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**Excessive Pricing in the
Pharmaceuticals Sector**

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Excessive Pricing Cases in the Pharmaceutical Sector

Year	Companies	Investigated Practice	Country	Fines
ongoing	Aspen	Excessive price increases	EU	
ongoing	Actavis	Excessive price increases	UK	
ongoing	Concordia	Excessive price increases	UK	
2016	Flynn / Pfizer	Excessive price increases	UK	£84.2 million
2016	Aspen	Excessive price increases	Italy	€5.2 million
2001	Napp	Hospital discounts and excessive community prices	UK	£3.2 million

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. (¶250)
- Court set out a 2-pronged test: “*[t]he questions therefore to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.*” (¶252)
- Court left open possibility of using other tests: “*Other ways may be devised – and economic theorists have not failed to think up several – of selecting the rules for determining whether the price of a product is unfair.*” (¶253)

Problems with the Legal Test

1. Is difference between price / costs excessive?

- Difficult to determine costs
- What is “excessive”? Isn’t this the same as “unfair” addressed in the second prong?

2. Is the price unfair?

- In itself? What is “in itself”?
- When compared to competing products? Difficulty of making comparisons among different products, across different geographies, at different points in time.

Recent Clarification of *United Brands* Test: Cost/Price Only One Alternative

- Application of the *United Brands* test discussed at length in Case C-177/16, *AKKA/LAA* (14 Sept. 2017) (reference from a Latvian court on licensing fees for musical works charged by national collecting society).
- Step 1 – The benchmark for assessing whether prices are deemed “excessive” can be done by a number of methods (not merely cost-price)
 - Comparison with prices charged in other Member States a valid method
 - Member States must be chosen on bases of “objective, appropriate and verifiable” criteria
 - Comparisons must be made on a “consistent” basis

Recent Clarification of *United Brands* Test: High Prices May Be Justified

- Step 2 – A “significant and persistent” difference from the benchmark price is “indicative of an abuse of the dominant position”
 - But dominant undertaking can provide justification for higher prices
 - Advocate General Wahl: it is only when there is no “rational economic explanation” that a high price will be abusive
 - *“I would point out that the economic value of the goods or service supplied by a dominant undertaking may, in the eyes of the customers, be higher than the benchmark price. Again, there may be a variety of reasons for that: for instance, the goods or service in question may be (or be merely perceived to be, perhaps for reasons relating to advertising or branding investment costs) of superior quality. Some features of the product or service may be regarded as particularly valuable by customers (or certain groups of customers), in spite of the fact that they are not reflected on the cost side. In those cases, the additional benefits or advantages provided to customers justify a higher mark-up over costs.”* (Opinion of AG Wahl, ¶128)

Difficulties with Applying Test in Pharma Sector

- Which costs? Most significant costs for drugs are the R&D costs. How do you allocate them across products, time and geographies? How do you account for 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 have generally been reluctant to launch cases:
 - High prices in a competitive market with low entry barriers are self-correcting
 - Application of legal test raises very difficult questions (e.g. what is an excessive price)
 - Interference with pricing could chill investment and 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
 - Difficulty of determining an appropriate remedy

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Napp (UK)

- 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 margin was over 80%, while it was less than 70% for Napp's most profitable competitor
- CAT upheld the OFT's decision

Gilead (EU)

- On 22 December 2014, the European Commission declined to open an investigation into allegations of excessive prices for Gilead's 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.

Gilead (EU)

- 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 (Italy)

- On 29 September 2016, the Italian competition authority (ICA) fined Aspen Pharma €5.2 million for abusing its dominant market position by increasing the price of its cancer drugs, the increases ranging from 300% to 1500%
- Products had been on the market for several decades and their patents had expired
- Aspen purchased these products from GSK in 2009, and then negotiated a substantial price increase with AIFA, the Italian medicines authority. In its press release, AIFA noted that it was the lowest price in Europe for these drugs
- Latium Regional Administrative Tribunal (TAR) upheld the ICA's decision on 26 July 2017

Aspen (Italy)

- The ICA applied the 2-part *United Brands* test:
 - 1) The ICA found a significant difference between Aspen's new prices and its production costs
 - Did not take into account R&D costs because Aspen did not engage in R&D
 - Did not take into account purchase price of Aspen trademarks

Aspen (Italy)

2) The ICA concluded these significant differences were not justified as:

- The increased prices were not due to additional costs
- Prices had not changed for decades
- Aspen did not contribute to any increase in the drugs' quality
- The price increases imposed a significant cost on national health expenditure (approx. 500% increase)
- Rejected comparison to prices in other Member States because difficult to make comparisons due to differences in health systems and regulatory regimes
- No consideration of demand for product – i.e. patients' willingness to pay – as you cannot put a price on a life-saving drug

Aspen (Italy)

- The ICA emphasized various “plus” factors in finding an abuse
 - Aspen had threatened to withdraw the product from the market if the health authority did not agree to the price increases
 - Aspen wanted 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
 - Aspen’s business model was to buy drugs and exploit market niches by raising prices – no R&D investment

Flynn Pharma / Pfizer (UK)

- On 7 December 2016, the UK CMA issued a decision finding Pfizer and Flynn Pharma had abused their dominant positions by imposing excessive prices for the anti-epilepsy drug phenytoin sodium
 - Fines of £84.2 million on Pfizer, and £5.2 million on Flynn
- Prior to 2012, Pfizer manufactured and marketed the (off-patent) 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 the CMA found to be 16 times higher than Pfizer’s historical prices
- The case is currently under appeal before the CAT

Flynn Pharma / Pfizer (UK)

MARKET DEFINITION

- CMA adopted a very narrow market definition to find the parties dominant:
 - the manufacture of Pfizer-manufactured phenytoin sodium capsules distributed in the UK; and
 - the distribution of Pfizer-manufactured phenytoin sodium capsules in the UK
- This is narrower than the molecule (excluding other brands and formulations)
- CMA justifies this narrow definition based on:
 - 1) Clinical grounds – stable patients cannot switch because of the drug’s narrow therapeutic index (i.e. small dosage changes lead to therapeutic failure or toxicity); thus there are no substitutes for Pfizer-manufactured product
 - 2) Limited actual switching – patients did not in fact switch to alternative products (though this occurred at least until MHRA guidance in 2013 advised against it)

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Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 1

- The CMA uses “cost-plus” benchmark
- Costs actually incurred:
 - Direct costs, indirect costs (e.g. common, joint costs)
- R&D costs not included
 - Flynn is not the same company that incurred the R&D costs to make Epanutin
 - Epanutin off-patent for many years so the R&D costs are considered to have been already recovered

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Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 1

- Setting a specific 6% ROS (Return on Sales)
 - Figure based on the 6% target for overall return in the PPRS (“the closest the UK comes to an agreed industry standard for the return on pharmaceutical products”)
 - Epanutin was formerly sold under the PPRS, which set rates agreed to in negotiations between the NHS and pharma companies
- 6% a worrying precedent for future cases?

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Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 1

- The CMA determines whether the price is excessive by assessing: difference between cost plus and the price actually charged
- The CMA finds Pfizer and Flynn's prices excessive because they materially exceed costs, plus a reasonable rate of return
 - 1) Scale of excess: From 30%-705% for Pfizer; from 30%-133% for Flynn
 - 2) Length of these excesses (over four years)

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Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 1

- CMA uses “alternative methods” to “cross check” whether prices are excessive, including:
 - Reference to past precedent: *Albion Water II* (CMA finds 46.8% above cost excessive); *Deutsche Post* (Commission finds 25% above cost excessive)
 - Sensitivity analyses to determine whether excesses are affected by methodology for allocating common costs (results show the “excess” remains regardless of choice of methodology)

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Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 2

- CMA assigns no economic value to product beyond cost plus
 - Economic value may include “additional benefits not reflected in costs of supply”
- a) Characteristics of phenytoin sodium capsules show no additional value beyond cost plus
 - Old drug, has been off-patent for a long time, superseded by other regimens, no value has been added recently by either party
- b) CMA rejects parties’ representations of additional added value:
 - the value placed on the drug by the MHRA Guidance
 - the Drug Tariff price for Teva tablets as a reasonable benchmark
 - costs that would result from drug’s withdrawal from the market

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Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 2

- CMA rejects demand-side value
 - If economic value of a product is not simply whatever the market will pay, is it therefore only cost plus?
- Drug Tariff price for tablets not a valid comparator
 - Even if customers cannot switch between tablets and capsules (i.e. not part of the same relevant market), isn't the price of a comparable treatment regimen a relevant comparator for assessing price (and demand-side value) of a drug?
 - CMA: The DH has not endorsed or approved tablet prices as providing “value for money”

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UNITED BRANDS TEST – STEP 2

- Price is “**unfair in itself**”
- CMA: “[I]n the absence of relevant non-cost factors, the very excessiveness of a price could be sufficient” to establish that it is unfair in relation to the economic value of the product.”

Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 2

- CMA considers pre-2012 UK price as a relevant benchmark to assess price in relation to economic value
 - Pfizer argued pre-2012 (under the PPRS) it was selling Epanutin at a loss (and it genericised the drug precisely because its sales were not covering its share of fixed costs)
 - CMA rejects this argument noting that while it might justify an increase in price, it does not justify an excessive increase
 - CMA finds pre-2012 is valid benchmark of economic value as no value is added to the product after 2012
- CMA also considers Pfizers' prices for same product in other EEA markets
 - Pfizer manufactures all product in Germany, yet made no similar increases in other markets
 - Yet, Pfizer said sales in all other Member States were profitable

Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 2

- As prices are unfair in themselves, the CMA finds it did not need to consider whether the prices are unfair in comparison to competing products
- CMA defines “competing product” in United Brands Step 2 as products that form part of the same relevant market and are “meaningful” comparators
- CMA rejects existence of potential comparators in the UK
 - Parallel imports and competing NRIM product are “price takers” with respect to Pfizer-Flynn’s list prices
 - CMA does not consider the Drug Tariff price of tablets a reliable benchmark as no meaningful comparison can be drawn between tablets and capsules (particularly as tablet prices are not necessarily cost-justified either)
 - CMA: “The fact that other companies may engage in similar pricing practices will not, in itself, show that the price being scrutinized is not unfair.”

Flynn Pharma / Pfizer (UK)

UNITED BRANDS TEST – STEP 2

- Are the two options at the end of *United Brands* (“unfair in itself” or in comparison) alternatives that a competition authority can choose?
- Is the CMA’s approach in *Pfizer/Flynn* consistent with the Court of Justice’s approach in the Latvian case?

Practical Guidance

- High risks arise from drastic price increases after drug is on market:
 - 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
 - Cases concerned off-patent medications no longer owned by their originators (i.e. the originating company is presumed to have already recuperated its R&D costs)
- 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