THE CAT WARNS ANTITRUST WATCHDOGS TO BE CAREFUL WHEN LOOKING AT EXCESSIVE PRICING

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I. INTRODUCTION

In the last couple of years, there has been a trend for antitrust watchdogs around the world to investigate excessive pricing, especially in the pharmaceutical sector. Last year, the European Commission opened its first investigation into excessive pricing in the pharmaceutical sector into the prices of Aspen's cancer drugs. This followed on from an investigation by the Italian competition authority fining Aspen EUR 5.2 million in 2016 for the pricing of the same drugs. Similar cases were also pursued in South Africa. In the UK, the Competition and Markets Authority ("CMA") opened a number of investigations of which at least two are ongoing and adopted a decision imposing large fines on Pfizer and Flynn Pharma ("Flynn").

This outbreak of excessive pricing investigations reverses the orthodoxy of previous decades. There was for many years a broad consensus that decisions of companies to increase their prices would usually have long-term pro-competitive effects by creating incentives for new players to enter markets. Price increases could only amount to antitrust violations in very specific circumstances, such as in the presence of very high and long-lasting barriers to entry. Moreover, competition authorities focused on exclusionary abuses rather than on exploitative ones, which also helped ensure that excessive pricing cases were off most authorities' agendas.

The judgment of June 7, 2018 in which the UK Competition Appeal Tribunal ("CAT") found that the CMA misapplied the relevant legal test when finding that Pfizer and Flynn unfairly priced their epilepsy drug, explains why antitrust authorities need to be careful when looking at excessive pricing. Both the outcome of the case (the CAT annulled the CMA's finding of abuse) and the wording of the judgment send a clear signal that competition authorities can elect to bring excessive pricing cases but, at the same time, their decisions must be "soundly based on proper evidence and analysis" and respect the presumption of innocence.

II. BACKGROUND

Phenytoin sodium is a long existing treatment for epilepsy and is still used to treat approximately 10 percent of patients in the UK. It was for many years sold at very low prices when, in 2012, Pfizer transferred its marketing authorization for the capsule form of phenytoin sodium to Flynn. Pfizer continued to manufacture the capsules and supply them to Flynn, which then sold them to the National Health Services ("NHS"). Flynn de-branded (genericized) the drug so that it was no longer subject to the UK's voluntary pricing scheme (only branded drugs are covered by this scheme). Following this de-branding, Pfizer's price to Flynn increased considerably and Flynn also increased the price at which it sold the drugs to the NHS. As a result, Flynn's price to the NHS rose to between 2,300 percent and 2,600 percent of Pfizer's previous price to the NHS. However, the new Flynn price was benchmarked at 25 percent below the price of phenytoin sodium in tablet form (which contain the exact same active ingredient), a price that the NHS had been paying for many years.

Following the opening of an investigation in 2013, the CMA found in December 2016 both Pfizer and Flynn guilty of abusing their dominant positions in the narrowly defined manufacturing and distribution markets for phenytoin sodium capsules by excessively and unfairly increasing their prices. For this abuse, the CMA imposed fines of £84.2 million and £5.2 million on Pfizer and Flynn, respectively, and ordered them to reduce their prices. In contrast to some previous abuse of dominance cases in the pharmaceutical sector, the CMA's decision is not based on allegations of an exploitation of a regulatory loophole or on a combination of exclusionary and exploitative practices; rather, the CMA proceeded with a pure excessive pricing decision.

To determine whether Pfizer and Flynn's prices were excessive, the CMA compared the companies' costs with a theoretical benchmark of "cost plus 6%." Using this approach, the CMA concluded that the new price was first excessive and then unfair "in itself" because it exceeded this benchmark. While this "cost plus" test was the core of the CMA's reasoning under both excessiveness and unfairness, the decision also referred to (as regards unfairness) four subsidiary elements, namely: the fact that the drug was old, that the price was only increased when Pfizer sold the marketing authorization to Flynn, the impact this practice had on the NHS and customers' reactions. The CMA also noted that prices in other EU Member States were lower, without analyzing why in any detail.

Both Pfizer and Flynn appealed the CMA's decision before the CAT.

III. THE PREVIOUS EUROPEAN CASE LAW

Before looking at the CAT's reasoning, it is helpful to recall the seminal European judgment applying the prohibition of abuse of dominance to unfair pricing practices. In *United Brands*,[2] the European Court of Justice ("ECJ") held that a price can be unlawfully excessive where "it ha[d] no reasonable relation to the economic value of the product supplied" and assessed the prices using the following test:

(1) whether the difference between the costs and the price was excessive ("**excessiveness limb**"); and

(2) whether the price was either unfair (a) in itself or (b) when compared to the price of competing products ("**unfairness limb**").

While the judgment sets out the above two-stage test, it is often overlooked that the ECJ noted that "other ways may be devised […] of selecting the rules for determining whether the price of a product is unfair."

Very recently (and in fact after the CMA's Decision), the ECJ confirmed in *AKKA/LAA*[3] that comparing prices in different Member States was a valid alternative method, as long as varying socio-economic conditions (demand-side factors) were taken into account.

In his opinion in the same case, Advocate General Wahl underscored that there are a variety of different methods that could be deployed to determine whether a price is excessive and that one should not focus blindly on one of them only. Given that there is not one test that can be used in all situations, and given each test has its own weaknesses, he concluded that the proper approach is to "combine several methods" where possible, to avoid errors and to reach a reliable conclusion. AG Wahl considered that an abuse can be established where there is a "sufficiently complete and reliable set of elements which point in one and the same direction," such that "almost no doubt remains" that there was an abuse, given the presumption of innocence which applies in abuse of dominance cases.

IV. THE CAT ACCEPTED THE CMA'S NARROW MARKET DEFINITION AND FINDING OF DOMINANCE

The CAT upheld CMA's findings on market definition and dominance. Specifically, the CAT accepted that the relevant markets were defined as (i) the manufacture of Pfizer-manufactured phenytoin sodium capsules distributed in the UK (for Pfizer); and (ii) the distribution of Pfizer-manufactured phenytoin sodium capsules in the UK (for Flynn). The CAT agreed with the CMA that phenytoin sodium capsules from other manufacturers did not exert a sufficient competitive constraint on Pfizer and Flynn (notably on prices), to be included in the relevant market. The CAT also agreed that there was no evidence of competitive interaction between tablets and capsules.

The CMA based this conclusion mainly on the facts that (i) there was limited, if any, substitution between capsules and tablets during treatment; and that (ii) price increases of one category did not result in significant shifts in the volumes of the other.

While these conclusions are based on the particular facts (this is an epilepsy treatment with a narrow therapeutic index), it is nevertheless worth noting that the market is the narrowest conceivable one in a pharmaceutical context: capsules of a specific active ingredient made by one company.

2 Judgment of the Court of February 14, 1978, *United Brands Company and United Brands Continentaal BV v. Commission of the European Communities*, Case 27/76, EU:C:1978:22.

3 Judgment of the Court (Second Chamber) of September 14, 2017, *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v. Konkurences padome*, Case C-177/16, EU:C:2017:689.

V. THE CMA APPLIED THE WRONG METHODOLOGY WHEN FINDING EXCESSIVENESS AND UNFAIRNESS

The CAT set aside the CMA's conclusions on abuse of dominance, taking issue with the methodology used to find that Pfizer and Flynn's prices were excessive and unfair. According to the CAT, the CMA decision was vitiated by fundamental legal errors in this respect:

> The CMA's conclusions on abuse of dominance were in error. The CMA did not correctly apply the legal test for finding that prices were unfair; it did not appropriately consider what was the right economic value for the product at issue; and it did not take sufficient account of the situation of other, comparable, products, in particular of the phenytoin sodium tablet. This means that the CMA's findings on abuse of dominance in this case cannot be upheld.[4]

Specifically, the CAT took issue with the following aspects of the CMA's reasoning.

On **excessiveness**, the CAT took issue with the fact that the CMA relied almost exclusively on a theoretical "reasonable rate of return" to determine whether the prices were excessive, instead of looking at market dynamics influencing the capsules' price. According to the tribunal "the CMA's approach owe[d] more to a theoretical concept of idealised or near perfect competition, than to the real world (where normal, effective competition is the most that should be expected)." Importantly, it held that the CMA has "on the whole avoided making comparisons with other products or companies and made little significant attempt […] to place Pfizer's and Flynn's prices in their commercial context." In the Tribunal's opinion, *United Brands* and more recently Advocate General Wahl's opinion in *AKKA/LAA* did not support the idea that the "cost plus" method chosen by the CMA is sufficient for establishing excessive pricing if other methods were available.

On **unfairness**, the CAT held that the CMA wrongly relied on only one part of the *United Brands* test ("price unfair in itself") and did not properly assess the prices of meaningful comparators. The most obvious comparators in this case were phenytoin sodium tablets (Pfizer and Flynn sold capsules), which were sold to the NHS at considerably higher prices (>25 percent) than the price of the capsules – a price set by the Department of Health. This comparison was inconsistent with the CMA's claims of unfairness.

The CAT further criticized the CMA's decision for not sufficiently taking into account **economic value**, which is the point of departure used by the ECJ when defining the legal test in *United Brands*. As a result, the CMA should have taken into account non-cost related factors, such as patient benefits, and the nature of the product together with all the surrounding circumstances when evaluating the economic value of the drugs. It noted that "simple percentages expressed as absolute mark-ups are not sufficient."

The CAT noted that it is not possible for an authority to ignore a *prima facie* valid argument that a price is fair under one alternative test and proceed to finding an abuse solely on the basis of another alternative test. Admittedly, the authority does not have to show that both tests are fulfilled to find an infringement, but it must show that the arguments for fairness of the prices under one test do not undermine the finding of unfairness under another test.

The CAT then held that the CMA should have devoted more attention to the possibility that phenytoin sodium tablets could be a suitable comparator. The prices of other epilepsy drugs were also potential comparators, although the CAT said that these were of less relevance.

In the light of existing case law, the CAT set out the approach which, in its opinion, should be applied in these cases. This involved the following steps:

First, the authority should consider a **range of possible analyses**, reflecting market conditions and the extent and quality of the data that can be obtained, to establish a benchmark price, or range, that reflects the price that would pertain under conditions of normal and sufficiently effective competition.

Second, it should compare that price (or range) with the price that has been charged in practice and determine whether that is **excessive**. Only if the differential is sufficiently significant and persistent can the price be excessive. The authority should also consider the size and stability

4 Judgment of the CAT of June 7, 2018, in Joined Cases 1275-1276/1/12/17, *Pfizer Inc and Pfizer Limited v. Competition and Markets Authority and Flynn Pharma v. Competition and Markets Authority*, [2018] CAT 11 at paragraph 4.

of that differential, the reasons for it, taking account of the fact that the conditions for excessive pricing will only usually occur where the market is protected from competition, or where there is regulatory failure and the relevant regulator has not intervened, as well as previous decisions and wider market conditions, including the evolution of pricing over time.

Third, if the differential is excessive, then the authority should consider whether the price is **unfair**. An authority can apply either alternative to judge unfairness (unfair in itself or unfair compared to competing products) but must give due consideration to any *prima facie* convincing argument that the pricing is actually fair under either alternative.

Fourth, if there is a finding of unfairness, the authority should assess the economic value of the product, and whether the price charged in practice bears no reasonable relation to it. The authority should also consider whether the dominant undertaking is reaping benefits that it would not reap under conditions of normal and sufficiently effective competition. These two criteria are a necessary part of finding an abuse.

And finally, **objective justification** should be considered.

The CAT also stressed the importance for the authority to keep in mind the **presumption of innocence** of the undertaking under investigation when it is going through these steps.

The CAT had the power to replace the CMA's conclusion on abuse with its own judgment, but it chose not to, because the failure of the CMA to investigate the relevant facts made it impossible for the CAT to take a position. Hence the CAT provisionally decided to send the case back to the CMA for further consideration in line with the judgment. Before making a final order to this effect, the CAT invited the parties to present their views on whether to remit the matter to the CMA and the scope of any such remittal.

VI. CONCLUSION

The CAT's judgment notes that "cases of pure unfair pricing are rare in competition law" and that "ex post price regulation through the medium of competition law presents many problems." Competition authorities should therefore be "wary of casting themselves in the role of price regulators" that carry the primary responsibility for price control. This follows similar warnings contained in the Opinion of Advocate General Wahl in the *AKKA/LAA* case. This judgment (together with Advocate General Wahl's Opinion) should therefore send a warning signal to the various competition authorities which have recently focused on excessive pricing cases.

The judgment offers a warning to the authority that has invested the most effort in the last few years in pursuing excessive pricing cases, namely the CMA, which is currently undertaking at least two other excessive pricing investigations. The CMA confirmed that these investigations "may now be severely delayed" and that it was lodging an appeal because of the judgment's implications for future excessive drug pricing cases.[5]

The CAT's ruling does not prevent excessive pricing cases. Indeed, the CAT accepted that there was "no reason in principle why competition law cannot be applied [to unfair pricing practices], provided this is done on the correct legal basis and the analysis of evidence is sound." But the judgment does send a signal to the CMA (and other authorities) that they must do a careful and thorough job, bearing in mind the presumption of innocence. The guidance from the CAT is clear:

> In a matter as important for government, for the public as patients and as taxpayers, as well as for the pharmaceutical industry itself, the law should be clear and any decisions made should be soundly based on proper evidence and analysis. It is important that there is a good legal foundation for any future action in this area.

5 See the CMA's statement at: www.gov.uk/government/news/cma-considers-appeal-in-phenytoin-case and the confirmation that it has lodged an appeal at https://www.gov.uk/cma-cases/investigation-into-the-supply-of-pharmaceutical-products.