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By Daniela Ampollini¹

The January 2012 decision² of the Italian Antitrust Authority (“IAA”) in the Pfizer case, involving Pfizer’s actions to counter the marketing of generic versions of its product Xalatan, has given rise to a debate which has hardly appeased. Many commentators have already provided their impression from a competition law perspective. I, a patent lawyer, will try to provide mine, starting from the meaning and function of the patent law categories involved.

The case started in October 2010 when the IAA decided to formally open an enquiry against Pfizer (the U.S. parent company as well as the Italian subsidiary), further to a complaint lodged by generic company Ratiopharm and supported by a number of other companies all interested in the manufacture and marketing in Italy of generic latanoprost. Latanoprost is an active substance invented and patented by the Swedish pharmaceutical company Pharmacia (which later merged into Pfizer), and contained in the medicinal product Xalatan, administered to patients suffering from glaucoma.

Pfizer’s patent rights on latanoprost were based on EP0364417 (EP ‘417),³ a patent claiming “Prostaglandin derivatives for the treatment of glaucoma or ocular hypertension” which was due to expire on September 6, 2009. On the basis of various national designations of this European patent, Pfizer had applied for and obtained Supplementary Protection Certificates (“SPCs”), pursuant to the then applicable Regulation no. 1768/92/EEC.

SPCs are titles whereby the duration of a patent claiming an active substance of a medicinal product is extended for a certain period of time, the rationale being to allow the patent holder to recoup at least part of the time used to obtain marketing authorization for the medicinal product. In order for a patent to be valid, the filing must precede any disclosure of the invention; at the same time, however, medicinal products can only be sold after the completion of lengthy administrative procedures, preceded by lengthy experiments and clinical trials, which have the effect of eroding the lifetime of patent exclusivity. Once a medicinal product is authorized, therefore, the law grants an SPC to stretch the patent duration for a time based on the time spent in the authorization procedure. According to the applicable provisions, an SPC application must be filed with the national patent office within 6 months from the grant of the patent or the issue of the first marketing authorization in the EEA, whichever is later.

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² <http://www.agcm.it/concorrenza/inteseabusi/open/41256297003874BD/9AEB2CC6CAB65EA2C1257996003333CD.html>.

³ [EP0364417](http://www.epo.org/patents/biblio/summary.do?class=EP&num=0364417).

For some reason, however, Pfizer had not asked for an SPC on latanoprost in Italy. Pfizer had, however, filed a number of divisional applications based on EP '417, one of these resulting in the grant of divisional patent EP 1225168 (EP '168).⁴

Divisional applications are a procedural tool that the patent holder may use in order to cure a situation in which the parent patent does not comply with the principle of the “unity of the invention.” According to this principle, the examination of a patent application may only lead to the grant of a patent for a single invention (or a group of inventions so linked as to form a single inventive concept). When more than one invention is contained in a patent application, unity is lacking and the applicant must choose only one of those inventions to complete the examination.

The law, however, allows the filing of divisional applications to claim any further invention that was originally contained in the original application. In other words, divisional applications simply “divide” the parent patent into more than one title. However, no additional rights derive from divisional applications in terms of duration or extent of protection. Divisional applications claim the same filing or priority date of the parent patent, and are valid only as long as the invention that is “divided” was, in fact, already included in the original patent application. (Until 2011, divisional applications of European patents could be filed until the very grant of the parent patent. Based on a recent amendment of the law, a 24-month deadline from the first examination office action applies for voluntary divisional applications.)

Divisional application EP '168 specifically claimed the formula of latanoprost as “divided” from the comprehensive class of products claimed in EP '417. It took advantage of the same filing date of the parent patent, and therefore the same expiry date of September 6, 2009, although it had been filed in 2002. It was granted on January 14, 2009, i.e. several years after the grant of the parent patent (which had initially been granted in 1994, and further maintained in an amended form in 2004 following opposition).

Within 6 months from the grant of EP '168, Pfizer filed an SPC application with, *inter alia*, the Italian Patent Office, which eventually granted an extension of Pfizer's exclusive rights on latanoprost until July 17, 2011. Pfizer also filed for a so-called “pediatric extension,” which would have extended the duration of the SPC for an additional 6-month period, as a reward for Pfizer carrying out experiments aimed at verifying the possibility of administering latanoprost to pediatric patients under the applicable EU regulations.

Thereafter, in 2009 and 2010 Pfizer filed several actions against generic companies in order to make them refrain from marketing generic latanoprost until after the expiry of the SPC. From what was reported, the actions were many and on several fronts. On the one hand, Pfizer started infringement proceedings before the ordinary courts. On the other, Pfizer resorted to the administrative courts in order to obtain a stay of the so-called “substitution list,”⁵ as regards to generic latanoprost, that had already been authorized by the Italian regulatory authority (which stay was granted in the first instance, although lifted in the appeal phase).

⁴ [EP 1225168](#).

⁵ Once an authorized generic product is included in the “substitution list” (which is published monthly by the Italian Regulatory Authority), the generic becomes “substitutable” with the originator. On the one hand, pharmacists will offer the generic to patients asking for the originator and, on the other hand, the price reimbursement by the National Health service will be limited to the lower generic's price even in the case of purchasing the originator.

It is against this background that Ratiopharm and other generic companies filed their complaint with the IAA, claiming that Pfizer's overall behavior amounted to an abuse of dominant position. In particular, they argued that they had legitimately relied on the assumption that Pfizer's exclusive rights in Italy would expire on September 6, 2009 (as Pfizer had refrained from asking for an SPC in Italy based on EP'417), and therefore they had made preparations to enter the market as of said date. By the filing of the divisional application and the subsequent SPC request, however, Pfizer had unlawfully frustrated such expectations and caused harm.

The IAA eventually found against Pfizer. In particular, the IAA concluded that Pfizer, by the filing of the divisional application, the SPC, and the request for pediatric extension, had wilfully carried out an exclusion strategy involving the artificial extension of Xalatan patent protection in Italy after the expiry of the main patent in September 2009. In addition, Pfizer had commenced complex litigation aimed at discouraging or increasing the costs of the sale of generic latanoprost or directly preventing its marketing, including sending cease and desist letters to generic companies, pressuring the Italian regulatory authority with a view to preventing the grant of marketing authorization to generic companies as well as their inclusion in the "substitution list," and filing high damage claims.

In essence, the IAA's reasoning was focused on the fact that Pfizer filed divisional application EP '168 for the sole purpose of obtaining the SPC and, therefore, blocked or at least delayed the entry into the market of generics which had lawfully assumed that the market would become free in September 2009. This reasoning is supported by reference to the contents of emails exchanged within Pfizer which would, *inter alia*, show that Pfizer's decision to file the divisional patent application had been driven by the goal of obtaining an SPC with an expiry date equal to that of the Xalatan patent protection in other countries, even though Pfizer was aware of the limited chances of success of any resulting litigation (the contents of this email correspondence is not in the public record). The following passages of the decision are rather eloquent in this respect:

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”⁶.

“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

⁶ ¶ 181

drug, but only to exclude generics from the Italian market of prostaglandins analogs.”⁷

The IAA’s reasoning has been widely criticized by the international legal community. One of the main points of criticism is the fact that the IAA went well beyond the principles established in *AstraZeneca* and other cases at the intersection of patent and competition law. It was rightly noted,⁸ for instance, that in the case of a refusal to license, a high legal test applies before resorting to Article 102 TFEU. In case of the provision of misleading information to a patent office (such as in *AstraZeneca*), the company in a dominant position uses improper means to secure patent protection to which it is not entitled. On the other hand, in the case at issue, the IAA was unable to identify any such behavior by Pfizer, so much so that it could find for the existence of the abuse only by misconstruing the very essence of patent law and the function of divisional patents in particular (by the almost unbelievable statements that a patent should not be used to exclude competitors—*and for what else?*—and that divisional applications are generally accompanied by the launch of new products—*what?*).

From a patent law perspective, Pfizer did absolutely nothing wrong. It exercised its right to file a divisional application based on EP’417 and, once granted, requested an SPC, thereby adding an SPC in Italy where no SPC had initially been requested. Such action is surely admitted by the applicable legislation. Furthermore, the divisional application had been filed in 2002, well before the expiry date of the parent patent in 2009. It is therefore difficult to believe that generics were caught by surprise by the Italian SPC when they had prepared to market generic latanoprost after September 2009.—Generics were surely aware of the filing of the divisional application in 2002, as well as of Pfizer’s right to subsequently file for an SPC application.

It has been stated⁹ in advocating the correctness of the IAA decision, that the latter is all about so called “competition in the merits,” which would imply that IP rights and the resultant monopoly are warranted only when the dominant company has engaged in a truly rewarding activity: a new product invented or launched, a new process is used, etc. It is argued that no such thing occurred in the Pfizer case; however, I sincerely do not understand why this should be, considering that Pfizer did discover latanoprost and followed the patent law rules in order to obtain patent rights (including the SPC) thereupon.

Having said the above, does it help to ask if EP ‘168 was, in fact, a valid patent? When the IAA published its decision, in fact even when it decided to formally open the investigations in October 2010, the EPO Opposition Division had already expressed the opinion that the patent was not valid. By a decision on October 6, 2010,¹⁰ EP ‘168 was revoked in the first instance as the Opposition Division was convinced that it had resulted in “added subject matter.” In essence, it was found that EP ‘168, while “dividing” the product latanoprost from the comprehensive class disclosed and claimed in EP ‘417, made use of added material that was not present in the original

⁷ ¶ 198.

⁸ <http://kluwercompetitionlawblog.com/2012/03/12/italian-patents-revisited/>

⁹ <http://kluwercompetitionlawblog.com/2012/02/07/evolution-or-revolution-the-italian-competition-authority-and-the-pfizer-decision-a-reply-to-thomas-graf/>

¹⁰ <https://register.epo.org/espacenet/application?number=EP02009255&lng=en&tab=doclist>

patent application, by making a non-obvious selection activity. In other words, the Opposition Division stated that EP '168 did not “divide” an invention that was already contained in EP '417.

But why should this matter? Was it sufficient for the IAA to note that Pfizer had filed an application for a patent that was later found to be invalid in order to issue the above-mentioned decision? I do not think so. It must however be noted that, under Italian law, there is no such thing as objective liability in case patent rights are enforced—for instance when a preliminary injunction is obtained—on patents that are later found invalid. The applicable provision is contained in Article 96 of the Civil Procedural Code, which generally provides that damages may be awarded in the case of abuse of process.

However, the mere fact that the enforced patent rights are later found invalid is not enough to ground a case under Article 96. A qualified degree of negligence must be proven and substantial damages are rarely awarded. From this perspective, one may think that, in a scenario in which the generic market is seen as one tool to try and save moribund state finances, the Pfizer IAA decision is an example of the (mis)use of competition law by a state agency in an attempt to safeguard state finances, an idea given credibility in view of allegedly unsatisfactory tools in other areas of the law.

The interesting thing is that the first instance decision of the EPO Opposition Division has now been reversed by the Board of Appeal's decision of May 10 2012¹¹ (the reasoning is not yet public). Therefore, EP '417 now seems to be a valid patent, which means that Pfizer was right in filing the divisional application and therefore right in requesting the grant of an SPC. Enforcing these titles—that is trying to stop generics from entering the market before the expiry of the exclusive rights—was therefore also obviously the right thing to do. As a result the above-suggested “political” justifications for the IAA decision now seem to be frayed as well.

¹¹ <https://register.epo.org/espacenet/application?number=EP02009255&lng=en&tab=doclist>