THE ADMINISTRATIVE SUPREME COURT CONFIRMS THE ICA'S DECISION TO CONDEMN PFIZER FOR ABUSE OF DOMINANT POSITION AIMED AT DELAYING THE MARKET ENTRY OF GENERIC PHARMACEUTICAL COMPANIES

Claudia D'Amore[1]

1. THE ICA'S DECISION

On 11 January 2012, the Italian Competition Authority (ICA) sanctioned the multinational pharmaceutical group PFIZER (in particular, Pfizer Inc., Pfizer Italia Srl and Pfizer Health A.B.) for an infringement of Article 102 TFEU, imposing a fine amounting to €10,677,706.

The investigation started in October 2010 - following a complaint filed by the generic company Ratiopharm Italia Srl - and concerned Pfizer's anti-competitive practices aimed at delaying the entry of generic pharmaceutical companies in the Italian market for the provision of anti-glaucoma drugs. In such market, Pfizer held a European patent (nationalized in many EU Member States) related to the *latanoprost* molecule and contained in a medicine called *Xalatan*, which showed therapeutic capabilities to cure eye hypertension and glaucoma. The patent was expected to expire in Italy in 2009.[2]

The evidence collected by the ICA showed that Pfizer adopted a patent-related unitary and complex strategy to impede competition from generic companies and to delay their entrance in the market, by carrying out the following conducts:

i) In 2002, thirteen years after the filing of the main patent, Pfizer filed before the European Patent Office a voluntary divisional application, whose claims also covered *latanoprost;*[3]
ii) Once obtained the European divisional patent in January 2009, Pfizer validated such patent only in Italy (where the protection of the main patent was shorter than in the rest of EU Member States) and then applied for the Supplementary Protection Certificate ("SPC"), in order to extend the protection in Italy until July 2011, like in other Member States;
iii) The group started a patent-related litigation before civil and administrative courts, to refrain generic companies from entering the market;

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[1] Italian Competition Authority

[2] In Italy, the patent protection had a shorter length than in other EU Member States because Pfizer did not ask for the Supplementary Protection Certificate, which would extend the duration of the patent protection.

[3] According to art. 76, 1°, of the European Patent Convention, the divisional patent takes the date of deposit and the date of expiry from the main patent's. However, the grant of the divisional patent allows to apply for a Supplementary Protection Certificate, extending thereof the duration of the protection.

iv) Pfizer also commenced actions aimed at preventing the national regulatory body ("AIFA") from granting generic companies marketing authorizations;
v) Pfizer further applied for an extension of protection by means of a paediatric experimentation with no real intention of developing such applications (but which, if granted, would have extended the length of protection for six more months, until January 2012).

In light of the above, the ICA considered that the divisional patent on *latanoprost* was merely aimed at allowing the release of an SPC - which Pfizer was no longer entitled to obtain in Italy - and consequently delaying the entrance of generic drugs. In this respect, the Authority found particularly relevant that: *i)* the divisional patent was validated only in Italy and in other two Member States where the main patent protection was supposed to be shorter than in the rest of Europe and *ii)* no new product or development of the first product (protected by the main patent) was released by the company, based upon such divisional patent.

According to the ICA's assessment, Pfizer had engaged into behaviours different from competition on the merits, by recurring to the abuse of administrative procedures and sham litigation, both part of a unitary and complex excluding strategy directed to create a situation of uncertainty that would prevent generic companies from entering the market with their equivalent drugs.
Such behaviours caused a 7-month delay in the entry of generic companies in the Italian market and a damage to the Italian National Health System amounting to about € 14 mio.

2. THE ANNULMENT OF THE ICA'S DECISION

Following Pfizer's appeal, in September 2012, the Regional Administrative Court of Lazio ("TAR") annulled the ICA's decision.[4] Firstly, the TAR deemed that the commitments offered by Pfizer during the proceedings had been unreasonably rejected, since they "*objectively*" met the concerns expressed by the Authority in its preliminary assessment. Secondly, the TAR considered that Pfizer only tried to protect its rights and legitimate its interests, through conducts deemed lawful pursuant to patent law, and that the Authority did not prove the existence of a "*quid pluris*" which would render unlawful the sum of such conducts. Finally, according to the TAR, the ICA should have evaluated the opportunity to stay the proceedings and wait for the decision on the appeal filed by Pfizer against the EPO annulment of the divisional patent (whose validity was then confirmed).

3. THE JUDGMENT OF THE COUNCIL OF STATE OVERTURNING THE TAR'S DECISION

The ICA lodged an appeal before the Council of State, the highest administrative Court on competition, against the TAR's decision. With judgment of 12 February 2014 No. 693, the Council of

[4] TAR, I, decision No. 7467, 3 September 2012.

State annulled such decision, thus confirming the ICA's position that competition law may tackle unfair practices which make use of patent laws and procedures to pursue unlawful exclusionary goals.

Firstly, the Council of State held that the definition of the relevant market provided by the Authority in its decision was legitimate and well-reasoned, and so were the findings of Pfizer's dominant position on such market, based on the criteria of therapeutic classes, frequently used by the European Commission. Similarly, the fine imposed on Pfizer for its abuse of dominant position was considered appropriate, having regard to the gravity and the duration of the infringement, and proportionate in light of the anticompetitive effects caused by the complex abusive conducts. The Judge also deemed that Pfizer's rights of defense had not been in any way restricted, given that the company could effectively participate in the whole administrative and judicial proceeding. Finally, the Council of State confirmed that the commitments offered by Pfizer during the proceedings were totally unsuitable to meet the anticompetitive concerns expressed in the preliminary assessment, mainly because the patent protection was supposed to expire very shortly and the infringing conducts had already caused permanent damage to competition.

As for the abusive nature of Pfizer's conducts, the Council of State considered that the TAR had erroneously evaluated such behaviours according to patent law, without considering their anticompetitive nature and effects. The Judge underlined that the application for a divisional patent related to a specification already protected by the main patent is a legitimate right pursuant to patent law. However, antitrust law requires to verify whether the *effective use* of such right is not anticompetitive.

During the judicial proceeding, the Council of State requested the parties to prove that Pfizer's divisional patent had been exploited in a new product or in a development of the existing products or in another activity different from those related to the main patent.[5] The evidence collected proved that *no real and concrete use* was made of such divisional patent, in contrast with the scope of patent law in the pharmaceutical field, which should be to make innovative drugs available to the public.

The Council of State concluded therefore that the dominant company could not engage in conducts that, although legitimate pursuant to patent laws, merely result in anticompetitive behaviours. In qualifying such conducts, the Judge, in line with the ICA's interpretation, held that such abuse of dominant position belongs to the broader category of "*abuse of rights,*" where the right is exercised for a purpose other than that for which it was granted: in the case at stake, it was hindering the entrance of competitors in the market. The Council recalled the conditions required in order to invoke the doctrine of the abuse of rights: (i) the existence of a right; (ii) the possibility to effectively use such right in different manners; (iii) the exercise of the right in a reprehensible manner, although formally legitimate; (iv) the resulting unjustifiable disproportion between the benefit of the right's owner and the harm

[5] Council of State, Order No. 2790, dated 22 May 2013.

caused to the counterparty. In other words, the abuse of rights does not suppose a formal infringement of laws, but the distorted exercise of the granted rights, for purposes different from those meant by the legislator[6].

According to the Council of State, the ICA correctly found that Pfizer, through the use of the main patent rights, could extend patent protection in Italy and thus delay the entrance of generic companies in the market, without effectively using the divisional patent - whose object was already protected by the main patent - and with a purpose different from the proper scope of patent law. Such conducts were moved by a clear and persisting anticompetitive intent to defer the commercialization of generic drugs, causing relevant damages to the National Health System. The Judge concluded that Pfizer's whole complex strategy consisted of several conducts, all proved and reasonably considered punishable by the ICA, such as: the filing of the divisional patent application (and the consequent request of a SPC) many years after the filing of the main patent application and containing claims still related to *latanaprost*; the absence of a commercial exploitation of a new product based upon such divisional patent; the patent-related Court litigations to refrain generic companies from entering the market; the actions aimed at preventing AIFA to grant genericists marketing authorizations; the application for a further extension of patent protection through paediatric experimentation. According to the Judge, all these complex conducts, although individually and abstractly legitimate, could correctly be defined as *abuse of rights*, specifically anticompetitive.

It is finally worth mentioning that the case follows the approach highlighted by the European Commission in its *Inquiry on the pharmaceutical sector*, which was concluded on July 8, 2009, contesting the existence of unlawful patent practices in the pharmaceutical sector. The findings of the inquiry suggested that in recent years originator companies have changed their patent strategies, trying to extend the breadth and duration of their patent protection and thus delay or block the market entry of generic medicines. Filing numerous patent applications for the same drug (forming so called "patent clusters" or "patent thickets") is a common practice. The inquiry showed that litigation can also be an efficient means, for originators, to create obstacles to the entrance of generic companies, in particular the smaller ones. The Commission stressed that "*if the existence and exercise of industrial property rights are not of themselves incompatible with competition law, they are not immune from competition law intervention*"[7].

As also clearly stated by the EU Court of Justice in the *AstraZeneca* case[8]: "*the illegality of abusive conduct under Article* [10]*2 EC is unrelated to its compliance or non-compliance with other legal rules and, in the majority of*

[6] Council of State, III, decision No. 2857, dated 17 May 2012.

[7] § 4.1 of the Executive Summary of the Pharmaceutical Sector Inquiry Report

[8] EU Court of Justice, case C-457/10P, decision dated December 6, 2012, §132

cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law"[9].

[9] Claudia D'Amore. *The Administrative Supreme Court confirms the ICA's decision to condemn Pfizer for abuse of dominant position aimed at delaying the market entry of generic pharmaceutical companies*. DOI: 10.12870/iar-9935.