Learning the Lessons on Excessive Pricing from Aspen

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Back in April 2017, The Times ran a story detailing how a drug giant had a "secret plan" to destroy a cancer medicine unless large price rises were agreed to by national purchasing authorities. A month later, the European Commission opened an investigation into Aspen. Almost four years later in February 2021, it accepted commitments from Aspen, closing an awkward excessive pricing case. The commitments (1) fix the price that Aspen is allowed to charge for six cancer drugs in most EEA Member States (including the UK as the case was initiated prior to 31 December 2020), and (2) include a commitment to continue supplying the medicines for a guaranteed five year-period. The Commitments apply for a second five-year period *unless* Aspen decides to discontinue commercialising a product in a Member State, which can only occur after an 18 month notice period to national authorities and an offer to sell the marketing authorisations to an interested third party.

The 88-page Commitments are largely *unchanged* from those originally proposed by Aspen which we discussed in a previous post in October 2020. Recently, the detailed 55-page public version of the Decision was published – and we discuss five lessons below.

1. **Start with a benchmark…**

The Decision applies the classic two-step *United Brands* test to analyse (1) whether the difference between Aspen's costs and price was *excessive*, and (2) whether Aspen's price was *unfair* "in itself" or when compared to competing drugs. To determine excessiveness, the Commission relied on a profitability analysis (although a variety of other measures can be used). In the Decision, Aspen's profits are compared to a *benchmark* comprised of the profit margins of 23 comparator companies selected because they earned the majority of their revenues from *off-branded* or *generic* medicines listed in the antineoplastics ATC-2 category L1 targeting cancer patients (i.e., with similar active substances). This benchmark covered 66 gross margins and 108 EBITDA observations. These comparable firms had a 54% median gross profit margin and a 23% median EBITDA margin. Once it established the benchmark, the Commission then relied on the 23% median EBITDA margin as a proxy for a "reasonable profit margin". This is referred to as the cost-plus level for the six Aspen medicines. Relying on this proxy, the Commission found that Aspen "earned persistently levels of excess profits very significantly over the cost-plus level", on average 280-300% in excess of the cost-plus level. Or, as the Commission noted, "on top of a reasonable return, Aspen earned additional profits roughly three times the level of cost-plus". Indeed, the Decision reports that, at the portfolio level, Aspen earned an EBITDA margin of between 80-90% and that "not a single Comparator company in the entire sample of observations achieved such a high margin".

One takeaway for firms facing excessive pricing risk is to undertake an internal analysis across a meaningful cohort of comparator firms to identify a reasonable profit margin in its sector. For example, in the pharma sector, the Commission was able to rely on *publicly* available data in the IQVIA database to build this benchmark – even though some of the benchmark products would not compete in the same *product market* as Aspen.

2. **An unfair strategy can play a part**

To determine unfairness in *Aspen*, the Commission focused on the fact that Aspen's price was unfair "in itself". Notably, other potential generic and innovative price comparator drugs were deemed "unsuitable" for comparison. In particular, the Commission found that Aspen had *not improved* the products through R&D, had designed a *strategy* to exploit national health systems, and the price increases were *disproportionate* and *without a legitimate reason*. The Commission drew on Aspen's internal documents to demonstrate that Aspen introduced price increases by threatening to de-list or withdraw its medicines from sale, threatening critically ill patients. Price increases were adopted in a manner to "defeat the purpose and effectiveness of the external reference pricing systems and to avoid parallel trade". For example, Aspen targeted significant price increases in Germany because German law allowed Aspen to "unilaterally set new, increased list prices" which were then used to seek increases in other Member States. In terms of proportionality, the unit cost of the product had faced only modest increases in the 10-40% range, while price had increased in the 180-430% range.

A key lesson here is that the Commission may usefully refer to "intent" and a firm's "strategy" as a relevant factor to support finding an *exploitative* abuse of dominance. Cases based on exploitation, as opposed to *exclusionary* practices, somewhat fell out of fashion at EU level since the Commission published its Guidance on Enforcement Priorities in 2009. Aspen may reflect a new trend to pursue exploitative abuses – and authorities may seek to continue to rely on concepts such as "intent" and "purpose" for framing abusive conduct, rather than market effects. Even perhaps, we are seeing *by object* cases creep into Article 102 TFEU enforcement. So, internal documents that reflect an exploitative price rise strategy will tend to reinforce a regulator's concern – and firms should pay attention to the strategy and claims they use during pricing negotiations or reimbursement discussions.

3. **Allocating costs intra-group requires clear methodology**

Another aspect of the case closely watched by industry is how the Commission calculated Aspen's internal costs – which are then used to determine a reasonable rate of return. Broadly, this is something of an accounting and economic exercise as opposed to a legal analysis. The challenge lies in disentangling (1) *appropriate* costs from *gratuitous* costs, (2) costs incurred by a firm producing *multiple* products where only one product line is alleged to be excessive, and (3) costs based on *intangible* assets.

For direct costs, the Commission permitted a modified version of the cost of goods sold (i.e. COGS) designed to ensure that Aspen is not able to achieve the same goals of an excessive pricing policy through excessive costs charged internally. Where a product is manufactured in-house, Aspen must demonstrate that its costs are calculated according to IFRS including fixed overheads but excluding depreciation, impairment or amortisation. For indirect costs, the Commitments set out a working methodology in Appendix 2. Allowable indirect costs include marketing authorisation costs, as well as other indirect costs consisting of the operation or management costs associated with Aspen entities that assist with the sale of the products and are related to that activity. These indirect costs are then "spread" or allocated to Aspen's products in the relevant countries.

It may be observed that costs associated with R&D or portfolio acquisition are not included as a recoverable internal cost in this case. As Aspen's medicines had been off-patent for 50 years, the Decision found that any R&D investments on the medicines had "long been recouped". For acquisition costs, Aspen had acquired the off-patent Cosmos portfolio from GSK in 2009 for $300 million and sought to argue that this purchase price should be taken into account as a cost to recover its investment. However, the Commission side-stepped this by noting (i) that future anticipated profits could not be used to justify excessive prices, and (ii) that Aspen had not accounted for any specific tangible or intangible assets when acquiring the portfolio from GSK, which made computing the return on cost of capital employed (ROCE) a "complex exercise, which was in the present case not required".

4. **Careful pricing for rare, off-patent or orphan drugs**

Publicly, the Commission has stressed that it is eager to preserve innovation incentives for *new* drug products (although it cannot rule out scrutiny even for new drugs). After the expiry of patent protection, it is generally assumed that prices fall steeply as generics enter the market (up to 90%). However, for rare, off-patent or orphan drugs with continued high prices, it may be prudent for firms to engage in a more in-depth analysis of potential justifications where profit margins are "significantly and persistently" in excess of a reasonable proxy.

Indeed, Aspen sought to argue that the six drugs presented the characteristics of an "orphan" under the Orphan Drug Regulation. The Decision rejects Aspen's justification on the basis its drugs had been on the market prior to the 1999 regulation and did not meet the criteria for orphan designation. It is noteworthy that in an ongoing different case *Leadiant*, the orphan drug chenodeoxycholic acid which was designated by the EMA in 2017 is subject to pricing investigation by national competition authorities in the Netherlands, Spain, Belgium and Italy.

5. **Remedy Design: Don't get angry, get even!**

Commitment decisions are generally *not* appropriate in cases where the nature of the infringement calls for the imposition of a fine. Accordingly, no fine was imposed on Aspen. Yet, at the same time, the Commitments impose a form of restorative justice by providing for "transitory rebates". Effectively, these reimburse national payors for the higher prices paid for Aspen's products from 1 October 2019 (when Aspen proposed the commitments). Patients who made co-payments even get a partial refund thanks to the transitional rebate structure. Interestingly, a similar approach was taken in the UK in another case involving Aspen. In July 2020, the UK Competition and Markets Authority (CMA) not only agreed on a fine with Aspen of £2.1 million for seeking to keep rivals out of the UK market for fludrocortisone but also extracted an £8 million (re)payment to the UK National Health Service (NHS), which may not have been obtainable in a formal decision.

Nevertheless, purchasers after 2012, when the price increases began, do not legally recoup any potential "excessive payment" under the Commitments and have no formal basis for a follow-on action. Officials have publicly noted that customers are free to pursue claims based on discovered internal documents (and may rely on the Commission's benchmark methodology as a starting point to calculate loss).

The upshot is that commitments remain an attractive way to settle complex cases for both regulator and target. The problem with determining which price is "fair" and "unfair" were at the forefront of the Commission's reluctance to deal with exploitative abuses and engage in detailed price regulation – a highly complex exercise even for sectoral regulators. The Decision allows the Commission to avoid hard questions on where the boundary for excessive and non-excessive sits for each product in each Member State – and yet extract some form of penalty or compensation for exploited customers. Equally, the Decision offers stakeholders some further context for analysing when pricing practices stray into unlawful territory. That said, judging by the fact that the case took four years to resolve, and despite the publication of an apparent smoking gun in a national newspaper, it is clear that concerns about whether EU competition law can replace specific price regulations remain.