The Court of Appeal's Judgment in Phenytoin

APRIL 2020

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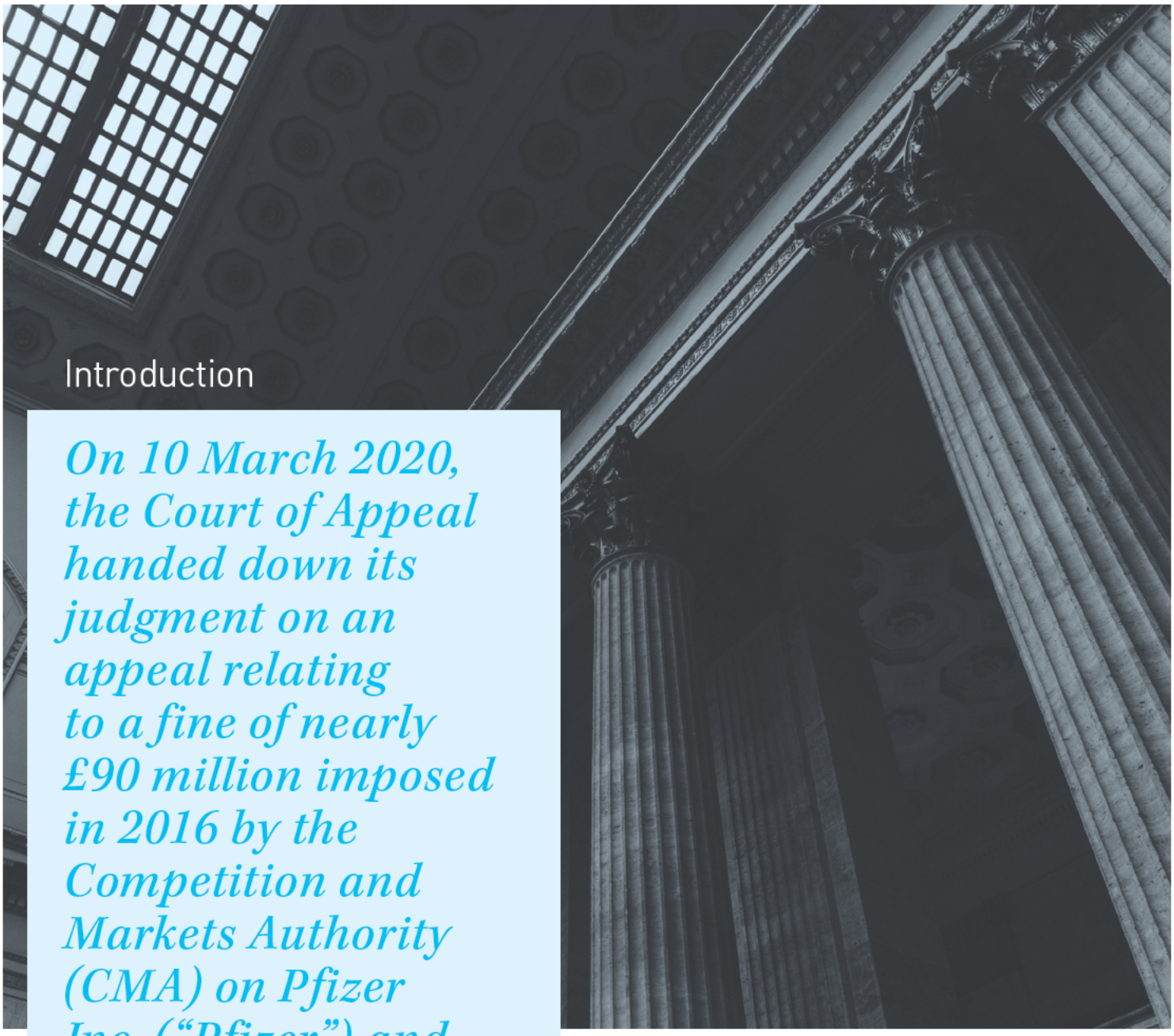

Introduction

On 10 March 2020, the Court of Appeal handed down its judgment on an appeal relating to a fine of nearly £90 million imposed in 2016 by the Competition and Markets Authority (CMA) on Pfizer Inc. ("Pfizer") and Flynn Pharma Ltd. ("Flynn") for excessive pricing of an anti-epilepsy medicine.

The judgment is a landmark ruling on the economic tests to be applied when considering whether prices charged by a dominant undertaking amount to an abuse of a dominant position, clarifying the interpretation of the tests established in the seminal *United Brands* case.[1]

Given the opportunities presented by the novel coronavirus (COVID-19) pandemic for excessive pricing of products in high demand and short supply, this clarification is of immediate relevance to both competition authorities and dominant undertakings.

1 Judgment of the Court of Justice in Case C-27/76, *United Brands Co. v. Commission of the European Communities*, EU:C:1978:22

Background

Phenytoin sodium is an anti-epilepsy medicine, available in both capsule and tablet forms. It is prescribed to around 48,000 patients in the United Kingdom.

Until 2012, Pfizer supplied phenytoin sodium capsules to the National Health Service (NHS) under the brand name Epanutin at a price of £2.83 per eighty-four × 100 milligram pack.[2] Since it was a branded medicine, this price was controlled by the Department of Health's Pharmaceutical Price Regulation Scheme (PPRS) under a "Cost-Plus" approach by reference to a 6 percent return on sales (ROS) above cost. In April 2012, Pfizer agreed to transfer its UK marketing rights to Flynn for a nominal sum of £1 and supply capsules to Flynn from its German manufacturing facility. In September 2012, Flynn de-branded the capsules, which removed them from the price-controlled scope of the PPRS, and increased the price charged to the NHS from £2.83 to £67.50 per eighty-four × 100mg pack (while paying Pfizer a wholesale price of £39.00 per eighty-four × 100mg pack).

In December 2016, following a three-year investigation, the CMA imposed a penalty of £84 million on Pfizer and £5 million on Flynn for having abused their dominant positions in the UK market for phenytoin sodium capsules since September 2012, and directed them to reduce their prices.

The CMA found that the 2012 price increases could not be justified by changes in underlying costs, and that Pfizer and Flynn had intentionally or negligently charged excessive and unfair prices for the capsules.

The CMA drew upon the two-limbed test established in *United Brands* to gauge whether a price has no reasonable relation to the economic value of the product supplied, which comprise:

1. an "Excessive Limb", which asks whether the difference between the costs actually incurred and the price actually charged is excessive; and if yes,
2. an "Unfair Limb", which asks whether the price that has been imposed is unfair, either "in itself" or "compared to competing products".

The CMA ruled that:

- the prices charged were excessive, as they generated a ROS significantly in excess of 6 percent;
- the economic value of the capsules was limited to the Cost-Plus level of 6 percent, and there were no relevant demand-side or non-cost factors which served to justify an increase in the economic value above that level, so the prices charged were accordingly unfair "in themselves" and abusive, because they bore no reasonable relation to the economic value of the capsules; and
- it was unnecessary to determine whether the prices were also *unfair* when compared to competing products.

Pfizer and Flynn appealed the CMA's decision at the Competition Appeal Tribunal (CAT), which quashed the decision in July 2018. The CMA and Flynn appealed the CAT's ruling at the Court of Appeal. Summarised below are the key elements of the Court's ruling as regards the economic tests to be applied to determine excessive pricing:

- the need for a benchmark competitive price under the Excessive Limb
- the relevant tests for unfair pricing under the Unfair Limb
- the need for a separate test of the relation of price to economic value

The Need for a Benchmark Competitive Price Under the Excessive Limb

The CMA based its finding of excessive pricing on a Cost-Plus analysis which assessed the level of ROS. The CAT ruled that to find prices excessive under the Excessive Limb, the CMA should have established a benchmark price that would pertain under conditions of normal and sufficiently effective competition, and then should have:[3]

- compared prices charged against that benchmark price; and
- considered whether the resulting differential was sufficiently significant and persistent as to be excessive.

The Court ruled that the CAT's position was not supported by case law and that:[4]

- the CMA had a margin of discretion as to how it considered the issue of excessive pricing under the Excessive Limb, it was not required to use any particular test, and *a fortiori* was not required to establish a benchmark price; and
- appropriate tests could include Cost-Plus analyses based on ROS or Return on Capital Employed (ROCE), the pricing of comparable products, "or indeed any other benchmark or combinations thereof capable of providing a 'sufficient' indication that the prices charged are excessive and unfair".

2 Indicative pack size and dosage.
3 Para. 40, Judgment.
4 Paras. 97 and 120 to 125, Judgment.

The Relevant Tests for Unfair Pricing Under the Unfair Limb

The CMA focussed on one of the alternatives under the Unfair Limb (*unfair in itself*). Although Pfizer had presented the CMA with evidence relating to the price of phenytoin sodium tablets as a relevant comparator to the phenytoin sodium capsules that were the subject of the investigation, the CMA stated that having considered the *unfair in itself* alternative, it was not necessary to consider the *unfair compared to competing products* alternative, on the grounds that as "alternatives", only one of the two needed to be satisfied.[5]

The CAT found that the CMA was entitled to focus on either alternative under the Unfair Limb, but that:[6]

- it should have given due consideration to any *prima facie*–relevant evidence advanced by the Defendants under the alternative not focussed on; and/or
- it should have considered the alternative not focussed on as a "*sanity check*", regardless of the evidence advanced by the Defendants.

The Court ruled that:[7]

- In broad terms, a price will be unfair when the dominant undertaking has reaped trading benefits which it could not have obtained in conditions of "normal and sufficiently effective competition" (i.e. "workable" competition). A price which is "excessive" because it bears no "reasonable" relation to the economic value of the good or service is an example of such an unfair price.
- The CMA's position was based on an "unduly rigid and literal" reading of *United Brands*[8]: It could not ignore *prima facie*–relevant evidence of any type (without restriction to the two *United Brands* alternatives) advanced by the Defendants, and had to evaluate fairly all evidence before it (but had discretion as to the appropriate depth of such an evaluation).
- There was no authority for the CAT's suggestion that, in the absence of evidence advanced by the Defendants, the CMA had to consider both Unfair Limb alternatives. Indeed, the CMA had a margin of appreciation that would have entitled it to consider any single method or combination of methods for determining whether prices were unfair (again without restriction to the two *United Brands* alternatives).

The Need for a Separate Test of the Relation of Price to Economic Value

- The *United Brands* decision found that a price is abusive if it has "no reasonable relation to the economic value of the product supplied".[9]
- The CMA concluded that the economic value of the capsules was limited to the Cost-Plus level of a 6 percent ROS that it had assessed under the Excessive Limb, and there were no relevant demand-side or non-cost factors which served to justify an increase in the economic value above that level, so the prices charged were abusive because they bore no reasonable relation to the economic value of the capsules.[10]

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5 Paras. 51 and 149, Judgment. The CMA did consider the evidence on phenytoin sodium tablets, but concluded that they were not appropriate comparators, although the CAT found that its analysis was not sufficiently deep (paras. 132 to 133, Judgment). The CMA appealed this finding on the basis that it failed to respect the CMA's margin of discretion (para. 126, Judgment), but the Court ruled that the finding was within the CAT's jurisdiction and rejected this Ground of Appeal (para. 152, Judgment).

6 Paras. 40 and 51, Judgment

7 Paras. 86, 89, 97, 107, 113, and 116, Judgment

8 Paras. 57 and 97, Judgment

9 Para. 250, *United Brands*.

10 Para. 159, Judgment.

The CAT found that the relation of price to economic value was a test that the CMA should have considered separately from the Excessive and Unfair Limbs.[11]

The Court ruled that:[12]

- the relation of price to economic value should be considered, but in principle this could be achieved as part of the Excessive Limb (for example in arriving at a Cost-Plus price) or as part of the Unfair Limb (for example in considering the price of comparable products); and
- the CAT was not correct to require it to be considered as a separate test, not least because that would risk the double counting of economic value.

Implications for Economic Tests in Future Cases

The Court appears to have confirmed that competition authorities have a significant margin of discretion as to how they approach the two limbs of *United Brands* and the question of economic value, including the acceptability of the following relatively simple interpretation of the tests:

- performance of a Cost-Plus analysis under the Excessive Limb to determine whether a price generates a ROS or ROCE that is significantly in excess of cost; and
- consideration of whether that excess is so great that the price has no reasonable relation to economic value and could therefore be considered unfair under the Unfair Limb, by reference to non-cost and demand-side factors, and/or the prices of comparable products.

Where strong evidence of comparable products is available, such an approach could make the economic evidence required in excessive pricing cases somewhat easier to identify and provide. However, evidence on comparables can raise a number of issues, not least in terms of whether they are truly comparable, and such evidence can therefore be hard to deploy.

Where strong evidence on comparable products is not available, a greater focus on non-cost and demand-side factors may be required in the assessment of economic value. There may be legitimate reasons (such as consumer benefit, reward for risk and innovation, etc.) in competitive markets where consumers pay prices significantly in excess of cost, but the analysis required may be complex.

Regardless of the approach a competition authority follows in a case, it is clear that it must fairly evaluate, in at least some depth, any evidence advanced by Defendants that is *prima facie* relevant to any limb (or to economic value). This hands a degree of power back to Defendants in terms of not only evidence considered, but also the overall approach that the authority is effectively forced to follow. Consequently, defendants may now have a much stronger incentive to advance available relevant evidence (e.g. evidence of comparable products and markets), and this could influence the approach adopted by the parties. This also may create a difficulty for an authority presented with large quantities of evidence of varying quality. How does it fulfil its obligation to evaluate fairly such evidence without devoting disproportionate effort to evidence that may be relatively weak?

The COVID-19 pandemic creates clear opportunities for excessive pricing, and the Court's ruling should help both competition authorities and dominant undertakings assess pricing behaviour. However, circumstances may require a reconsideration of several well-established concepts. For example:

- In an environment where the need for certain products is pressing and in short supply, even firms with very small market shares may be at risk of being judged temporarily dominant. This could expand greatly the number of firms that would need to have regard to the criteria for excessive pricing.
- In circumstances where supply chains are suffering widespread fundamental disruption and working arrangements are challenging, firms may face much higher input costs. This could limit significantly the relevance of comparable prices pertaining in more normal times.

11 Paras. 162 and 166, Judgment. The CAT also found that the CMA had wrongly ascribed no value to the contribution of patient benefit to economic value, beyond that incorporated in the Cost-Plus analysis, in its assessment of that relation. The Court ruled that the CAT was entitled to make this finding of fact (paras. 165 to 166, Judgment).

12 Para. 172, Judgment.

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This matter was undertaken prior to Mr. Harman joining BRG.

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