009 inquiry in the pharmaceutical sector, and then already many had to comment that this cannot seriously be considered an indicator of an abusive behaviour. The AGCM decision unfortunately does not provide much detail on the exact content of those email communications: no doubt it would be very interesting to read them. As regards the calculation of the fine, it is noteworthy that this was done taking into account a duration of the unlawful conduct going from the filing of the divisional patent application in 2002 to the time of expiry of the SPC, in July 2011, notwithstanding the fact that AGCM had to admit that Pfizer's behaviour would have delayed generic entry of 7 months only. In summary, the fine was calculated also (and mostly) in respect of a behaviour that had no external effect whatsoever, and therefore did not impact the market. Finally, there are some worth reading paragraphs in the decision, which give an idea of what AGCM knows and thinks of patent law. Firstly, in paragraphs 236 and 237 of the decision, AGCM in substance says that the Italian bolar exception (Article 68 (1) IP Code) would determine a situation in which only the marketing, and not the manufacture, of the generic drug – during the lifetime of patent rights – would result in infringement. Comments unnecessary, I suppose. Secondly, here is the passage in which AGCM discussed the relationship between patent law and antitrust law (paragraph 181): *"The fact that patent law contains rules to sanction the invalidity of patents does not pose a limit to the application of antitrust law. In fact, the legitimate application of antitrust rules lies in the different perspective and purposes of said rules as opposed to sector legislation. In the case at stake, it is noteworthy that in listing the requirements for the granting of a patent – i.e. novelty, inventive step and industrial application – the European Patent Convention does not contemplate any limit with respect to a possible anti-competitive use which the applicant intends to make of the granted title. A fortiori, therefore, the patent offices – either European or national – cannot consider a possible anti-competitive use of patents, either at the time of grant or when oppositions are filed. These profiles remain therefore within the domain of antitrust law"*. The obvious comment is that the use of a patent is by definition an anti-competitive one. I have the impression (which is also supported by the following passage in paragraph 198: *"a further evidence of the excluding nature of Pfizer's divisional application, is the absence of the launch of a new drug which generally follows the grant of a divisional patent. This demonstrates – independently from the absence of an obligation in this sense, as Pfizer pointed out – Pfizer's will not to launch a new drug, but only to exclude generics from the Italian market of prostaglandins analogs"*) that AGCM believes, as the layman often does, that the purpose of a patent is to allow the patentee to do something, rather than to allow the patentee to exclude others from doing something.

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