

# 22<sup>nd</sup> ANNUAL IP LAW & POLICY CONFERENCE FORDHAM

## Session 6B – Competition Recent Developments

### The Pfizer Italian Antitrust Saga

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# Factual background



**September 1989:** Pharmacia files a patent application for various compounds, including *latanoprost*

**April 1994:** grant of the patent (EP417)

**July 1996:** first MA for *latanoprost*

**1997:** SPCs sought and granted in all European states, except Italy, Spain, Luxembourg

**2002:** Pfizer's acquisition of Pharmacia



## Factual background

**June 2002:** Pharmacia, during the acquisition, files a divisional application based on EP417

**January 2009:** grant of the divisional (EP168)

**June 2009:** SPC sought and granted in Italy → patent protection realigned with the rest of the EU (extended from September 2009 to July 2011)

**July 2009:** C&Ds sent to GXs

**July 2009:** Revocation actions filed by GXs → Pfizer counterclaims for infringement



## Factual background

**May, 2010:** first GX to enter the market (Ratiopharm)

**May/June, 2010:** Pfizer's complaint with the Administrative Court seeking the suspension of Ratiopharm's MA → Suspension granted, including the substitution list

**May/June, 2010:** Ratiopharm's complaint to the Italian Antitrust Authority (IAA)

**July 2010:** Consiglio di Stato (CS) revokes the suspension of Ratiopharm's MA

**October 2010:** Opposition division revokes EP168 and the IAA raids Pfizer's Italian offices



## Factual background

**January 2012:** The IAA finds that Pfizer's conduct amounted to an abuse of dominant position (fine > EUR 10.000.000)

**May 2012:** EPO's BoA decision → EP168 is valid

**September 2012:** the Regional Administrative Court (RAC) reverses the IAA's decision finding Pfizer's conduct legitimate

**December 2012:** Ratiopharm's appeals the RAC decision

**February 2014:** the Consiglio di Stato (CS) reinstates the initial IAA's decision



# The IAA decision

Decision based on the following main assumptions:

- Pfizer's divisional application had the “**sole purpose**” of obtaining the SPC and delaying GXs entry
- GXs had legitimate expectations that patent protection was to expire in September 2009
- EP168 had been revoked by the opposition division

On this basis, quoting the ECJ AstraZeneca decision in Case C-457/10, the IAA states that:

EP168 amounted to an IP right Pfizer “*was not entitled to*”

Pfizer “*was perfectly aware that the application for its divisional patent was abusive*” and

the litigation against GXs was not intended “*to protect valid rights*”

# The IAA decision



Evidence found in dawn raids was crucial

The IAA had seized **various emails** – not disclosed in the decision – crucial to show:

- Pfizer’s “exclusionary intent”
- its awareness of the limited chances of success of any litigation based on the SPC
- its awareness of the antitrust risks deriving from its conduct



# The RAC decision

IAA decision reversed:

- Pfizer had done nothing else than engaging in the mere exercise of patent rights
- No additional element (no “*quid pluris*”) to support a finding of abuse

Numerous references to the Astrazeneca decision, where the ECJ found that “*quid pluris*” in the wilful provision of elusive or erroneous information to a patent office

- Lastly, EP168 found valid by the BoA



# The RAC decision



## Some quotes:

“It is evident to this Court that in order to ascertain that Pfizer’s behaviour was illicit under an antitrust perspective, **the alleged exclusionary strategy carried out shall consist of more than a succession of lawful conducts. In other words, a *quid pluris* beyond the sum of lawful conducts is necessary**”

“This conclusion [i.e. the conclusion that the filing was lawful] is not affected by the circumstance that the application had been filed, according to the IAA, as soon as the more limited patent protection in Italy had become apparent for Pfizer. This filing indeed undoubtedly reflected a faculty of the undertaking, so that its exercise cannot be seen, for this sole reason, as adopted within an [unlawful/anticompetitive] exclusionary strategy”



# The CS decision

IAA initial decision reinstated

Entire decision based on the following premise:

- **the divisional patent application had been filed by Pfizer with the sole purpose of obtaining a SPC in Italy and preventing GXs entry**

According to the CS, this amounts to an abuse of rights by the dominant undertaking as this would not be the rationale behind divisional patent applications:

- “The abuse of a dominant position which Pfizer is accused of is nothing but the specification of the more general concept of abuse of right. This concept presupposes the **existence of a right which is however used artificially, for a goal which is inconsistent with that for which such a right is granted** : in this case, the exclusion of competitors from the market.”



# The CS decision

No need of a “*quid pluris*” for a conduct consisting in the exercise of rights to be unlawful from a competition law perspective:

- **what counts is whether the rights are exercised for their original purpose (or, rather, for a “inconsistent purpose”)**

CS reasoning echoes the ECJ’s words regarding the second abuse in the Astrazeneca case: the exercise of legal faculties can amount to an abuse if the sole purpose of this exercise is to prevent generic entry.

# The CS decision



## Astrazeneca decision, some quotes:

Paragraph 132: “the fact that under Directive 65/65 AZ was entitled to request the withdrawal of its MAs for Losec capsules in no way causes that conduct to escape the prohibition laid down in Article 82 EC. As that court pointed out, the illegality of abusive conduct under Article 82 EC is unrelated to its compliance or non-compliance with other legal rules and, in the majority of cases, abuses of dominant positions consist of behavior which is otherwise lawful under branches of law other than competition law.”

Paragraph 134: “an undertaking which holds a dominant position has a special responsibility and [...] **cannot use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relating to the defence of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.**”

# The CS decision



Crucial difference from AZ's withdrawal of the MAs for Losec:

If we talk of divisional patents and SPCs, what possible justification can a company provide, other than the legitimate expectation to exclude competition?

# Lessons to be learned



- The IAA heavily relied on Pfizer’s internal communication showing Pfizer’s “exclusionary intent”. Once again, crucial weight was played by proof of intent.
- Dominant companies must ensure they take steps to avoid any language which might suggest an anti-competitive intent.



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