Pfizer and Flynn Pharma: A long and winding road

March 2020

Following a substantial increase of up to 2,600 per cent in the price of anti-epilepsy drug phenytoin sodium, the UK Competition and Markets Authority (CMA) fined Pfizer and Flynn Pharma (the Companies) nearly £90 million for unfair prices charged to the National Health Service (NHS).

In June 2018 after the Competition Appeal Tribunal (CAT) set aside the CMA's decision and biggest ever fine,[1] we asked whether we were at the end of the road for excessive pricing cases.

On 10 March 2020 the Court of Appeal largely upheld the CAT Judgment, quashing the fines and referring the case back to the CMA.[2] What next?

The past

Until 2012 Pfizer manufactured and sold phenytoin sodium capsules under the brand name Epanutin. Pfizer then sold the distribution rights to the drug to Flynn Pharma. In 2012 the NHS spent approximately £2 million on phenytoin sodium capsules. By 2013 the figure was £50 million – a price increase of up to 2,600 per cent, with the price of a 100mg pack of the drug rising from £2.83 to £67.50.[3]

In 2016 the CMA concluded that by raising their prices both companies had abused a dominant position in their respective markets, arguing that the companies had "*deliberately exploited the opportunity offered by de-branding*", costing the NHS and taxpayers "tens of millions of pounds". The CMA imposed fines of £84.2 million and £5.2 million on Pfizer and Flynn Pharma respectively.[4]

The Companies appealed the Decision to the CAT and in June 2018 the CAT agreed with the Companies - the CMA had incorrectly applied the legal test for unfair pricing. The CAT set aside the Decision and referred the case back to the CMA.[5]

As expected, the CMA appealed the CAT Judgment to the Court of Appeal.

The present

The Court of Appeal ultimately agreed with the CAT - considering the correct approach to applying the United Brands test in detail, quashing the Companies' fines and remitting the case back to the CMA.

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[1] *Pfizer and Flynn Pharma* [2018] CAT 11, CAT judgment of 7 June 2018 (CAT Judgment).

[2] *Pfizer and Flynn Pharma*, Court of Appeal judgment of 9 March 2020 (Court of Appeal Judgment).

[3] *Pfizer/ Flynn Pharma* (Case CE/9742-13), CMA decision of 7 December 2016 (Decision).

[4] *CMA fines Pfizer and Flynn £90 million for drug price hike to NHS*, CMA press release dated 7 December 2016.

[5] For further detail, see Pfizer and Flynn Pharma: The end of the road for excessive pricing cases?, a Slaughter and May client briefing of 13 June 2018.

While not necessarily the anticipated outcome, especially with the European Commission intervening on behalf of the CMA, the Court of Appeal's Judgment offers much-needed guidance to regulators and industry as to what constitutes excessive pricing.

What should regulators do in all cases?

As set out by Sir Geoffrey Vos, "*the first step in the analysis for the excessive limb is likely in most cases to be for the competition authority to consider whether the costs of production or the costs actually incurred in relation to the product in question, including of course a reasonable rate of return, can be ascertained*" (i.e. the CMA should conduct a cost-plus analysis). The Court accepts that this cost-plus analysis may not always be possible or appropriate, but that it will likely be the preferred starting point.

However, the Court is clear that it is within the CMA's discretion to choose its approach to determining excessive pricing and, to the extent that it conducts a cost-plus analysis, the CMA is not obliged to go beyond such analysis in every case. For example, while a benchmark is required (given fairness, excessiveness and reasonableness are all relative concepts), a hypothetical benchmark price against which to compare the actual pricing, beyond a simple cost-plus analysis, is not necessary. This was an area of disagreement between the CAT and the Court of Appeal. The CAT concluded that the CMA should, as part of its analysis, construct a hypothetical benchmark or range of prices against which to measure the actual prices charged. The Court of Appeal disagreed - to the extent that the CAT compelled the use of a particular test, the CAT "misconstrued the case law".

While the CMA maintains "*a margin of manoeuvre or discretion*" in how it goes about meeting its obligations, it retains "*a duty to conduct a fair evaluation of all the evidence before it*". The CMA must "properly and fairly" evaluate any evidence adduced by the relevant parties. This evaluation may then be reviewed on appeal.

And in this case?

With respect to Pfizer and Flynn Pharma, while the Court of Appeal accepted that the CMA was not obliged to go beyond a cost-plus calculation in every excessive pricing case, the CMA should have done so here.

The Companies presented evidence that the price was fair by reference to comparator products and the CMA should not ignore prima facie valid arguments. The United Brands test allows for an assessment as to whether a price is "unfair in itself" or "when compared to competing products". However, the CMA cannot ignore evidence adduced by the parties that the prices were fair by reference to competing products even if the CMA has chosen to opt for the unfair in itself test (in this case the cost plus approach). Interpreting the United Brands test in any other way would be "unduly rigid and literal".[6]

The Court concluded that the CAT was not bound by the CMA's margin of manoeuvre or discretion (though this discretion did exist). The CAT was entitled to find that the CMA investigation was insufficiently deep or insufficiently intense with respect to its review of any comparator products.

Going forward, the CMA is also required to review its approach to patient benefit when assessing the economic value of the phenytoin sodium capsules. In 2018 the CAT concluded that the CMA failed to accord any weight to economic value attributable to patient benefit. According to the CAT and the Court of Appeal, the CMA should have done so and must consider the impact of this conclusion (if any) on review.

[6] Case C-27/76 - *United Brands*, Commission decision of 14 February 1978.

The future

The Court of Appeal judgment sets out the correct methodology when assessing unfair and excessive pricing in the pharmaceutical industry. The CMA must now apply this guidance both to its re-review of the Pfizer and Flynn Pharma case and to any other ongoing excessive pricing cases.

Despite appearing to reject its appeal, the CMA has welcomed the Court of Appeal Judgment, referring to it as "*an important step forward in clarifying the legal test for excessive and unfair pricing*".[7] The CMA has said it will "*carefully review the elements that the court has decided to refer back to it*", and plans to "move forward with its case" against Pfizer and Flynn Pharma.

The CMA warns that it "*remains committed to its work to robustly tackle any illegal behaviour by drug companies ripping off the NHS*". There is clearly more to come from the CMA both with respect to this case and what appears to be its broader pursuit of pharmaceutical companies - and the CMA is not alone. Despite rejecting three of the CMA's four grounds of appeal, Sir Geoffrey Vos began his Court of Appeal Judgment with a reminder that "*literally overnight, Pfizer and Flynn increased their prices for phenytoin sodium capsules by factors of between approximately 7 and 27, when they were in a dominant position in each of their markets*". This is not the end of the road.

The law

The seminal *United Brands* judgment is the starting point for any excessive pricing case.

> *"…charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse…"*
> *para 250*

> *"The questions…to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products…" para 252*

[7] CMA welcomes Court of Appeal judgment in Phenytoin case, CMA press release of 10 March 2020.

Key takeaways

THE CMA
…must fairly and properly evaluate any evidence relied on by the parties
…must examine evidence of comparator products if put forward by the parties under investigation
…however, can rely on any one method/body of evidence (for example, a cost-plus analysis) if no other evidence is put forward – the CMA has discretion to decide the appropriate methodology
…is not **obliged** to conduct a "full investigation" of comparable products **in every case**
…may, if a cost-plus test is applied, compare the price charged against a benchmark higher than cost (such as a reasonable rate of return on sales)
…does not need to identify a hypothetical benchmark price in assessing whether prices were excessive
…should consider any benefits patients derive from the use of a drug as providing at least "some" economic value

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