TRIBUNAL SETS ASIDE CMA DECISION AGAINST PFIZER AND FLYNN PHARMA IN LANDMARK JUDGMENT

On 7 June 2018, the UK's Competition Appeal Tribunal set aside a decision by the Competition and Markets Authority (CMA) which had found that Pfizer (and another company Flynn) had abused their dominant position by charging excessive and unfair prices for an anti-epilepsy medicine, phenytoin sodium capsules (link). The Tribunal set aside the penalties imposed, including the record-breaking £84.2m fine against Pfizer. It found that the CMA did not correctly apply the legal test for finding that the 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 the other, comparable, products, in particular the phenytoin sodium tablet. The judgment represents a significant setback to the CMA's legal strategy in cases of excessive pricing and it has confirmed that its other investigations "may now be severely delayed". However, authorities around the world continue to pursue excessive pricing investigations against pharmaceutical companies including in Denmark, Italy, South Africa and Russia.

THE FACTS

Pfizer's phenytoin capsules (marketed as Epanutin, a branded off-patent medicine) had been loss-making for a number of years under the PPRS, an agreement between industry and the Department of Health for branded medicines. An identical tablet product was marketed by another company at a price at least 30 times higher than the capsule price. Pfizer concluded a deal with Flynn under which it continued to manufacture the product whilst Flynn marketed the capsule. Flynn launched the capsules as a generic medicine at an increased price in September 2012, although at a lower price than the tablet. As a result of the deal, the price of the capsules increased by up to 2,600% and the CMA estimated that NHS expenditure on capsules increased from around £2m per year in 2012 to about £50m in 2013.

Key issues

- The Tribunal has set aside an important CMA decision on excessive pricing and has clarified the relevant legal test.
- Had the CMA's approach been upheld, it may have had important implications, particularly for the pricing of pharmaceutical products.
- The Tribunal found that the CMA was wrong to restrict itself to a "cost plus" approach and to exclude other methods of calculating whether a price is excessive.
- The CMA did not correctly apply the legal test for finding that prices were unfair and the Tribunal set aside the fines against Pfizer and Flynn.
- Companies should take particular care in setting the prices of products which may face limited competition.
- Careful consideration should be given to any substantial increase in the price of such a product including: how far above cost the new price will be; how it compares to rival products; and how it compares to products in other markets.
- Clifford Chance acted for Pfizer during the investigation and in its successful appeal to the Tribunal.

THE CMA'S DECISION

Following a long investigation, which began in May 2013, the CMA issued a Decision against Pfizer and Flynn in December 2016. They found that both companies held a dominant position in the manufacture and supply of Pfizer-manufactured capsules respectively and each had abused that dominant position by charging excessive and unfair prices. The CMA imposed a record £84.2m fine on Pfizer and a £5.2m fine on Flynn (the statutory maximum that the CMA could have imposed) and directed both companies to lower their prices for capsules. At the heart of its decision, the CMA adopted a "cost plus" approach when determining whether the prices were excessive and unfair. It considered that for each of Pfizer and Flynn a return on sales of no more than 6% was reasonable (complaining that the product was "old" and "off patent"). The CMA's cost plus 6% approach if upheld may have had important implications for the pharmaceutical industry, where products can and do routinely earn returns far in excess of their costs. This was also the first standalone case of excessive pricing to be brought; historically these cases have also involved allegations that competitors had been excluded from the market. Pfizer and Flynn launched separate appeals to the Tribunal in February 2017 and those appeals were heard together over a four week period in October/November 2017.

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THE TRIBUNAL'S JUDGMENT

Market definition and dominance

In its Decision, the CMA adopted an unprecedentedly narrow market definition. Pfizer and Flynn were dominant in the market for Pfizer-manufactured phenytoin capsules and the distribution of those capsules in the UK respectively. That finding was self-proving given that only Pfizer can produce "Pfizer-manufactured phenytoin capsules". The CMA justified this restrictive approach on the basis that patients who were stabilised on capsules could not switch to other capsules (so-called "continuity of supply"). In their appeals, Pfizer and Flynn both argued that the CMA had wrongly excluded rival capsules (made by NRIM) from the relevant market definition. Pfizer also challenged the CMA's characterisation of continuity of supply, including through expert medical evidence and through an examination of pharmacists dispensing behaviour. Overall, the Tribunal agreed with the CMA that continuity of supply had a significant impact, in practice, on pharmacists' dispensing practice, tending to favour the existing supplier of products on which patients were already stabilised. However, it found that the position was not as unequivocal as the Decision concluded as there was still a degree (even if limited) of switching from Flynn to NRIM. There was clearly some competitive interaction between Flynn and NRIM, but this interaction was limited in scope and effect.

Both parties also challenged the CMA's findings of dominance on the grounds that the Department of Health had countervailing buyer power (as a monopoly purchaser with price setting powers). However, the Tribunal said that it was not necessary to decide the precise extent of the Department of Health's powers as a question of statutory interpretation or otherwise and did not find that Pfizer and Flynn were subject to countervailing buyer power from the Department of Health whether as a purchaser or as an actual or potential regulator of prices. Whilst the Tribunal upheld the CMA's conclusion on

dominance, it sounded an important note of caution about the CMA's approach in this case. It was wrong to regard as relevant only those products defined as falling within the relevant market and to disregard entirely any competitive pressure from those products defined as falling outside it. This was an important indication of the Tribunal's overall approach: products falling outside the defined market (e.g. the phenytoin tablet) may still be relevant when considering the question of abuse.

The legal test for excessive and unfair pricing

The leading judgment on excessive pricing from the Court of Justice of the European Union is *United Brands v Commission* (C-27/76). In that judgment the CJEU said that charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be an abuse. That judgment also established a two-limb test: (1) the price must be "excessive" (in *United Brands*, it was said that this could be calculated as the difference between the cost of production of the product and the selling price); and (2) the price must be "unfair" either in itself or when compared to competing products. The Court of Justice also made clear that "other ways may be devised" of selecting the rules for determining whether the price of a product is unfair.

Abuse - Excessive

The CMA considered whether the capsule price was unfair by adding what is described as a reasonable rate of return for each of Pfizer and Flynn to the costs they incurred. It submitted that the "excessive" limb of the test only required the CMA to establish a material difference between the price and cost. The Tribunal found that the CMA was wrong to restrict itself to a cost plus approach and to exclude other methodologies, rather than seeking to establish a benchmark price (or range) that would have pertained in normal competition. The CMA's approach owed more to a theoretical concept of idealised competition than to the real word. *United Brands* does not establish that cost plus is, in isolation, a sufficient method for establishing the excess if other methods are available and, particularly, if they suggest different results. An authority cannot simply choose that method of calculating the excess that is most favourable to establishing an infringement, to the exclusion of other methods.

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Abuse - Unfair

To satisfy the second limb of the test the price must either be unfair in itself or when compared to competing products. The CMA submitted that it had complete discretion to choose between those two alternatives: there was no legal obligation to have regard to comparators (such as the identical tablet which was sold at a higher price than the capsule). The Tribunal disagreed with that approach. The CMA could not simply re-present its findings under the "excessive" limb to justify a finding of unfairness. It cannot be right that an authority can simply ignore a *prima facie* valid argument that a price is fair. This was necessary not only as a matter of logic but also in order to accord with the burden of proof and respect the presumption of innocence. In the Tribunal's view, the CMA should have done a sufficient investigation into the competitive conditions surrounding the most obvious comparator (the tablet) to properly inform its decision. It was not an answer to state that there was no obligation to conduct a full investigation.

Economic value

The CMA also excluded from its calculation of the value of the capsule all factors other than its cost plus methodology. It justified this on the basis that, for example, it considered that the capsules were old and that patients were captive. Pfizer's medical expert demonstrated that phenytoin remains a useful and effective treatment for a significant number of patients and the CMA did not contest that evidence. The Tribunal found that the CMA's outright rejection of any value at all to patients surprising and found that there was clearly some economic value to be derived from the therapeutic benefit to patients. However, it said that some allowance must be made for the extent to which the choice of switching from phenytoin may be restricted.

The Tribunal found that the CMA did not correctly apply the legal test for finding that the 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 the other, comparable, products, in particular the phenytoin sodium tablet. On that basis it set aside the CMA's decision on abuse and all consequential matters such as the penalty.

Suggested framework

The Tribunal suggested a framework for standalone excessive pricing cases. An authority should:

- Consider a range of possible analyses to establish a benchmark price or range that reflects the price that would pertain under conditions of normal and sufficiently competitive competition. It is not entitled to select one method and ignore others that are credible.
- Compare that price (or range) with the price that has been charged to determine whether it is excessive.
- Where the difference is excessive it must consider whether it is unfair. In doing so it can consider either whether it is unfair in itself or when compared to competing products but it must consider any *prima facie* argument that the price is fair under either.
- If it is unfair, it should consider the economic value of the product and whether the price charged bears no relation to it.
- Give consideration to any objective justification advanced by the company and recognise the presumption of innocence.

Penalty and next steps

The Tribunal decided that, in view of its decision on abuse of dominance, it was not necessary to come to a decision on the financial penalties imposed by the CMA. It set aside the penalties against Pfizer and Flynn. If it had to decide, it would have likely regarded the very substantial uplift for deterrence applied to Pfizer as difficult to justify particularly having regard to the new price control powers of the DH which have recently been passed into law. The Tribunal reached the provisional view that the question of abuse should be remitted back to the CMA and has requested submissions from the parties. The CMA has also indicated (via a press release, link) that it intends to appeal the judgment of the Tribunal to the Court of Appeal.

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What does this judgment mean for the industry?

The Tribunal's judgment has further clarified the law in this area, but it may be subject to appeal.

- Companies should take particular care to monitor the prices of products which are off-patent but face limited competition.
- Careful consideration should be given before substantially increasing the price of such a product. Such a decision may not just have reputational consequences but lead to legal liability.
- If a price increase is considered, careful consideration should be given to how far above cost the new price will be; how it compares to rival products; and how it compares to products in other markets. Those considerations should be recorded and legal advice should be sought.
- Even where the government/regulatory authorities have agreed to or acquiesced to rival product being priced at a much higher level, that may not be a sufficient defence.

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Clifford Chance acted for Pfizer during the CMA's investigation and in Pfizer's successful appeal to the Competition Appeal Tribunal.