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Competition Appeal Tribunal quashes the CMA's excessive pricing decision against Pfizer and Flynn Pharma

James Killick (White & Case) · Wednesday, June 13th, 2018

Summary

On 7 June 2018, the UK Competition Appeal Tribunal (CAT) held that the UK Competition and Markets Authority (CMA) misapplied the relevant legal test when finding that Pfizer and Flynn Pharma (Flynn) unfairly priced their epilepsy drug. The CAT quashed the record £84.2 million and £5.2 million fines that the CMA imposed on Pfizer and Flynn, respectively.

The CAT criticised the CMA for failing to properly evaluate the drug's economic value – which is after all the core of the legal test in excessive pricing cases – and sufficiently analysing the prices of comparable products, which contradicted the allegations of unfairness. Moreover, the CAT held that given the presumption of innocence an authority cannot ignore a *prima facie* valid argument that a price is fair under one test and proceed to finding an abuse solely on the basis of an alternative test.

While the CAT quashed the CMA's fine and its findings of abuse, it did not itself make any finding as to the existence of an abuse. The case is now likely to be remitted to the CMA, which must consider its next steps.

More broadly, the judgment sends a clear signal that the excessive pricing cases, which have in recent years become popular with some European competition authorities, including the European Commission, should remain rare and that the authorities should be wary of stepping in the shoes of price regulators, unless this is “*soundly based on proper evidence and analysis*”.

Background

Phenytoin sodium was launched 80 years ago, but is still used today to treat approximately 10% of epilepsy patients in the UK. It was for many years sold at very low prices. In 2012, Pfizer transferred its marketing authorisation for the capsule form of phenytoin sodium to Flynn, but continued to manufacture the capsules and supply them to Flynn, which then sold them to the National Health Services (NHS). Flynn decided to de-brand (“genericise”) the drug with the effect that it was no longer subject to the UK's PPRS voluntary pricing scheme (only branded drugs are covered by under the PPRS). Pfizer's sale price to Flynn increased considerably and Flynn also increased the price at which it sold the drugs to the NHS by between 2,300% and 2,600%

compared to the price that Pfizer had previously been selling the drug. One final, important fact is that the new Flynn price was benchmarked at 25% below the price of phenytoin sodium tablets (i.e. tablets of the identical active ingredient), a price that the NHS had been paying for many years.

The CMA's Decision

Having opened an investigation in 2013, the CMA found both Pfizer and Flynn guilty in December 2016 of abusing their dominant positions in the narrowly defined market for Pfizer-manufactured phenytoin sodium capsules by excessively increasing their prices. The CMA imposed fines of £84.2 million and £5.2 million on Pfizer and Flynn, respectively, and ordered the companies to reduce their prices. In contrast to some previous abuse of dominance cases in the pharmaceutical sector, the CMA did not base its case on any allegation of an exploitation of a regulatory loophole or on a combination of exclusionary and exploitative practices; rather, it proceeded with a pure excessive pricing decision, a point which is stressed on many occasions by the CAT in its judgment. The CMA's decision relied on a comparison between cost and price to determine whether the prices were excessive. The decision was based on an abstract analysis, which compared the price 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 the cost-plus benchmark. While the cost plus test was the core of the CMA's case on both excessiveness and unfairness, the CMA's decision also referred to (as regards unfairness) four subsidiary elements, namely: the drug was old, the price was only increased when Pfizer sold the marketing authorisation to Flynn, the impact this practice had on the NHS and customers' reaction. The CMA also noted (without analysing the underlying reasons for this fact) that the drug was cheaper in other EU Member States than in the UK.

The relevant caselaw

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*,^[1] 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 (in fact after the CMA's Decision), the ECJ confirmed in *AKKA/LAA*^[2] 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. Given that there is no 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.

The CAT criticised the CMA’s methodology

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.

On **excessiveness**, the CAT criticised the CMA for relying almost entirely on a theoretical “reasonable rate of return” to determine that the prices were excessive. The tribunal said that “*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)*”. 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*”. The CAT held that *United Brands* did not establish the “cost plus” method chosen by the CMA as a sufficient method for establishing excessive pricing if other methods were available, in particular if these methods came to different results.

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%) than the price of the capsules – a price set by the Department of Health. This comparison clearly contradicted the CMA’s claims of unfairness.

The CAT also criticised the CMA for not sufficiently considering economic value, which is after all the point of departure that the ECJ used while defining the legal test in *United Brands*. The CMA had failed to take 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 emphasized that an authority cannot 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 an alternative test. While the authority is not required to show that both tests are fulfilled to find an infringement, 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 considered phenytoin sodium tablets as a suitable comparator in more depth. The prices of other epilepsy drugs were also potential comparators, albeit of less relevance.

The CAT's view as to the appropriate framework for future cases

Having considered the case law in detail, the CMA then set out the approach that it considered should be applied in future 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 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.

Finally, objective justification should be considered.

The CAT stressed that in reaching a conclusion the authority must recognise the *presumption of innocence* in favour of the undertaking under investigation when going through these steps.

The clarity offered by the CAT as to the legal test is helpful, especially given the number of excessive pricing cases currently ongoing in the UK and elsewhere in Europe and beyond (as to which see below).

The CAT's conclusions

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.

The problem of the CMA decision was the fundamental legal errors in the abuse parts. In the CAT's words:

“[T]he 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.”

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.

The broader principle: unfair pricing cases should be rare in competition law

The CAT's judgment underscores 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 send a warning signal to the European and other competition authorities which have recently focussed on excessive pricing cases. For example, last year the European Commission opened its first investigation into excessive pricing in the pharmaceutical sector to review 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.

The judgment comes as a most direct warning to the authority that has invested the most effort in excessive pricing cases, namely the CMA, which is currently pursuing at least two other excessive pricing investigations. The CMA confirmed that these investigations “*may now be severely delayed*” and that it was actively considering an appeal because of the judgment's implications for future excessive drug pricing cases.^[3]

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 should do a proper job.

In the particular case of pharmaceutical markets, the CAT put this very aptly:

“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.”

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

[2] Judgment of the Court (Second Chamber) of 14 September 2017, *Autorties?bu un komunik?šan?s konsult?ciju a?ent?ra / Latvijas Autoru apvien?ba v Konkurences padome*, Case C-177/16, EU:C:2017:689.

[3] See the CMA’s statement at: www.gov.uk/government/news/cma-considers-appeal-in-phenytoin-case.

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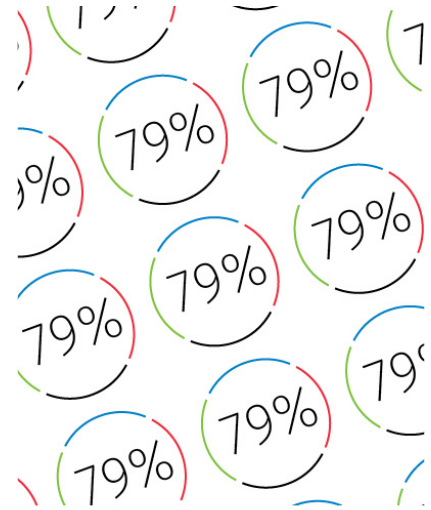
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