Italian Supreme Court rules on the Latanoprost case in Decision of 2 January 2024

Introduction

On 2 January, the Italian Supreme Court put an end to the 'latanoprost saga' by rejecting Pfizer Italia S.r.l. ("**Pfizer**")'s appeal against the Rome Court of Appeal decision ordering Pfizer to pay the Ministry of Health and the Ministry of Economy and Finance (jointly, "**Italian Government**") EUR 13,360,464 as compensation for damage caused by abuse of a dominant position.

Factual background

A. Latanoprost patent history

- On 6 September 1989, Pharmacia AB filed European patent application EP0364417 ("**EP'417**" or "**Parent Application**") claiming several active ingredients, including latanoprost, for the treatment of glaucoma.
- On 9 February 1994, EP'417 was granted and validated in several European countries, including Italy ("**Parent Patent**").
- In the second half of the '90s, Pharmacia started marketing its latanoprost-based drug under the brand name 'Xalatan' and, in 1997, applied for – and was granted – a supplementary protection certificate ("**SPC**") in almost all the countries where EP'417 had been validated (thus extending patent protection in those countries until 17 July 2011) except for Italy, where the expiry date remained 6 September 2009.
- On 26 April 2002, during negotiations for Pfizer Inc.'s acquisition of Pharmacia, Pharmacia filed the second-generation divisional application EP1225168 ("**EP'168**" or "**Divisional Application**") derived from EP'417. EP'168 was granted on 14 January 2009 and validated in a few European countries, including Italy ("**Divisional Patent**"). An opposition procedure was brought against EP'168, which was initially revoked by the European Patent Office ("**EPO**") but then restored, in amended form, on appeal.
- In 2003, Pfizer Inc. acquired Pharmacia and, the following year, Pfizer Health A.B. became the owner of EP'168.
- In April 2009, Pfizer applied for – and was granted – an SPC in Italy based on EP'168, thus extending patent protection for latanoprost also in Italy until 17 July 2011.
- In January 2011, Pfizer applied for – and was granted – a paediatric extension, thus extending patent protection for latanoprost in Italy and in other European countries

by a further 6 months, i.e., until January 2012.

B. The ICA investigation

In October 2010, following a complaint filed by generic drug manufacturer Ratiopharm Italia S.r.l., the Italian Competition Authority ("**ICA**") commenced proceedings against Pfizer for abuse of a dominant position, given that Pfizer at that time held 60% of the Italian market for prostaglandin analogues.

By decision of 11 January 2012, the ICA found Pfizer liable for abuse of a dominant position and fined the group EUR 10.6 million for having "artificially" prolonged patent protection for Xalatan in Italy from September 2009 to July 2011 – through the Divisional Application and related application for an SPC – and then to January 2012 through the paediatric extension. The ICA claimed that Pfizer's exclusionary tactics included sending cease-and-desist letters to generic drug manufacturers and pressuring the Italian Medicines Agency (AIFA) to deny marketing authorisations for generic drugs and to deny their inclusion in transparency lists.

In September 2012, the Lazio Regional Administrative Court ("**TAR**") fully overturned the ICA's decision. The TAR held that Pfizer had merely exercised its patent rights at both the administrative and judicial levels. It emphasised that for an undertaking to be liable for abuse of a dominant position, the contested conduct must demonstrate a clear intent to exclude competitors in a way that goes beyond (*quid pluris*) the mere summation of actions that are per se lawful (such as Pfizer's). The TAR also criticised the ICA's failure to consider that the EPO's revocation decision was not final (and in fact was overturned on appeal). Furthermore, it noted that the ICA had misapplied European caselaw on abuse of a dominant position through (mis)use of patent rights.

However, by decision of 12 February 2014, Italy's highest administrative court, the Council of State (*Consiglio di Stato*), reinstated the ICA's findings. The Council of State held that whether Pfizer's Divisional Application and the related application for an SPC were lawful was irrelevant because the case did not concern the lawfulness of Pfizer's conduct under patent law – "rather, [it concerned] the anticompetitive effects of a series of acts that could in theory be lawful in themselves". The Council of State noted that abuse of a dominant position is a specific form of the more general concept of abuse of rights, which "presupposes the existence of a right which is artificially used, however, for a goal which is incoherent with that for which such a right is granted: in this case, the exclusion of competitors from the market". The Council of State stated that Pfizer's exclusionary intent was confirmed by the fact that the Divisional Patent did not protect an innovative new drug and indeed was not followed by the launch of a new drug on the market.

The Italian Government's legal action

In November 2014, following the ICA's decision, the Italian Government sued Pfizer for the additional costs incurred by the Italian healthcare system due to increased spending on latanoprost-based products for patients. The claimed damages were calculated by taking the difference in price between Xalatan and equivalent drugs subsequently placed on the market and multiplying it by the number of Xalatan packages sold between October 2009 and May 2010 (i.e., the period between when the Parent Patent expired and when generics entered the market).

On 24 July 2017, the Court of Rome rejected the Italian Government's claim, holding that the claimants had not proven that, without Pfizer's allegedly abusive conduct, the generic drug manufacturers would have entered the market on the patent's original expiry date (6 September 2009) – nor had they proven the damage allegedly suffered by the Italian healthcare system.

The first-instance decision was reversed on appeal, and the appeal decision was then upheld by the Italian Supreme Court this past January.

The Italian Supreme Court agreed with the Rome Court of Appeal on the following:

- The lawfulness and/or validity of the Divisional Patent and the related SPC was irrelevant because 'abuse': (a) is an objective concept referring to the conduct of a dominant undertaking which, through methods other than those of 'competition on the merits', hinders competition; and (b) can consist of conduct which is otherwise lawful under branches of law other than antitrust law. Moreover, according to EU caselaw, any IP strategy pursued by a dominant undertaking solely to impede competition (i.e., without any other genuine economic interest) falls outside the scope of 'competition on the merits' (the Supreme Court referred to ECJ Judgment of 6 December 2012, *AstraZeneca /Commission*, C-457/10, and ECJ Judgment of 3 July 1991, *AKZO v Commission*, C-62/86).
- The filing of the Divisional Application years after the Parent Patent was granted and of an SPC application based on the Divisional Application enabled Pfizer to prolong patent protection for latanoprost in Italy without following up with the launch of a new drug, and "thus [Pfizer] performed conduct aimed at excluding competitors".
- Several "serious and concurrent" elements uncovered by the ICA's investigation suggested that generic drug manufacturers delayed their entry into the market because they did not want to risk Pfizer commencing infringement proceedings.
- The damage incurred by the Italian healthcare system was to be quantified as: (a) the

difference between the reimbursement granted by the Italian healthcare system before and that granted after the entry of the generic version of Xalatan, multiplied by (b) the number of Xalatan packages sold between October 2009 and May 2010.

Conclusion

The Italian Supreme Court's decision appears to be based on erroneous assumptions about the nature and purposes of the patent system in general and of divisional patents, SPCs and paediatric extensions in particular, as better explained below:

- The patent system's main purpose is to incentivise the development and disclosure of new inventions by granting patent owners time-limited monopolies. This is especially important in the pharma sector – as demonstrated by the introduction of extension schemes under SPCs and paediatric extensions.
- SPCs are designed to offset (at least partially) the exclusivity time that patent owners lose because of the long, complex administrative procedure between filing a patent application and securing marketing authorisation. SPCs can indeed prolong a patent right for up to 5 years, with a further 6 months available for medicinal products for children through paediatric extensions.
- If a patent and its related SPC are granted and survive opposition proceedings or invalidity actions before national courts, it means that the patent owner properly exercised its rights within the scope of the patent system to protect its research and investments. It is thus surprising that the Italian Supreme Court did not criticise the Rome Court of Appeal for having considered the outcome of the EPO opposition proceedings irrelevant in the assessment of Pfizer's conduct (proceedings which confirmed the Divisional Patent's validity, albeit in amended form).
- The fact that the Divisional Application was filed years after the Parent Application but was not followed by the launch of a new drug does not seem indicative of abuse of a dominant position, either. Divisional patents are widely used tools in patent law at EU and national level as they allow subject matter already disclosed in, but not claimed by, a given parent application to be added as new claims. They thus cannot be used to extend patent protection for anything not already invented at the time of the parent application's filing. Filing a divisional application serves to enhance the protection of the invention within the limits of the original application, and is not necessarily, and in practice not even normally, connected to the launch of new products.
- Divisional applications are attributed the same date as the parent application and thus do not extend patent protection beyond that of the parent patent; this makes it hard to see what difference it makes if they are filed many years after the parent

application.

- In conclusion, Pfizer simply employed a common IP strategy – i.e., filing a divisional application – that was clearly aimed at correcting an oversight by Pharmacia when it applied for the SPCs based on the Parent Patent. Clearly, the patent system is set up to grant patent owners the right to prevent third parties from using their inventions – so it is all the more difficult to understand how using the means provided by the system to ensure the proper protection could somehow constitute anticompetitive conduct under antitrust law and how the Court could mention the reliance of generic manufacturers on the possibility to market the drug upon patent expiry as a relevant factor, when the holder still had the legitimate means to obtain the SPC.

Furthermore, the Pfizer case is unique and thus differs from *AstraZeneca v Commission* (T-321/05) and *ITT Promedia v Commission* (T-111/96), which are the leading cases on anticompetitive misuse of administrative and judicial procedures. In the *AstraZeneca* case, it was established that AstraZeneca had abused its dominant position by submitting: (a) "misleading representations" to patent offices and before national courts to obtain or maintain SPCs to which AstraZeneca was not entitled or to which it was entitled for a shorter period; and (b) requests for deregistration of the marketing authorisations, thus preventing generic drug manufacturers from benefitting from the abridged procedure and consequently obstructing the introduction of generic products and parallel imports. In the *ITT Promedia* case, it was established that initiating legal proceedings amounts to an abuse of a dominant position if the action is "manifestly unfounded", cannot reasonably be considered an attempt to assert rights vis-à-vis competitors but only serves to harass the opposite party, and is aimed solely at eliminating competition.

The outcome of the 'latanoprost saga' is especially unfortunate because if this approach is followed in the future, it could pave the way for a dangerous broadening of the scope of Art. 102 TFEU. This could increase legal uncertainty for key players in the pharma sector and, in the long run, reduce the value of patents in this sector. Consequently, it could stifle R&D of new drugs and, ultimately, impede the innovation-based competition which underpins the life sciences sector.

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