

# Flynn Pharma and Pfizer

## Competition aspects

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# Introduction

- Record fine (£90m) imposed by CMA on Flynn Pharma and Pfizer for charging excessive prices to the NHS
  - See <https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs>
- Case now before the CAT
- This presentation looks at some of the key issues and the underlying policy considerations

# Excessive pricing in the EU

- The Commission has never adopted a decision in a pure excessive pricing case
- Very little historic enforcement activity, and only in hybrid cases
  - *United Brands* (1976) – exclusionary conduct
  - *British Leyland* (1984) – parallel trade issues
- Commission had signalled very strongly that ‘pure’ excessive pricing cases would be difficult to pursue
  - Rejection of complaints in *Port of Helsingborg* (2004)

# Excessive pricing in the EU

- But the door is more open at EU level – since 21 November 2016

*“The last thing we should be doing is to set ourselves up as a regulator, deciding on the right price. But there can still be times when we need to intervene. [...]”*

*There can be times when prices get so high that they just can’t be justified. [...] The best answer is often to adjust regulation, or to give the health systems that buy those medicines better bargaining power. But as the recent action by the British and Italian competition authorities shows, there can be times when competition rules need to do their bit to deal with excessive prices.”*

Commissioner Vestager, Chillin’ Competition Conference, 21 November 2016

- In May 2017, Commission opened an investigation into Aspen’s pricing of five cancer drugs.

# National views on excessive pricing

- National competition authorities have been increasingly active

*Napp (UK, 2002)*

*Aspen (Italy, 2016)*

*Flynn (UK, 2016)*

*Concordia (UK, ongoing)*

- Recent cases are pure excessive pricing cases
- Contrast Napp, which was a mixed case (exclusion then exploitation)
  - Patients take drug (morphine) first in hospitals then in community
  - Exclusion: predatory pricing in hospitals (big discounts, matching prices by competitors, effectively foreclosed the hospital segment)
  - Exploitation: excessive pricing in community (prices over 10 times higher the hospital segment)
  - Excessive pricing was only part of the abuse; a form of recoupment

# An enforcement dilemma

Competition authorities used to say that they did not want to intervene in excessive pricing cases

- Preferred to tackle exclusionary conduct
- Competition authorities are not price regulators
- How to determine a “competitive price”?
- Interference with pricing could chill innovation

**But...**

The prohibition against “unfair prices” is in the Treaty:

- Article 102(a) TFEU: an abuse may consist in "*directly or indirectly imposing unfair purchase or selling prices*"
- *United Brands*
- Competition authorities come under political pressure to act against “high prices”

# The legal test (many questions)

Charging a price which is excessive because “*it has no reasonable relation to the economic value of the product*” is abusive

What costs?

1. Whether the difference between the **costs** and the price is **excessive**

AND

What is excessive?

2. Whether the price is either unfair (a) in itself or (b) **when compared** to the price of competing products

Which comparison model to use?

*ECJ in United Brands (1978)*

# Phenytoin: key facts

- Phenytoin sodium capsules are an established drug, launched in the UK in 1938, but still used to treat epilepsy today
  - Price regulation of branded medicines enforces progressive price-cutting over time
  - Price of phenytoin had reached point where it was below cost
- There were no generics in the market at the relevant time
- Phenytoin has a narrow therapeutic index (NTI)
  - Patients that are stable on a particular drug should stay on it
- Many patients are treated with and stable on phenytoin
  - Difficult for Pfizer to withdraw from market despite incurring losses

# Phenytoin: key facts

- Pfizer sold MA to Flynn, who de-branded drug
  - De-branding placed phenytoin into pricing scheme for generic drugs, not PPRS
  - Pfizer continued to manufacture to maintain continuity for patients
- Price increased after drug was de-branded
- But new price was benchmarked against another formulation of same drug – phenytoin sodium tablets (sold by a different company)
  - Capsules were significantly cheaper ( $\pm 25\%$ ) than price of tablets
  - Tablet price had earlier been lowered by 70% as a result of DoH intervention in 2008

# Market definition and dominance

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- Narrowest possible market definition (manufacture/distribution of Pfizer-manufactured phenytoin sodium capsules) led to finding of dominance
  - Alternative market definition = phenytoin sodium capsules until November 2013 when MHRA strengthened advice against switching between manufacturers' products
- CMA rejected argument on DoH buyer power (DoH had been able to force 70% reduction in price for tablets of same drug in 2008)
- Finding of dominance despite entry of another generic capsule
  - NRIM entered in April 2013 and took >30% of sales of 100mg capsule
  - Possible as most prescriptions for phenytoin sodium capsules are 'open'
  - Flynn dropped its price in response to NRIM's entry

# The abuse

- Both manufacturer and MA holder accused of excessive pricing
  - Flynn price to NHS and Pfizer price to Flynn both found to be excessive
  - Novel to have two abuses by companies in vertical relationship
  - Decision accepts that Pfizer had no control over Flynn's prices to NHS
  
- It is a pure excessive pricing case
  - CMA originally alleged anticompetitive agreement but dropped this part of case

# Excessive pricing abuse - 1

- CMA focuses on price/cost comparison (1<sup>st</sup> limb of *United Brands* test)
  - Uses a cost plus test with 6% as benchmark for whether price excessive (imported from PPRS)
    - But under PPRS 6% is a portfolio-wide measure – individual drugs can generate higher returns
    - Under PPRS, 6% subject to margin of tolerance (up to 9% allowed)
  - Other generic drugs on market earn higher returns
  - Decision rejects inclusion of portfolio R&D costs in assessment of costs
- Economic value said to be no more than cost-plus
  - Demand-side factors largely ignored
  - E.g. phenytoin still relied on by many patients and per dose cost similar to other AEDs

# Excessive pricing abuse - 2

- Price of comparable product not accepted as benchmark
  - Phenytoin sodium tablets have same active ingredient
  - Price of tablets had been reduced following intervention by DoH in 2008
    - Tablet price decreased by 70% immediately after intervention
    - Decision does not accept revised price was effectively approved by DoH
    - CMA implies tablets are excessively priced
  - Evidence that Flynn priced capsules by reference to tablet price
    - Capsules 25% cheaper than tablets
    - Patients would likely have switched to tablets if capsules had been discontinued

# Summary: unusual points in the case

- Pure excessive pricing case – historically rare
- Narrowest possible market definition
- Decision focusses heavily on extent of price increase, but rejects comparison with closest comparable product
- Benchmark of cost plus 6% imported from PPRS
- No weight given to demand-side factors
- Novel to have abuses by two vertically related players

# Policy questions to think about

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- Were the experts who said that competition enforcement should not focus on excessive prices (at least partly) wrong? What changed?
- Should competition law set the benchmark despite regulations governing pharmaceutical prices as well as HTA bodies like NICE?
- Risk of setting a precedent for other authorities around the world?
  - NB Recent South African case
- Impact on competitive forces (entry) and innovation?
- Should competition law act as the sweeper?

# Is the CMA now a price regulator?

- Government factsheet for the Health Service Medical Supplies (Costs) Act 2017 (which enables “Secretary of State to require companies to reduce the price of an unbranded generic medicine”):
  - **“2.3 How will the government determine when a price is unreasonably high?”**
  - The department will work with the industry representative body and the Competition and Markets Authority to determine when a price is ‘unreasonably high’.”

<https://www.gov.uk/government/publications/health-service-medical-supplies-costs/health-service-medical-supplies-costs-bill-factsheet>

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Questions?

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Thank you

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