Competition Week

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Antitrust and pharmaceutical competition: remarks from the Italian experience

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The views expressed here are personal and do not necessarily reflect those of the Italian Competition Authority

Outline

Introduction

Antitrust enforcement in the pharmaceutical sector

- **Antitrust enforcement in the pharmaceutical sector bears a long history, but in recent years we have observed an increasing number of cases and the emergence of new issues**
  - Price fixing and market sharing
  - Misleading conduct
  - Abuse of regulatory procedures
  - Pricing abuses
  - Patent settlements
  - Parallel trade

- **Pivotal role of intellectual property issues and their relationship with competition**

Introduction

The Italian Competition Authority's enforcement activities

- **ICA's enforcement activities in the last three years:**

  - **some relevant cases recently closed**
  - proceedings *A431 Ratiopharm/Pfizer* (see decision no. 23194 of January 11, 2012)
  - proceedings *I760 Roche-Novartis/Farmaci Avastin e Lucentis* (see decision no. 24823 of February 27, 2014)

  - **three cases related to the pharmaceutical sector currently in the "pipeline"**
  - proceedings *A473 Fornitura acido colico* (see decision no. 24674 of December 10, 2013)
  - proceedings *I770 Arca/Novartis-Italfarmaco* (see decision no. 24770 of January 29, 2014)
  - proceedings *A480 Incremento prezzi farmaci Aspen* (see decision no. 25186 of November 19, 2014)

Outline

The Xalatan case

The proceedings

- **In October 2010 the ICA opened an investigation against Pfizer**
  - complaint filed by a generics producer
  - further submission by the European Generic Medicines Association
- **In January 2012, the ICA condemned the Pfizer group for an abuse of dominant position, in violation of art. 102 (TFEU)**
- **Pfizer was fined by € 10,6 million**

The Xalatan case

The case in a nutshell

- **Xalatan: best-selling drug for treating visual glaucoma and ocular hypertension**

- **Pfizer was found to have put in place a complex legal strategy aimed at *artificially* lengthening the patent protection of Xalatan, thereby delaying the entry of generics in the market**

- **The aim of Pfizer's strategy was to protect its market share from the entry of equivalent drugs artificially extending patent protection from September 2009 to July 2011, bringing it in line with the duration of patent protection in other European countries**

The Xalatan case

The relevant market and the dominant position

- **Relevant (national) market: glaucoma medicines based on prostaglandin analog**
  - More powerful
  - Less side-effects
  - Can be used in patients with other (frequent) medical conditions
  - Higher price

- **Dominant position**
  - Pfizer: 60% market share
  - Two competitors only: 20,9% and 19,1% market shares
  - Barriers to entry

The Xalatan case

The facts

- 1989: Pharmacia files a request before the European Patent Office (EPO) for a patent
- 1994: The patent was granted and was meant to expire in September 2009
- 1997: Pharmacia requested in many European countries, but not in Italy, a Supplementary Protection Certificate (SPC) → patent protection was extended to July 2011 (but not in Italy)
- 2002: Pfizer acquires Pharmacia and applies for a divisional patent
- 2009: The divisional patent is granted
- 2009: Pfizer applies for a SPC before the Italian Office for Patents and Trademarks
- 2009: The SPC is granted

→ the duration of Xalatan protection in Italy was lengthened and aligned with that of other European countries

The Xalatan case

The abuse (1/2)

- **What did the ICA question?**
  - The ICA questioned Pfizer's strategy of artificially extending patent protection from September 2009 to July 2011 by means of requiring the divisional patent and additional SPC rights
  - The ICA clearly did not question Pfizer's application for a divisional patent as such

- **What elements did the ICA consider?**
  - The timing of the divisional patent request
  - The divisional patent had no other purpose than that of enabling Pfizer to request an SPC in Italy
  - The patent was validated only in Italy
  - No new product was released by Pfizer

The Xalatan case

The abuse (2/2)

- **Pfizer also put in place a complex “dissuasive” strategy against new entrants**

- For instance, Pfizer issued a series of warnings to the generics producers, resulting in litigation and claims for damages in case of commercialization of generic drugs before the new deadline of patent protection of Xalatan (July 2011)

- **Several documents proved Pfizer’s intent to exclude competitors**

The Xalatan case

The effects

- **The effects of Pfizer's conduct**
  - Pfizer's conduct did no lead to any new drug being marketed on the basis of the divisional patent
  - Entry of generic drugs was delayed
  - It was estimated that the delayed entry of generics producers for about seven months has allowed the company to continue to enjoy an extension of its monopoly rent quantifiable approximately as € 17 million, causing an increased expenditure for the Italian NHS estimated at approximately 14 million euros

The Xalatan case

Judicial review - the lower administrative Court

- **The Lower Administrative Court quashed the ICA's decision**

- **The Court maintained that Pfizer's conduct was legitimate as the company had done nothing more than exercising its rights**

- In order to be considered anticompetitive, Pfizer's conduct had to be accompanied by a clear exclusionary intent and additional elements (quid pluris) that goes beyond the existence of a set of legitimate actions carried out by the competent administrative and jurisdictional authorities

- The Court considered that these additional elements were lacking

The Xalatan case

Judicial review - the highest administrative Court

- **The Highest Administrative Court dismissed the ruling of the Lower Administrative Court**

- **The Court maintained that the issue is not the authorization, granted through the patent regulatory framework, to request a divisional patent, but Pfizer's use of such an authorization in the specific circumstances**

- **The issue is not whether or not the conduct was contrary to patent laws, but the anticompetitive effect of a series of acts, which are legitimate on their own**

- The ICA was right to find Pfizer's conduct to have a further and different goal than patent protection: keeping generics out of the market for as long as possible
- Pfizer never actually used the divisional patent to market new products

Outline

The Avastin case

The proceedings

- In February 2013 the Italian Competition Authority opened proceedings against the Roche Group and the Novartis Group in relation to an alleged anticompetitive agreement in breach of Article 101 of the Treaty on the Functioning of the European Union.

- In February 2014, the ICA found that Roche and Novartis had violated art. 101 of the TFEU

- Fines: Novartis group € 92 million and Roche group € 90,5 million.

The Avastin case

The facts

- **Medicines used for curing some severe and widespread eye diseases such as Age-related Macular Degeneration (AMD), the primary cause of blindness in industrialized countries**
- Avastin is a registered product for the treatment of cancer, but has been widely used off-label for the treatment of AMD
- Lucentis is a drug based on a very similar molecule to that of Avastin but was specially registered for eye diseases (previously treated with Avastin)

- **Both products are licensed by Genentech (Genentech and Novartis have jointly developed Lucentis for ophthalmic use), a wholly-owned subsidiary of Roche.**
- Novartis has a 33% stake in Roche

- **Significant cost difference between the two products:**
- Avastin: € 81
- Lucentis: € 900 (previously € 1,700)

The Avastin case

The agreement

- **Roche and Novartis parent companies, also through their Italian branches, have pursued a concerted artificial differentiation of the two drugs Avastin and Lucentis**

- this was done by the companies coordinating in presenting the former as more dangerous than the second, thus conditioning the choices of doctors and health services

- **Why was it a profitable strategy?**

- Roche has interest in increasing Lucentis' sales because through its subsidiary Genentech (which developed both drugs) receives relevant royalties from Novartis
- Novartis, in addition to the profits from the sale of Lucentis, holds a significant stake in Roche

The Avastin case

The effects

- **Wide range of negative consequences deriving from the illicit agreement**

- greater difficulty of the Italian NHS in the ability to treat many patients
- estimated increase in public expenditures of € 45 million only in 2012, increasing to as much as € 600 million per year.

The Avastin case

The scope of the ICA's intervention

- **The ICA did not challenge the decision to develop two different drugs with the same mechanism to treat two different diseases nor the price difference between the two drugs**

- **The ICA did not *endorse* the off-label use of Avastin**

- it simply considered from a relevant market analysis viewpoint that that both Avastin and Lucentis were part of the same market (as many internal documents of Roche and Novartis directly evidenced, by developing direct confrontation of their own market shares)

- **The ICA only considered the antitrust profiles of the company's conducts**

- focused on the parties' coordinated exploitation of the complexities of the regulatory pharmaceutical framework in order to subdivide healthcare markets and extract monopolistic profits, eventually bringing a harm to consumers
- this coordination went over and beyond the vertical licensing agreement between the parties

The Avastin case

Judicial review

- **The regional administrative court having first-instance jurisdiction on the appeal recently fully upheld the ICA's decision**

- The Court pointed out that the ICA had not erred when it ruled that the two drugs at issue belonged to the same relevant product market, as both of them were capable to meet the same therapeutic needs and were then substitutable

- The Court held that the only objective of the agreement examined between Roche and Novartis was to restrain competition by limiting the sales of the cheaper product in order to increase the sales of the more expensive product, which was more profitable for the parties

- **The companies have already declared their intention to further appeal in front of the highest administrative Court**

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Thank you!

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