Abuse of Dominance in the Pharmaceuticals Sector:

Excessive Pricing

David Hull

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Excessive Pricing: The Dilemma

- Excessive pricing is often seen as the quintessential evil of monopoly
- But recognition that high prices create incentives to innovate and invest and attract competition to the market
- How do you distinguish between acceptably high prices and excessive prices?

Legal Test for Excessive Pricing

- Article 102(a) provides that an abuse may consist of "*directly or indirectly imposing unfair purchase or selling prices* …"
- In *United Brands* (1978), the Court of Justice said that charging a price which is excessive because "*it has no reasonable relation to the economic value of the product*" is abusive.
- Court of Justice set out a 2-pronged test:
  1. Whether the difference between the costs and the price is excessive; and
  2. Whether the price is either unfair
     a) in itself or
     b) when compared to the price of competing products.

Problems with the Legal Test

- Is difference between price / costs excessive?
  - Which costs? Most significant costs for drugs are the R&D costs. How do you allocate them over time and across countries?
  - Difficult to determine costs
  - What is “excessive”?
- Is the price unfair “in itself”?
  - What is “in itself”?
- Is the price unfair when compared to competing products?
  - Comparisons difficult

Difficulties with Applying Test in Pharma Sector

- Costs do not capture all the costs of the high failure rate in bringing a drug to market.
- Higher prices may reflect superior efficacy and fewer side effects, which reduces long-term costs to national health budgets – need to look at health technology assessments.
- National pricing and reimbursement regimes limit freedom of pharma companies in setting prices.

Addressing Excessive Pricing in Pharma Sector: Policy Issues

- Competition authorities are generally reluctant to launch cases:
  - Application of legal test raises very difficult questions (e.g. what is the correct price)
  - Interference with pricing could chill innovation in a key sector – high prices are the carrot that encourages companies to invest in R&D
  - Unnecessary in light of the strong buyer power exercised by national health authorities and other payors. Some Member States now considering joint buying arrangements.
  - Pricing of medicines a national issue for Member States

Napp (UK)(2001)

- Napp sold sustained release morphine to hospitals at steep discounts and charged much higher prices to pharmacies, which the OFT found to be excessive.
- OFT found that the prices charged to pharmacies were above the level that would be charged in a competitive market.
- Exclusionary conduct in hospital sector linked to excessive pricing in pharmacy sector
- OFT looked at a range of comparators:
  - Prices were between 30 and 50% higher than competitors
  - List prices to pharmacies were, in some instances, more than 2000% higher than those in hospitals
  - Prices to pharmacies were 500% higher than those for export
  - Napp's gross market was over 80%, while it was less than 70% for Napp's most profitable competitor
- CAT upheld the OFT's decision.

Hepatitis C Drugs

- On 22 December 2014, the European Commission declined to open an investigation into allegations of excessive prices for Hepatitis C drugs, despite pressure from members of the European Parliament.
- Commissioner Vestager responded to the Parliamentary Question (P-008636/2014) as follows:

> *Pursuant to Article 168(7) TFEU, Member States are responsible for health and medical care, including the allocation of resources assigned to these areas. Each Member State may therefore take measures to regulate or influence the prices in these areas.*
>
> *For this reason, price-setting by pharmaceutical manufacturers and healthcare systems in general takes place on a national level, allowing Member States to exercise their bargaining power. …*
>
> *Moreover … the market for hepatitis C drugs is a rapidly moving therapeutic area, with several new classes of direct-acting antivirals now in advanced stages of development. This would seem to suggest that this is a dynamic market.*

Hepatitis C Drugs

- On 15 March 2015, Commissioner Vestager responded to a follow-up Parliamentary Question (000261/2015) as follows:

  Since the Commission's earlier response, as it can be ascertained from public sources, the factual situation surrounding this particular medicine has evolved further. For example, another novel medicine such as AbbVie's Viekira Pak has entered the market to compete with Sovaldi in addition to, for example, Janssen's Olysio. Furthermore, several Member States have concluded or are negotiating pricing and reimbursing agreements with respect to this group of novel Hepatitis C medicines.

Aspen

- On 27 November 2014, the Italian competition authority launched an investigation into allegations that Aspen Pharma abused its dominant market position by increasing the price of its cancer medications from 250% to 1500%.
- According to the authority, Aspen had made efforts to increase the prices in Italy up to the levels in other EU countries, in order to limit the levels of parallel trade of the product out of Italy.
- The authority also alleges that Aspen threatened to withdraw the marketing authorization of the product if the health authority did not agree to the price increases.
- This case is on-going – a new Statement of Objections was recently sent to Aspen and a hearing is scheduled for July and a decision expected by September.

Flynn Pharma / Pfizer

- On 6 August 2015, the UK CMA issued a statement of objections to Pfizer and Flynn Pharma concerning allegations of excessive pricing for an anti-epilepsy drug.
- According to the CMA, prior to 2012, Pfizer manufactured and marketed the drug under the brand name Epanutin.
- Pfizer then transferred the UK marketing rights to Flynn Pharma, which "genericised" the drug and started selling it in September 2012 at prices alleged to be 25 to 27 times higher than Pfizer's historical prices.
- The statement of objections covers both Pfizer's supply prices to Flynn Pharma and Flynn Pharma's prices to the market.
- This case is on-going.

Summary Guidance

- High risks arise from drastic price increases after drug is on market:
  - On-going cases in the UK and Italy concern drastic price increases (250% or more)
  - Cases involved drugs that were already on the market – easier to bring case as a “fair” price (i.e. the price prior to the increase) has already been established – no need to compare with competing products
- Such risks would not appear to arise in the context of:
  - Initial price setting or pricing and reimbursement negotiations with the health authority
  - Moderate price increases