Kluwer Competition Law Blog

Aspen: Quick Fix But Missed Opportunity

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1. **What are commitments?**

The recent effort by the Commission to settle the *Aspen* case suggests that commitment decisions are the preferred route to settle complex excessive pricing cases at EU-level. Previous commitment cases where high prices have been at issue include Rambus, Standard & Poor's and Gazprom. The EU rules allow the Commission to make legally binding Aspen's promise to amend its business practice *and lower drug prices*. In return, the Commission closes its investigations without imposing a fine or finding an infringement of the EU competition rules. All going well, commitment decisions are a fast and flexible competition tool.

That said, EU commitment decisions are without prejudice to the powers of national courts to apply Articles 101 and 102 TFEU to separately decide a case. Here, the Commission was faced with a situation where a pharma company (Aspen) significantly raised prices for six vital cancer drugs – and the Italian competition authority (AGCM) had imposed a fine of € 5.2 million in 2016 in this case and ordered Aspen to reduce its prices. Settling by commitment leaves open the possibility for divergent approaches and for a national court to award damages if a victim sought to bring a full-fledged standalone action and could prove anticompetitive harm. The issues are live – as illustrated on 6 October 2020, when the CMA opened an investigation into Essential Pharma, after it allegedly threatened to withdraw a bipolar drug (Priadel and Camcolit) after seeking a price hike of 2,600%. Reportedly, Essential Pharma dropped its plan to withdraw the drug on 7 October. From a policy perspective, *Aspen* looked like a prime opportunity for the Commission to clarify a complex area of law by decision rather than commitment.

2. **What has Aspen promised to do?**

The Aspen commitments fall into three strands:

- Aspen promised to reduce its net prices for the cancer drugs in the EU and EEA (other than Italy) by an average of 73% (although there are variations on price between Member States due to per-unit costs differences). The proposed prices are maximum net prices, i.e. price-ceilings, and Aspen is free to apply lower prices.
- Aspen's price reduction will apply for 10 years from the day of notification of the Commission's decision accepting the commitments. A price review is planned after five years. Interestingly,

the price reduction is back-dated to apply from 1 October 2019 onwards (when Aspen first approached the Commission with a concrete commitments proposal) and Aspen will reimburse payors for the amounts paid in excess of the reduced prices including interest (not only to the payors but also to patients who paid any amount as co-payment).
- Aspen guarantees to continue supplying the cancer drugs for the first five years. After that, Aspen may only discontinue supply if it (i) gives at least one year notice to the competent regulatory authority, and (ii) offers the drugs' marketing authorisation to any interested third party purchaser.

3. **So, competition rules prohibit high prices?**

Prohibiting unfair prices is written into Article 102(a) TFEU. One way prices can be unfair is if they are excessively high. To the average European consumer or cancer patient, this makes total sense. Yet, regulators traditionally steered clear of pure excessive pricing cases – with only a handful of decided cases – and US antitrust law avoids it altogether. In *United Brands* (1978), the Court of Justice held that a dominant firm's price is excessive if has no reasonable relation to the economic value of the product supplied. In truth, this is not an operational test: economic theory suggests that price is simply the intersection of a supply and demand curve (i.e., no more than a customer is willing to pay) and in reality, firms often earn substantial positive margins even under competitive conditions. While rarely deployed, European authorities appear minded to still carry the "big stick" for exceptional cases.

4. **But, when are prices excessive?**

There is no pre-defined percentage definition of excess. At EU level, for example, the Commission found that 25% above cost was excessive in *Deutsche Post* (2001), while in the UK the CAT held 46.8% was excessive in *Albion Water II* (2008). To measure excessiveness, authorities have relied on a mix of tests. One way, among others, is to illustrate the price is excessive when compared to its costs, and if so, that the price is unfair in itself or when compared to other competing products. In *Napp* (2002), the OFT used a combination of six indicia to establish the price was 'well above what would have been expected in competitive conditions' by looking at competitor's prices, international prices, pricing in related markets, prices of unbranded products and pricing during different time periods. In *Port of Helsingborg* (2004), the Commission *rejected* an excessive port fee complaint after it analysed a detailed cost allocation and benchmark comparisons with other ports, including return on equity, as it ultimately concluded that it could not determine what was a reasonable profit margin for the port operator given non-cost factors. In *Latvian Copyright* (2017), the Court of Justice simply re-affirmed the *United Brands* approach and held that an appropriate and well-reasoned *comparison* of three countries (Latvia, Lithuania and Estonia) for copyright collection fees was a sufficiently representative benchmark. This is at least sensible in that there is no need for a minimum number of markets to be compared so long as the selected countries within the benchmark are objective, appropriate and verifiable: i.e., involve similar consumption habits and other economic and sociocultural factors, such as gross domestic product per capita and cultural and historical heritage. Recently in *Pfizer/Flynn* (2020), the UK Court of Appeal ruled that a combinatorial approach is not a mandatory obligation but that a comparative approach using multiple benchmarks may simply be good practice.

5. **What is unusual about the pharma pricing cases?**

The recent wave of investigations concerns excessive pricing in the (third) off-patent stage of a drug's lifecycle when there is little or no generic entry. The Commission justifies excessive pricing scrutiny at the third stage on the basis that "the inventor has already benefitted from legal exclusivity as a reward for innovation" (which assumes that costs incurred by a producer in the R&D phase are not spread across the product's third off-patent stage). The Commission estimates that when a drug moves to the third off-patent stage of the life-cycle, prices may fall by up to 90% when generics enter the market. Yet, generic entry does not always occur. Clearly, absent R&D costs, drug production costs are typically modest and in line with other commodity manufacturing industries. The recent competition cases all involved chunky price hikes:

- In Denmark, *CD Pharma* (Syntocinon) involved a price rise of 2000%.
- In Italy, *Aspen* (Leukeran, Alkeran, Purinethol and Tioguanine) prices for the Cosmos drugs increased by 250% – 1500%
- In the UK, *Pfizer/Flynn* (Phenytoin) involved a price increase of about 780% to 1600% (Flynn had in fact proposed to de-brand the drug to enable a price increase).

Indeed, in the EU *Aspen* case, the Commission initially suggested that the price was 300% above Aspen's relevant costs. The proposed 73% price reduction indicates that the Commission is willing to allow Aspen an 8% profit margin on its cost base (which is broadly similar to the 6% reasonable rate of return used by the CMA in *Pfizer/Flynn*).

A further point of contention is that applying a comparison methodology to these type of cases is not straightforward. Member States (or public or private healthcare insurers) are typically the payors of pharma products, doctors are prescribers, while patients are the end-consumers – thus, involving a uniquely fragmented dynamic where supply and demand are less relevant considerations for a highly inelastic product set. While there is no pan-European uniform reimbursement system, there are various and complex reimbursement schemes in place at each national level to decide how to spend national drug budgets. Most Member States operate and benefit from, a bespoke regime to evaluate the need for, and efficacy, of expensive drugs.

6. **Are commitments a useful tool to settle excessive pricing cases?**

Most agree that competition law should only intervene on excessive pricing in extremely limited circumstances: a fact borne out by the low intervention level across the EU over the past 60 years – and especially in the pharmaceutical sector where regulators (other than NCAs) have certain powers (and experience) to intervene on pricing and reimbursement issues. Others also argue that an authority should accept the most efficient remedy. This may explain the Commission's desire to avoid a formal decision in *Aspen*. So, after a three-year investigation, European consumers may get a "quick fix" to the pricing problem.

Yet, these investigations should arguably deliver more bang for the buck. If the Commission proceeds to settle the case, it will lose a valuable opportunity to clarify and provide wider guidance on the precise parameters of permissible pricing behaviour at EU-level in the context of an off-patent medicine. To their credit, each of the Danish, Italian and UK competition authorities

established an excessive price in a detailed final decision. In the long run, pharmaceutical companies and stakeholders may benefit from clearer EU level precedent.

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