Recent Pharmaceutical Excessive Pricing Cases. Is there a new trend?

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Yes there is a new trend – EU level

- **EU level → Commission's stance in 2014/2015 (*Gilead*) *vs*. today (*Aspen*)**
  - Questions to Commissioner Vestager by MEPs in Nov 2014 and Jan 2015 concerning the potential abuse of dominance by pharma company Gilead in relation to the excessively high price of its drug Sovaldi for hepatitis C.
  - REPLY: "*…in order to be captured by the application of Article 102 TFEU, an undertaking must be abusing its dominant position by restricting competition* ***through means differing from competition on the merits****…****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****…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 […]"*

A quick look at Gilead's Solvadi example

- When sofosbuvir (Sovaldi) was introduced in late 2013, it was a unique therapy successful in the treatment of hepatitis C. There was tremendous patient demand for the product. Gilead, with the advice of a team of investment bankers and pharmaceutical market specialists, took advantage of the situation to set a price of **$84,000 for a twelve-week course** of treatment and earned over **$14 billion in the first year of sales**.
- Gilead did not develop Sovaldi. The drug was initially developed by a smaller biotechnology company, Pharmasett, which Gilead purchased for $11 billion in 2011. Prior to its acquisition by Gilead, Pharmasett had been planning to introduce sofosbuvir **at less than half the price eventually set by Gilead (approximately $35,000 for a course of treatment)**.
- It is of interest that **the cost of production for the course of treatment is $350 or less**.
- Competing products were approved by the FDA and introduced approx. 1.5 years after the introduction of Sovaldi and Gilead was forced to reduce price significantly.

Yes there is a new trend – EU level (2)

- In May 2017 EC launches its first investigation into excessive pricing in the pharmaceutical sector targeting several Aspen generic oncology products.
  - Commissioner Vestager "*When we get sick, we may depend on specific drugs to save or prolong our lives. Companies should be rewarded for producing these pharmaceuticals to ensure that they keep making them into the future. But when the price of a drug suddenly goes up by several hundred percent, this is something the Commission may look at. More specifically, in this case, we will be assessing whether Aspen is breaking EU competition rules by charging excessive prices for a number of medicines*"
- This new trend definitely aided by previously published EU Parliament Resolution (2/3/2017) on EU options for improving access to medicines
  - "*The EP…calls on the Commission to continue and, where possible, to intensify the monitoring and investigation of potential cases of market abuse, including so-called 'pay for delay',* ***excessive pricing and other forms of market restriction specifically relevant to the pharmaceutical companies operating within the EU, in accordance with Articles 101 and 102 TFEU****"…*

Yes there is a new trend – EU level (3)

- EU level – Aspen investigation
  - The investigation concerns Aspen's pricing practices for niche off-patent cancer medicines containing five active pharmaceutical ingredients sold in different formulations and under multiple brand names (**which it acquired after their patents had expired)**.
  - Whereas the pricing of original medicines that are protected by patents is usually highly regulated by the various price regulation schemes of the Member States, the price for out of patent drugs is often no longer regulated but left to free competition to achieve lower prices (**not the case for Greece**).
  - The Commission is investigating information which indicates that Aspen imposed very **significant and unjustified price increases of up to several hundred percent, enforced by threats to withdraw the medicines in question from the market in some Member States**.
  - The investigation relates to the **whole of the EU but excludes Italy**, where the national competition authority had already adopted an infringement decision against Aspen (see below).
- The Commission (and national authorities) appears to draw a distinction between expensive but innovative medicines, on the one hand, and old off-patent medicines that experience significant price increases, on the other hand. Recent cases focus on older molecules, where price increases have been observed, and for which there are allegedly high barriers to entry.

Yes there is new trend – national level

- National level – **Italy**:
  - In May 2015, the Italian Competition Authority (AGCM) launched a sector inquiry into vaccines for human use, taking into account "*the importance of vaccines in terms of health care costs borne by the National Health Service (over € 300 million per year)" and "the fact that the prices of some of the key vaccines seem to be on the increase*".
  - in September 2016 the Italian competition authority imposed a fine of more than €5million on Aspen for a breach of Article 102 TFEU by setting unfairly high prices for life saving cancer drugs. Having purchased the package of drugs from GlaxoSmithKline, whose patents expired many years ago, Aspen started aggressive negotiations with the Italian Medicines Agency, which involved threats of withdrawal of the products from the Italian market, in order to secure a high increase in prices ranging between 300% and 1,500% of the initial prices. On 14 June 2017 Aspen lost all grounds of its appeal against the AGCM decision!
- National level – **France**:
  - In November 2017 the French competition authority ("Autorité de la concurrence") announced a new inquiry into the pharmaceutical sector. The inquiry will focus on two major subjects: (i) the pharmaceutical distribution chain; and (ii) medicine pricing.

Yes there is a new trend – national level (2)

- National level – **UK**:
  - On 7 December 2016, the Competition and Markets Authority (CMA) imposed a record £84.2 million fine on the pharmaceutical manufacturer Pfizer, and a £5.2 million fine on the distributor Flynn Pharma for charging excessive and unfair prices in the UK for phenytoin sodium capsules, an anti-epilepsy drug. The CMA found that when Pfizer transferred the marketing of the drug to Flynn Pharma in late 2012 the price increased by up to 2,600%. The CMA noted that as a result of this price increase, the NHS expenditure on phenytoin sodium capsules increased from about £2 million a year in 2012 to about £50 million in 2013. The CMA also ordered the companies to reduce their prices within 4 months, but did not specify the exact price level for future sales.
  - On 16 December 2016, the CMA issued a statement of objections alleging that Actavis UK has breached EU and UK competition law by charging excessive and unfair prices in relation to the supply of hydrocortisone in the UK. That investigation is looking at whether Actavis UK has abused a dominant position by charging excessive prices to the NHS for the drug following a 12,000% price rise over the course of several years. The investigation is continuing.

Yes there is a new trend – national level (3)

- National level – **UK** (cont'd)
  - On 21 November 2017 the CMA provisionally found (Statement of Objections) that Concordia abused its dominant position to overcharge the NHS by millions for an essential thyroid drug (liothyronine tablets). It found that in 2016, the NHS spent more than £34 million on the drug, an increase from around £600,000 in 2006. The amount it paid per pack rose from around £4.46 before it was de-branded in 2007 to £258.19 by July 2017, an increase of almost 6,000%, while production costs remained broadly stable.
- ***UK being the Pioneer in excessive pricing pharmaceutical cases***: the *Napp* case (2001)
  - In 2001, the UK Office of Fair Trading (OFT) fined Napp for abusing its dominant position by operating a discriminatory discount policy. Napp supplied sustained release morphine (under the trade name MST) to hospitals at a level below cost, and to patients in the community at prices that were found to be excessive.

The EU case law re excessive pricing

- General remarks:
  - Pricing abuses represent a significant share of abuse of dominance cases. The vast majority of such cases concern '**exclusionary abuses**', i.e. **pricing strategies adopted by dominant firms to foreclose competitors** (loyalty rebates, predatory pricing, price squeezes, selective price cuts, etc.). Only a small minority of cases concern so-called "exploitative abuses", which cover instances where a dominant firm is accused of exploiting its customer. **Under exploitative abuses, it is the high price itself that is deemed problematic, whereas under exclusionary conduct high or higher prices tend to be the result of the exclusionary practice.**
  - The fear **not to act as "price regulator"** (Commission Annual Report 1975) – US approach (*Verizon v. Trinko* case – US Supreme Court).
  - The **difficulty to substantiate** such cases (e.g. production costs) and **to impose sanctions and remedies** (see example of CMA in Pfizer/Flynn case) – lack of expertise to define the "fair price".
  - European Commission's Guidelines stress that it will focus its enforcement efforts on exclusionary rather than exploitative abusive conduct. Nonetheless, "**enforcement actions aimed directly against excessive prices may be appropriate where there is limited potential for market self-correction due to high entry barriers and regulatory failure".**
  - EU report on excessive prices for the OECD (2011)

The EU case law re excessive pricing (2)

- The lead case of CJEU: ***United Brands v. Commission*** decided in 1978.
  - **Two-part test** for determining whether a price is excessive within the meaning of Article 102 TFEU (article 86 at the time):

  "*In this case charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse.*

  This excess could, inter alia, be determined objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its cost of production, which would disclose the amount of the profit margin.

  The questions therefore to be determined are **[1]** ***whether the difference between the costs actually incurred and the price actually charged is excessive, and,*** **[2]** ***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***."
- Possibility that there may be an excessive price that is yet fair!

The EU case law re excessive pricing (3)

- In 1986 the Court of Justice upheld the Commission decision finding ***British Leyland*** was abusively charging significantly higher price (six times greater) for the issuance of certificates for left-hand drive cars than for right-hand drive cars, despite the fact that the cost of inspection for left and right hand drive cars were almost the same.
- In ***Bodson v. Pompes Funèbres***, a preliminary ruling decided in 1988, the CJEU said that differences between prices charged by exclusive funeral home concessionaires and those not operating under concession could be used as the basis for determining whether the prices charged by the concession holder were fair.
- In a preliminary ruling in ***SACEM***, an action brought by discotheque owners against a French copyright society, the CJEU in 1989 said that significant differences in royalty rates charged in France and other EU member states could form the basis for an excessive pricing action.
- The Commission successfully secured a settlement undertaking in ***Deutsche Post*** in 2001 because, inter alia, the German postal service had charged mailings coming from the United Kingdom excessive surcharges without justification.
- In ***Port of Helsingborg***, a proceeding decided by the Commission in 2004, the finding was that excessive prices were not charged by a port operator in light of its specific geographic and other circumstances.
- In ***Rambus***, based on its preliminary conclusions the Commission secured a commitment on the limitation of royalties charged in respect to a technical standard.

The EU case law re excessive pricing (4)

- **Latvian collecting societies - case C-177/16**: the Latvian Supreme Court requested clarification from the CJEU on how to assess excessive pricing allegations under EU competition law - Judgment delivered on 14 September 2017 - Key takeaways:
  - Where appropriate, a comparison between prices charged in different national markets is a valid method (amongst others) to verify whether prices are excessive. There is no minimum number of markets that needs to be included in the comparison.
  - The comparison of prices must be done on a consistent basis which includes taking into account the PPP (purchasing power parity) index when comparing prices in countries in which the economic conditions differ from the national market in question.
  - It is permissible to make a comparison within one or several specific segments if there are indications that alleged excessive pricing is affecting those segments. There is no need to look at the average prices across all segments.
  - There is no minimum threshold above which a price must be regarded as 'appreciably higher' to qualify as indicative of abuse. A difference in prices may qualify as 'appreciable' if it is both significant and persistent over time.
  - Once an authority establishes that prices in one market are 'appreciably higher' than in other markets, the burden falls on the dominant company concerned to provide an objective justification of the difference.
  - AG's Wahl Opinion not fully followed by the CJEU (e.g. *authorities should "strive to examine a case by combining several methods" of determining whether prices are excessive and that it is of utmost importance for the authority to consider other indicators that may corroborate or conversely cast doubt on the results of that method)* - AG Wahl inspired by the methodology in the NAPP case

The excessive & unfair

- Cost-price analysis (**first step of United Brands exercise**):
  - Calculating what is a reasonable profit can be a complex exercise. Generating a high margin over costs alone is not conclusive of abuse in this context. Cost plus a reasonable profit margin may represent a baseline below which a price should not be considered excessive, but a price above that baseline may not necessarily be abusive.
  - Need to take into account not only the cost of capital but also the investment risks involved in the industry concerned. The fact that there are substantial R&D risks involved in developing products before they reach the market is also relevant.
- Intrinsic economic value analysis (**first limp of second step of United Brands exercise**):
  - The law recognises the validity of consumers' perception of the value of a product as an important aspect of this analysis. In *Port of Helsingborg* the European Commission stated in this regard that:

"*[t]he demand-side is relevant mainly because customers are notably willing to pay more for something specific attached to the product/service that they consider valuable. This specific feature does not necessarily imply higher production costs for the provider. However, it is valuable for the customer and also for the provider, and thereby increases the economic value of the product/service.*"

“In that case the excellent location of the port of Helsingborg, which allows ferries to cross the Oresund in an expeditious way, was taken into account. As such, a proper assessment of the economic value of a product should take into account factors such as cost savings resulting from superior efficacy, for example.”

The excessive & unfair (2)

- Benchmark comparators (second limb of the second step of the United Brands exercise)
  - A comparison of the prices charged by the dominant company with prices it charges in neighbouring markets (*Deutsche Post*)
  - A comparison of the prices charged by the dominant company with prices other companies charge in other markets (*Bodson*)
  - A comparison of the prices charged by the dominant company over time
- The example of Napp/MST (UK/2001):
  - Comparison of the prices for MST tablets with those of Napp's competitors
  - Comparison of prices for MST tablets over time
  - Comparison of the prices of MST charged to the community and hospitals
  - Comparison of the prices of MST charged to the community and for export
  - Comparison of Napp's profitability on sales to the community and hospitals
  - Comparison of Napp's margins with those of its competitors

Conclusive remarks

- Before any such test (re excessive & unfair pricing) dominance must be established – authorities may be tempted to define markets narrowly!
- Type I v. Type II errors: Type I errors may bear significant social costs
- Greek cases finding excessive pricing (AEPI saga – new Appeal Court decision 1103/2017, Macedonia airport) or rejecting allegations (complaint against HELPE/Motor Oil) – **no such case in the pharmaceutical sector**
- Waiting the Commission's *Aspen* case outcome
- EU Parliament Resolution (2017) "*price of a medicine should cover the cost of the development and production of that medicine, and should be adequate for the specific economic situation of the country in which it is marketed, as well as being in line with the therapeutic added value it brings to patients, while ensuring patient access, sustainable healthcare and reward for innovation*" + role of Health Technology Assessments (HTA)
- **Greek regulatory frame re pricing (both for in and off-patent medicines) renders rather unlikely such abuses**.