European Commission Launches ‘Excessive Pricing’ Investigation in Pharma Sector

The European Commission announced yesterday that it has launched a formal investigation into Aspen Pharma’s pricing of five cancer drugs. The Commission will investigate whether Aspen Pharma abused a dominant position, in breach of Article 102 of the Treaty on the Functioning of the European Union (TFEU), by imposing significant price increases for the drugs in question. The Commission will also investigate allegations that Aspen Pharma threatened to (or did) withdraw the drugs in some EU Member States.

Cases alleging unfair – or excessive – pricing are notoriously complex, and the Commission’s investigation of Aspen Pharma may cause it to have to play the role of an unofficial price regulator (in addition to the Member State authorities that have primary responsibility for drug procurement in the EU).

**Excessive Pricing: Old Theory, New Application**

In recent years, the Commission and the EU’s national competition authorities have investigated different types of allegedly anticompetitive conduct by pharmaceutical companies. This has included a number of high profile investigations into patent settlements between originator and generic manufacturers as well as allegations of abuses of regulatory procedures. But the Commission had not — until yesterday — initiated a single investigation into alleged excessive pricing in the pharmaceutical sector. Although the EU Treaties have long been clear that unfair (or excessive) pricing can constitute an abuse of a dominant position, the Commission has not brought any such cases for decades. The Commission’s reluctance to open excessive pricing cases (in any sector) had long been attributed to the perceived difficulties in substantiating such cases (they require – among other things – definition of a relevant market, proof of dominance on that market, and proof that the prices at issue are genuinely excessive, without there being much guidance available on what that means in practice).

The current Competition Commissioner Margrethe Vestager appears to have overcome this reluctance (aided, no doubt, by a recent report on drug pricing from the European Parliament) and had mentioned on several occasions in the past six months that the Commission was considering pursuing excessive pricing allegations. Indeed, in yesterday’s press release, the Commissioner was characteristically forthright, noting that “when the price of a drug suddenly goes up by several hundred percent, this is something the Commission may look at.” The implication appears to be that the investigation of Aspen Pharma is unlikely to be the only allegation of excessive pricing in the pharmaceutical sector that the Commission is considering. The Commission seems to have found what it considers a fruitful new application for the old theory of unfair (or excessive) pricing.
National Scrutiny

The Commission’s investigation follows an investigation by the Italian Competition Authority (ICA), which fined Aspen Pharma over €5 million in September 2016 for charging allegedly excessive prices for four of its cancer drugs (Alkeran (melphalan), Leukeran (chlorambucil), Purinethol (mercaptopurine) and Tioguanine (thioguanine)). According to the ICA, Aspen Pharma had adopted an aggressive negotiating strategy with Italian regulator Agenzia Italiana del Farmaco and achieved price increases between 300 percent and 1,500 percent for its drugs. The ICA was of the view that Aspen Pharma was the only supplier of these medicines in Italy and that Aspen Pharma had threatened to stop supplying patients in Italy if its price increases were not accepted.

The Commission’s current investigation appears to build on the ICA’s findings and will cover the entire European Economic Area except for Italy.

It is also notable that the UK’s Competition and Markets Authority (CMA) has been looking into multiple allegations of excessive pricing in the pharmaceutical sector. In December 2016, it imposed fines on an innovative manufacturer and a distributor, finding that the companies involved had abused a dominant position by charging excessive and unfair prices. The CMA focused in particular on allegations that prices had increased significantly, and that UK prices for the drug at issue had been many times higher than prices elsewhere in Europe. The decision is on appeal before the UK’s Competition Appeal Tribunal, but the CMA also has a number of other ongoing investigations into alleged excessive pricing in the pharmaceutical sector.

Potential Implications

Commissioner Vestager had already made it clear that she saw excessive pricing cases as being an important enforcement tool in the pharmaceutical sector. In combination with the cases in Italy and the UK, the Commission’s case against Aspen Pharma demonstrates that competition enforcers at the EU and national levels will be on the look-out for excessive pricing cases. Pharmaceutical manufactures will therefore need to have even greater regard for competition law considerations when considering significant price increases.

It is, however, far from straightforward for enforcers to establish excessive pricing abuses.

Findings on relevant market definition are open to challenges that are derived not only from general economic principles but also from the highly specific context of the sector at issue. In the oncology sector, for example, ‘off-label’ usage of drugs approved for other uses can be of great significance. Significant enough, perhaps, to broaden a market definition to the extent that a company under investigation is no longer considered dominant.

In addition, proving that a price is excessive is also fraught with difficulty. In Aspen Pharma, the ICA started by assessing whether there was an excessive discrepancy between the manufacturing costs of, and the prices charged by, Aspen Pharma. The pharmaceutical industry would likely argue that it needs to be able to recover not only the costs of production of the product at issue, but also the costs of researching and developing the product, as well as the costs of researching other candidate products that never make it to market. These are critical issues that one would expect to see tested as the Commission’s case against Aspen Pharma moves forward. The ICA also looked at a range of other factors, including the changes in Aspen Pharma’s prices over time, the alleged lack of economic justification for the increases at issue, and
geographic price comparisons (e.g., comparisons with prices charged for the same product in other EU Member States).

In addition, there is a risk that the Commission and other national competition authorities, by taking on excessive pricing cases, may go beyond their traditional role and become (albeit reluctant) price setters. Competition authorities will also need to ensure sufficient safeguards and legal certainty as to when and on what basis a price becomes “excessive” as this is an area where companies are subject to quasi-criminal fines.

**Clarity From the EU Courts?**

Perhaps reflective of the fact that the Commission has taken so few excessive pricing cases, there is a relative lack of guidance from the EU Courts on when prices might be excessive. However, that might be about to change. In an opinion on April 6, 2017 in the AKKA/LAA case, influential Advocate General Nils Wahl has attempted to provide more practical guidance. However, even Advocate General Wahl considered that there may be multiple benchmarks to which enforcers could have regard when determining whether prices might be excessive. Judgment in the AKKA/LAA case is expected this summer; the pharmaceutical industry will doubtless be waiting with interest.

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work or Patrick Harrison

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