Briefing

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Excessive pricing in pharmaceuticals

When does my price increase become an antitrust problem?



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Competition authorities do not view themselves as price regulators. Most do not want to decide whether a price is right or not in an industry. That is something the market will decide through normal forces of supply and demand. Problems can arise though, where the normal forces of supply and demand do not work, especially because one player has market power or is dominant in a product. In those circumstances the dominant company has a special responsibility not to abuse its market power.

The law of abuse of dominance[1] tells dominant companies that they cannot set 'unfair purchase or selling prices' and they cannot 'apply dissimilar conditions to equivalent transactions'. This presents dominant companies with a Goldilocks problem: pricing too low (below cost) is seen as forcing rivals out of the market where otherwise such rivals would bring supply and demand back into kilter; pricing too high is also a problem as it exploits customers who typically must buy from the dominant company (remember the 'rip off Britain' campaign?). So companies need to get it 'just right'. But what is just right? And if a company charges different prices to different customers, e.g. according to their ability to pay, are they not applying 'dissimilar conditions to equivalent transactions' and so risk a different antitrust breach?

Competition authorities have therefore generally shied away from pricing interventions and in particular excessive pricing cases. This has changed recently as we have seen a concerted effort by authorities in the UK and the rest of Europe with a host of cases in the pharmaceuticals sector.

Some of these are still ongoing so that much of the authorities' theories are still subject to change. The purpose of this note is to provide a snapshot of the authorities' discernible thinking and (likely) direction of travel rather than a wider analysis of the merits of that thinking or direction.

Background: How to spot an excessive price?

The European Court of Justice defined a price as excessive if it bears 'no reasonable relationship to the economic value of the product supplied'.[2] That sounds intuitive yet somewhat subjective. The court then sets out a cumulative two-stage test in which one has to establish:

1. 'whether the difference between the costs actually incurred and the price actually charged is excessive'; and, if yes:

2. 'whether a price has been imposed which is either unfair in itself or when compared to competing products'.[3]

In relation to the first step, the Court of Justice has acknowledged that there may be different methods for establishing that a price is excessive. Comparing the sale price and the cost of production is just one of them. The second step is essentially an assessment of whether the difference established in the first part is the result of

[1]Article 102 TFEU, Chapter II Competition Act 1998 and their equivalents in other EU member states.
[2]C-27/76 *United Brands v Commission*, paragraph 250.
[3]*United Brands*, paragraph 252.

an abusive use of market power or the result of other (legitimate) reasons.

The court has acknowledged that the European Commission is most likely to look at excessive pricing cases in markets where barriers to entry are particularly high[4] as very high barriers stop the market from self-correcting.

Yet, there are significant questions around the definition of 'economic value', 'excessive' and 'unfair' as well as the circularity of the definitions. This has caused much debate and confusion over the years.

As a result, the current slate of investigations across Europe is significant.

The current slate of excessive pricing cases: common features

A number of authorities have started or completed investigations into excessive pricing of pharmaceuticals. They share a number of common features that give pointers as to why they cause interest from the authorities.

Typically, they involve pharmaceutical products that at one stage were patent protected. After patent expiry the products continued to be sold but no new rivals entered the market either because the product was very niche and therefore did not promise large sales volumes or because for some reasons it was difficult to manufacture or replicate. Whilst branded products typically are price or profit regulated, generic products are not. The company, often following a sale of the product, changes the status from branded to generic and then generally increased the price by many multiples beyond the historic price.

The competition authority then is concerned why a company who has presumably been making adequate returns during the patent period and beyond needs to increase the price by such multiples. There may well be good commercial reasons for this. Maybe the product was always undervalued, maybe as part of a product basket where the originator made significant price concessions as a trade off with other products in their portfolio but the price increase in this situation acts as a catalyst for regulatory scrutiny. Let's look at some of these features in more detail.

Acquired products

The focus of the investigations has typically been on products that were acquired from another manufacturer. For example, in assessing Aspen Pharma's prices the Italian Competition Authority highlighted that initial costs (such as R&D, innovation and other medico-scientific expenditure) would have been borne by the original developer (GSK) from whom Aspen Pharma purchased the drugs. As such, the Italian Competition Authority said that Aspen Pharma, who had also not developed any qualitative improvement to the products or to the service level associated with them, could not justify the high prices. In establishing the excessiveness of the prices, the Italian Competition Authority further relied on the very high rates of return that Aspen obtained from its acquisition of the marketing rights of the drugs for the Italian market.

Level of price increase

The acquisition of a product may also be a catalyst for a price change. For example, because the new owner may no longer need to make the trade-offs that companies sometimes need to make under a regime that price regulates or, such as the PPRS, profit regulates a basket of products. As such, another parallel between the cases is that the prices typically represent multiple fold increases. For example, the cases involved the following increases:

- Actavis UK (CMA): over 120 fold increase.
- Aspen Pharma (Italian Competition Authority): up to 15 fold increase.
- Pfizer and Flynn Pharma (CMA): 23 to 26 fold increase.

Patent expiry

In finding that the prices were unfair, the authorities have typically relied (among other things) on the fact that the drugs had long been off-patent. For example, in Phenytoin, the CMA accepted that pharmaceutical companies may properly seek to recover substantial R&D overheads through higher prices by way of the protection afforded by patents. Such protection allows a period of exclusivity in which a patentee can earn high margins as a reward for pharmaceutical innovation. However, the CMA's view was that that a manufacturer of an old, off-patent product should not expect to sustain prices significantly above that level.

Similarly, the Italian Competition Authority highlighted that Aspen Pharma's drugs had been in circulation (in their current formulation) for several decades. As such, initial costs, which would usually form the basis for high prices, would have largely been recovered.

Relationship with price regulation schemes

The price of certain pharmaceutical products can be regulated through national schemes. For example, this is partly done through the Pharmaceutical Price Regulation Scheme (PPRS) in the UK and through classification in the Prontuario Terapeutico Nazionale in Italy. Since the purpose of these schemes is clearly to regulate prices[5], the increases that have been investigated have typically involved the products being withdrawn from the schemes.

[4]Opinion of AG Wahl, Case C-177/16 *Biedrība 'Autortiesību un komunicēšanās konsultāciju aģentūra – Latvijas Autoru apvienība' v Konkurences padome,* paragraph 48.

[5]The PPRS does not regulate individual prices but regulates the total profits an originator can make on its portfolio of products.

For example, in Phenytoin the prices of Epanutin (the branded version) were regulated as part of Pfizer's portfolio of branded drugs through the PPRS. Pfizer and Flynn entered into agreements under which Pfizer transferred its Marketing Authorisations for Epanutin to Flynn for a nominal fee. Following the transfer, Flynn genericised the product and withdrew it from the PPRS. This allowed the price to increase and was subsequently set by reference to Flynn's list price.

Similarly, the Italian Competition Authority found that Aspen Pharma had threatened to withdraw the (unsubstitutable) drugs from the Italian market if the Italian Medicines Agency did not agree to either: i) increase the prices of the drugs; or ii) move the drugs to a different regulated category which would allow the prices to increase.

The legal 'loophole' in the UK whereby the price of generic medicines falls outside the PPRS and statutory schemes has recently been closed. The UK's Health Service Medical Supplies (Costs) Act 2017 gives the government broad power to control the price of unbranded generics. The circumstances and manner in which the government will intervene will be consulted on. Going forward, we may see the government using these new powers to control prices of unbranded generic medicines as opposed to through antitrust investigations.

What is the direction of travel?

The authorities have been at pains to point out that they do not want to become price regulators. Most recently Margrethe Vestager (the current European Commissioner for Competition) urged caution saying '[t]he last thing we should be doing is to set ourselves up as a regulator, deciding on the right price.'[6] However, the Commissioner went on to outline three examples of when intervention may be necessary: Gazprom, standard-essential patents, and pharmaceuticals.

We see similar statements by national competition authorities. In its latest annual plan the CMA has explicitly said that it would focus on 'suspected unfair pricing in the supply of certain pharmaceutical products'.[7] Just this month the president of the French Competition Authority noted the recent cases saying that this would prompt the authority to take a closer look.

The trend of investigations into excessive prices is likely to continue with a focus on pharmaceuticals. High risk products are those that have seen price increases in multiples. While authorities do not want to be price regulators they are willing to interfere where they feel that some 'gaming of the system' has occurred. It seems reasonably clear that the authorities see significant price changes in established products as a beacon to investigate.

While the current focus is clearly on pharmaceutical products, other industries that rely on strong IP protection or have similarly high barriers to entry should consider keeping these developments on their radar.

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[6]Speech by Margrethe Vestager, 'Protecting consumers from exploitation' (Chillin' Competition Conference, Brussels, 21 November 2016).
[7]CMA, 'Annual Plan 2017/18' (CMA59, March 2017).

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What are the cases?

Aspen Pharma (EEA)

Authority	European Commission	The EC will investigate information indicating that Aspen has imposed "very significant and unjustified price increases of up to several hundred percent, so-called 'price gouging'".[8] The EC has information that, for example, to impose such price increases, Aspen has threatened to withdraw the medicines in question in some Member States and has actually done so in certain cases. The investigation covers all of the EEA except Italy where the Italian Competition Authority has already adopted an infringement decision against Aspen Pharma.
Parties	Aspen Pharma	
Issue	Excessive pricing	
Product	APIs: chlorambucil, melphalan, mercaptopurine, tioguanine and busulfan	
Status	The EC opened an investigation in May 2017.	The EC is investigating whether Aspen Pharma has engaged in excessive pricing in relation to certain cancer medication which Aspen acquired after their patent protection had expired.

Aspen Pharma (Italy)

Authority	Autoritá Garante della Concorrenza e del Marcato (the Italian Competition Authority)	After Aspen Pharma acquired the products (whose patent protection had expired) it entered into negotiations with the Italian Medicines Agency with the "sole aim to obtain a high increase in prices, even in the absence of any necessary economic justifications".[9] During the negotiation Aspen Pharma threatened to withdraw the supply of the medicines to the Italian market. This resulted in price rises of up to 15 fold for the products (which were not substitutable).
Parties	Aspen Pharma Trading Ltd Aspen Italia s.r.l. Aspen Pharma Ireland Ltd Aspen Pharmacare Holdings Ltd	
Issue	Excessive pricing	
Product	APIs: chlorambucil, melphalan, mercaptopurine, and tioguanine.	
Status	Aspen Pharma has appealed the Italian Competition Authority's decision to the TAR Lazio.	The Italian Competition Authority imposed a fine of €5.2 million.

[8]European Commission – Press Release (Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines) 15 May 2017
[9]Autorita Garante della Concorrenza e del Marcato – Press Release (Price increases for cancer drugs up to 1500%: the ICA imposes a 5 million Euro fine on the multinational Aspen) 14 October 2016

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Aspen Pharma and Deco Pharma (Spain)

Authority	Comisión Nacional de los Mercados y la Competencia ('CNMC') (the Spanish Competition Authority)	Aspen Pharma and Deco Pharma (Aspen's distributor in Spain) are alleged to have caused a deliberate shortage of certain medicines in the Spanish market in order to avoid the applicable regulated price so as to import them from other European countries (France, Italy, Holland, etc.), thus allowing Aspen to set higher prices.
Parties	Aspen Pharma Ireland Ltd Aspen Pharmacare Holdings Ltd Aspen Pharma Trading Ltd Deco Pharma SL	
Issue	Excessive pricing	
Product	Undisclosed	
Status	The CNMC opened an investigation on 25 January 2017.	The investigation resulted from information received from the Italian Competition Authority.

Actavis UK

Authority	Competition and Markets Authority (UK)	Actavis UK (formerly Auden McKenzie) acquired a product (hydrocortisone tablets), deregistered the branded product, sold it as a generic (i.e. outside of the UK's PPRS regime) and increased the prices by multiples of 9.5 and 12.
Parties	Actavis UK (formerly Auden McKenzie)	
Issue	Excessive pricing	
Product	Hydrocortisone tablets	
Status	Ongoing	Statement of Objections ('SO') was issued in December 2016.

Concordia International

Authority	Competition and Markets Authority (UK)	Suspected unfair pricing by way of charging excessive prices in the supply of certain pharmaceutical products, including to the NHS.
Parties	Concordia International RX (UK) Limited	
Issue	Excessive pricing	
Product	Undisclosed	
Status	Ongoing	Initial investigation decision on whether to proceed by September 2017.

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