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Excessive Prices: the *Aspen* case

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The (US) *Aspen* Case

The (Italian) *Aspen* case (1)

- Four oncological drugs (**Cosmos drugs**), developed in the ’50-’60 and **not covered by patents**

- In 2009, Aspen purchased the relevant trademarks and, later on, started a series of **initiatives to increase the prices** of the products concerned

- In September 2016, the ICA imposed a fine exceeding €5 million on Aspen for having imposed **excessive prices**

The (Italian) *Aspen* case (2)

- According to the ICA, Aspen engaged in a **very aggressive negotiation strategy** vis-à-vis the Italian Medicines Agency (AIFA)

- This negotiation strategy resulted in **substantial price increases**, ranging from 300% to 1,500%

- In line with *United Brands*, the ICA applied a **two-prong test**
  - ✓ First, it considered the **disproportion between prices and costs**
  - ✓ Second, the ICA verified whether the prices were **unfair**, taking into account a number of additional factors

The negotiation strategy

- The ICA contested Aspen's **extremely aggressive negotiation** strategy:
  - ✓ Repeatedly requesting AIFA to include Cosmos drugs among **C Class** drugs (whose prices are not reimbursed by the NHS and can be freely determined by pharmaceutical companies), if the requested price increase was not accepted
  - ✓ **Threatening to withdraw** the drugs from the Italian market
  - ✓ Using a "**stock allocation mechanism**" to limit parallel imports and create transitory shortages in the Italian markets
- Aspen's alleged strategy had some **similarities with other practices** that have been considered abusive
  - ✓ **Misuse of rights** in administrative proceedings
  - ✓ Strategies aimed at increasing prices by creating an **artificial shortage/decrease in output** (see, *e.g.*, the investigations concerning alleged market manipulation in the energy sector)
- Eventually, however, the ICA focused on the **analysis of prices**

The two-prong test: price-cost analysis (1)

- The ICA established the **disproportion between prices and costs** on the basis of two parameters
  - ✓ the **difference between prices and costs**, measured through the **gross contribution margin** (revenues minus direct costs)
  - ✓ the **difference between revenues and a 'cost plus' benchmark**, including (i) direct costs, (ii) the share of indirect costs (selling and distribution, administrative expenses, other operating expenses) allocated to the products concerned, and (iii) a profit margin (return on sales, or ROS, considered equal to 13% in light of the ROS of the two main generic firms)

- The difference between prices and costs was **considered excessive**
  - ✓ The **gross contribution margin**, which was already sufficient to cover indirect costs before the change in prices and further increased
  - ✓ the **difference between revenues and the 'cost plus' benchmark**, which ranged from [100-150]% and [350-400]% of the cost plus

The two-prong test: price-cost analysis (2)

- The price-cost analysis may appear to a certain extent **redundant**

- The decision reflects the well-known difficulties in carrying out a price-cost test: many technical aspects of the ICA's analysis are **open to question** (including the choice of profitability benchmarks, which did not seem to adequately consider the premium nature of the Cosmos drugs)

- In any case, notwithstanding the significant difference between prices and costs, this analysis was **not considered sufficient** for a finding of infringement

The two-prong test: unfairness analysis (1)

- The ICA carried a **detailed unfairness analysis**, based on a number of additional factors

1) **Intertemporal comparison** between prices
   - ✓ Increases between 300% and 1,500%
   - ✓ The increases were not necessary because of losses or very low margins

2) **Lack of economic justification**
   - ✓ The only reason put forward by Aspen was the need to align prices with those charged in other MSs
   - ✓ Not justified by an increase in costs
   - ✓ No need to recoup investments

3) **Lack of benefits** for patients
   - ✓ No improvement in the quality or effectiveness of the products

The two-prong test: unfairness analysis (2)

4) **Nature** of Cosmos drugs and **characteristics** of the Aspen group

- ✓ Drugs not covered by patents
- ✓ No investments in research and development

5) **Harm to the national health system**

- On the other hand, the ICA **did not take into account other factors** that are normally considered relevant in the assessment of excessive prices
  - ✓ The **prices charged by other producers in the same markets**: no valid alternatives
  - ✓ The **prices charged by Aspen in other MSs**: different conditions / high prices in other MSs could reflect a similar strategy to increase prices

Economics and fairness

- Unfair prices continue to be a **unique area** of antitrust enforcement
- In the past decades, we have experienced a **gradual shifting** from a multi-valued approach (focusing also on fairness) to an economic-based approach, including in abuse of dominance cases (albeit with more resistance)
- In the case of excessive prices, **economic analysis** taken alone apparently does not provide sufficient guidance
  - ✓ A **price-cost comparison** may be useful to establish when a price is not excessive, but not to determine when it is abusive. A price exceeding the cost-plus benchmark is not, as such, excessive
  - ✓ In economic terms, the right price is the result of the **interplay of demand and offer**. How can we say when it becomes excessive?
  - ✓ Antitrust authorities and courts have **resorted to other tools and criteria**, namely a fairness analysis, in accordance with the wording of Article 102 and case law

Value-based pricing

- In the pharmaceutical sector, pricing decisions follow a particular pattern, which takes into account, *inter alia*, the **clinical benefits** of the drugs concerned, as well as the **possible saving** of other costs for the health system from the use of the products
- Cosmos drugs are **life-saving products**. Their economic value should reflect their clinical benefits. Many regulatory authorities in the EU had already accepted significant increases in the prices of Cosmos drugs
- The ICA did not take into consumers' willingness to pay (and, thus, the value of the products for them): the main reason was that, in case of life-saving products, consumers' **willingness to pay tends to infinity**
- However, there should be a **(reasonable) premium** reflecting the intrinsic value of the products (trade-off between allocative and dynamic efficiency)

The drastic price increases

- In *Aspen*, the ICA carried out a **detailed fairness analysis** taking into account **many relevant factors**
- However, one of the relevant factors seemed to play a crucial role in the ICA's analysis: the **drastic increases in price**, between 300% and 1,500%
- Similar to the US *Aspen* case, the problem arose because of a **disruptive change in the prior course of action** of the dominant firm, which negatively affected other parties
- According to the ICA, this change was **not justified** by any objective factor
  - ✓ Increase in costs
  - ✓ Need to cover R&D expenses or to ensure incentive to invest
  - ✓ Improvements in the quality and effectiveness of the products to the benefit of users

A focal point for antitrust intervention (1)

- Price increase cases are **natural candidates** to antitrust intervention, as demonstrated also by decision practice and case law
- Based on some appropriate benchmarks (evolution of prices over time in the same market, in other geographical markets, etc.), it should be possible to identify a **physiological price oscillation band**
- **Price increases exceeding a multiple** of the maximum physiological variation, without any apparent justification, may be considered *prima facie* anomalous
- In such cases, antitrust intervention may be warranted, unless available evidence demonstrates that the price increases were **justified** by some objective factors (including the need to reward innovation)

A focal point for antitrust intervention (2)

- Antitrust intervention in case of (i) anomalous and (ii) unjustified price increases would be **consistent with both fairness and economic considerations**
- Empirical investigations and behavioural studies on **fairness**
  - ✓ Price increases are considered unfair when firms **increase their profits at the expense of customers** (dual entitlement)
  - ✓ Acceptable when justified by **exogenous shocks** (*e.g.*, increase in input costs), or the company **increases its profits without harming customers** (*e.g.*, same prices following a decrease in costs)
- **Economic analysis**
  - ✓ Need to **adjust prices** in case of exogenous shocks
  - ✓ Need to **safeguard incentives to invest**: higher profits are justified in case of development of new products, improvement of existing ones, or introduction of cost-reducing production processes