Excessive Pricing in the Pharma Sector

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Recent OECD Developments

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BETTER POLICIES FOR BETTER LIVES

Disclaimer

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Structure

1. Exploitative Abuses

2. Excessive Pricing

3. Difficulties With Pursuing Excessive Pricing

4. Recent Excessive Pricing Cases in Pharma

5. Conclusions

Exclusionary and Exploitative Abuses

- Monopolies are undesirable because fewer goods are consumed by society than is ideal.

However:

- Monopolies not prohibited

- Only abuses of dominant position / monopolisation are prohibited
  - Many country only prohibit exclusionary practices

Are Exploitative Abuses Prohibited?

Cross-Oceanic Debate

- **USA, Mexico, Australia** – exploitative abuses are not recognised
- **EU** – some exploitative abuses are recognised, usually in regulated sectors

Why this difference?

- **USA** – large, dynamic market without extensive State intervention, coupled with long-standing antitrust enforcement – dominant firms obtained position “on the merits”
- **EU** – competition rules more recent. Tradition of State owned companies and economic
  - Despite liberalisation efforts, many sectors still face insufficient competition.

Why not pursue Excessive Pricing?

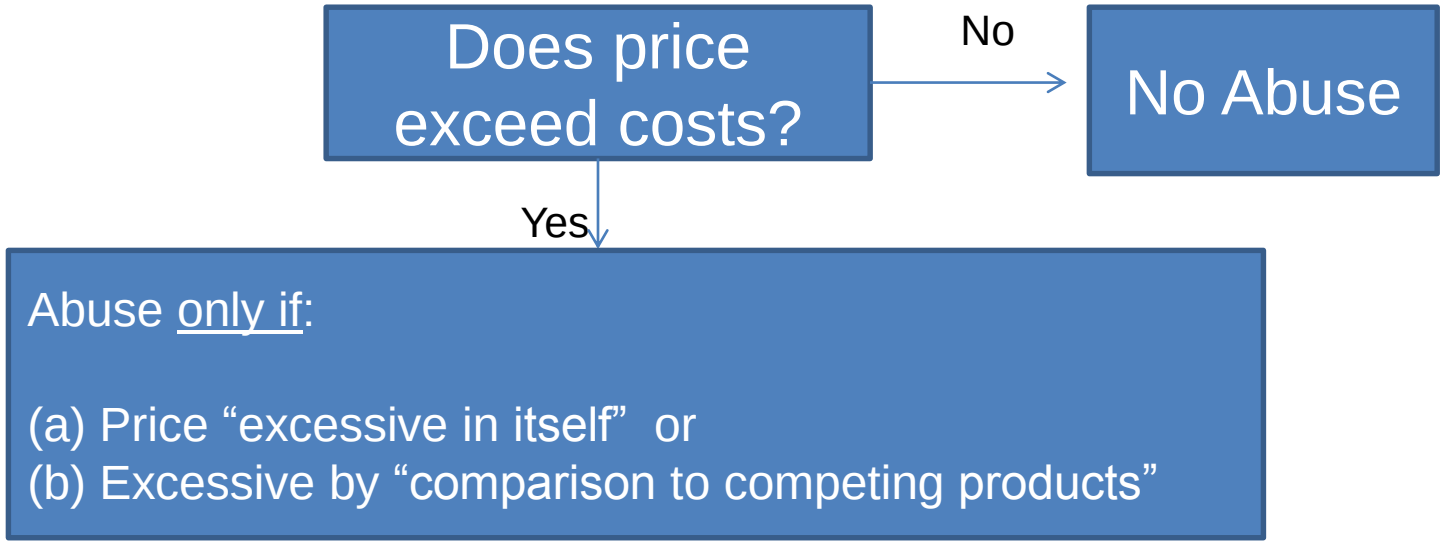
- Monopolies may be able to make substantial profits BUT profits are main way to encourage investment, quality and good service

> *"The opportunity to charge monopoly prices – at least for a short period – is what attracts 'business acumen' in the first place; it induces risk taking that produces innovation and economic growth."*
> Verizon v Trinko (U.S. Supreme Court)

- Very difficult to work out what "excessive pricing" is
- Even if we identify "excessive pricing"
  - Identifying and imposing appropriate remedies is very difficult
- "False positives" carry high risks for long term welfare
  - Impact on business incentives (e.g. innovation, quality)

Excessive Pricing

- In a perfectly competitive market, price = (average variable) cost
- "*Charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied is … an abuse*." (…) (United Brands)



Difficulties with Excessive Pricing

- What is “economic value” if not price? What is “excessive”?
- What is the relevant cost?
  - Various possible costs (total; variable; marginal; avoidable; average variable; average avoidable; etc.)
  - Whose cost (inefficient dominant company, or hypothetical effective competitor)?
  - Cost assessment extremely complicated in practice – and, in some cases, EU recognised it was practically impossible (e.g. *Deutsche Post;* AG Jacobs Opinion on *Lucazeau* and *Tournier* cases)
- European authorities tend to rely on price comparisons:
  - Across borders (*United Brands; Deutsche Post*)
  - In same sector (*Scandlines; Pompes Funebres*)

Difficulties with Excessive Pricing

- Even price comparisons, however, face serious limitations, due to differences in:
  - Currencies
  - Geographical constraints
  - Transport costs
  - Regulatory context
  - Risk profiles
  - Demand profiles

- Very often, no effective comparators
  - Particularly in dynamic, R&D intensive industries

Difficulties with Remedies

Other than fines, what remedies can be imposed?

- Price Setting
  - Difficult to determine level at which price becomes excessive
  - Must adapt to changing market conditions
  - Requires constant monitoring of price and market conditions
  - Impact on other dimensions of competition

- Transparency Requirements
  - Only works if there are substitutes or viable competitors of which customers are unaware

- Structural remedies
  - Horizontal Breakup
  - Vertical Restructuring

Excessive Pricing in Pharma – UK

NAPP v OFT (2001)

Background

- NAPP launched first sustained release morphine product in the UK.
- Under patent until 1992. At the time of the case, there were two other companies in the market.
- Two relevant markets segments:
  - Community (or general practitioner) segment
  - Hospital segment
- NAPP held market share over 90%

Excessive Pricing in Pharma – UK

NAPP v OFT (2001)

OFT Decision

- Price is excessive if: (a) above competitive market price; and (b) there is no competitive pressure to bring prices down to competitive levels

- Findings of fact regarding NAPP prices for community segment:
  - Earned in excess of 80% profit margins whereas its competitors earned “less than 70%”
  - Its prices were 33%-67% higher than competitors in 2000
  - Prices did not change for 10 years after the expiration of its patent
  - Napp’s community segment charges were:
    - ✓ Over 10 times more than hospital prices, and
    - ✓ Between 4 and 7 times higher than export prices

Excessive Pricing in Pharma – UK

Pfizer and Flynn Pharma (2016)

- Up until 2012, Pfizer sold an anti-epilepsy drug, under patent and subject to National Health Service (NHS) price regulation
  - Sold under voluntary price scheme (i.e. agreement entered into between Government and the branded pharmaceutical industry to control price of drugs supplied to NHS)
  - Companies which do not sign up to this scheme are regulated by a statutory scheme
    - ✓ Statutory scheme not applicable to sellers of generics (i.e. Flynn Pharma)
- When patent expired Pfizer:
  - Kept selling generic version of the drug
  - Granted distribution rights to Flynn Pharma

Excessive Pricing in Pharma – UK

Pfizer and Flynn Pharma (2016)

- Pfizer part of the voluntary scheme
  - Government cannot control price of medicines manufactured by Pfizer's under statutory scheme
- Flynn Pharma de-branded the drug, with the result that:
  - Voluntary price regulation also ceased to apply
  - Pfizer and Flynn could freely set their own prices!

- Regulatory loophole (because generics market presumed to be competitive) allowed:
  - Pfizer to sell drug to Flynn at prices 8 to 17 times higher than previous NHS prices
  - Flynn to then re-sell drug at prices 25 and 27 times higher than previous final prices

Excessive Pricing in Pharma – UK

Pfizer and Flynn Pharma (2016)

CMA Decision

- Pfizer and Flynn held dominant position on market for manufacture and supply of this specific anti-epilepsy medicine

- NAPP test applied – prices found to be excessive
  - Despite Pfizer arguing that: (i) medicine was loss-making before de-branding; (ii) price was cheaper than equivalent drug supplied to NHS

- Largest fine ever by CMA imposed on Pfizer (GBP 84.2 million)
  - Flynn also fined (GBP 5.2 million)

- Case currently under appeal

Excessive Pricing in Pharma – UK

On-going Investigations

- **Actavis** (statement of objections – December 2016)
  - De-branding of 10 mg hydrocortisone tablets and increasing price by 12,000%

- **Concordia International** (investigation on-going)
  - Generics company buys licenses to patented drugs, de-brands them and raises prices up to 600%

Bottom Line:

- Excessive Price as tool to close regulatory loopholes
  - New law to deal closing loophole already adopted

- Unclear what test for “excessive pricing” is or how excessive price is calculated

Excessive Pricing in Pharma – Italy

Aspen (2016)

- Alpen was fined EUR 5 million for increasing the prices of its anti-cancer drugs between 300% and 1,500%

- Aspen acquired the rights to commercialise these drugs from GSK, and then adopted an aggressive negotiating strategy:

  - Requested that drugs be re-classified, so that their prices would no longer be regulated by agreement.
    - ✓ Aspen would then be able to freely set prices

  - When this was refused, Aspen:
    - ✓ Demanded a substantial upward revision of prices
    - ✓ Caused a shortage of the drugs in the Italian market by preventing parallel imports
    - ✓ Threatened to terminate supply of the drugs to Italy if negotiations were to fail.

Excessive Pricing in Pharma – Italy

Aspen (2016)

- The Italian authorities were forced to accept the price increase, due to the irreplaceable and life-saving nature of the Cosmos drugs

- Two-step test, in line with EU test: (a) Is there an excessive discrepancy between manufacturing costs and prices? (b) Are prices applied by Aspen excessive and unfair, taking into account a range of factors?

- The range of factors included: changes in the prices over time, the lack of economic justification for the increases, the absence of any "extra economic" benefits for patients, the nature of the drugs, the characteristics of the Aspen group, and the damage (as a result of the increased cost) to the National Health Service

Excessive Pricing in Pharma – Italy

Aspen (2016)

- Particularly important that
  - Drugs already were several decades old
  - All costs incurred and recouped by originator
  - No new entrants given limited scope of marketing authorisation.

- Hence:
  - No risks to investment and innovation
  - Business model of Aspen based on the exploitation of market failures created by market regulation
  - Aggressive tactics, and situation akin to “essential facilities” and “constructive refusal to supply”

Excessive Pricing in Pharma – EU

Aspen (2017)

- European Commission opened investigation on Aspen's excessive pricing practices in May 2017. Investigation of:

"*Aspen's pricing practices for niche medicines containing the active pharmaceutical ingredients chlorambucil, melphalan, mercaptopurine, tioguanine and busulfan. The medicines in question are used for treating cancer, such as hematologic tumours*"

- Case seems to be very similar to Italian case

Summary

- "Excessive pricing" has a reasonably precise legal meaning but
  - Types of conduct prohibited are very broad.

- There are strong policy arguments against not prohibiting excessive prices
  - Or to prosecute excessive prices only in exceptional circumstances

- The risks of mistakenly sanctioning a pharmaceutical company for excessive pricing is high
  - Risks of chilling innovation and investment
  - Impact on long-term consumer welfare

- In most cases, limited risk of impact on incentives to invest
  - Cases relate to medicines no longer under patent
  - Cases connected to the exploitation of regulatory loopholes or market failures created by regulation

- A regulatory approach is usually preferable

Thanks for your attention!

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More on the OECD's work: http://www.oecd.org/daf/competition/