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UK Competition Appeal Tribunal Quashes Fines in First Pure Excessive Pricing Case

Article By:

Tatiana Siakka

On 7 June, the UK's Competition Appeal Tribunal (CAT) annulled in part a decision by the UK's Competition and Markets Authority (CMA) imposing fines of nearly £90 million on two pharma companies, Pfizer and Flynn, for charging excessive prices for the anti-epileptic drug, phenytoin sodium capsules. The case is notable as it marks the first time that the CAT has ruled on a pure excessive pricing case in the pharma sector.

In its decision, the CMA had found that both Pfizer and Flynn held a dominant position in their respective markets and that each company had abused that position by significantly raising the prices of phenytoin sodium capsules from £2.83 to £67.50 – corresponding to a price increase of 2,600%. The price increase followed from Flynn's decision in 2012 to genericise the drug with a view to effectively removing it from the sectoral pricing regulation that applies to branded medicines.

Pfizer and Flynn appealed the CMA's decision before the CAT. Although the Tribunal upheld the CMA's findings on market definition and dominance, it found that the CMA misapplied the two-limb test for excessive pricing established by the European Court of Justice in its seminal judgment in *United Brands*. That test involves assessing (i) whether the price is excessive by comparison to the cost of production (the 'excessive' limb); and if so, (ii) whether a price is unfair either in itself or when compared to competing products (the 'unfair' limb).

As regards the 'excessive' limb, the Tribunal held that the CMA was wrong to restrict its assessment to a cost plus[1] approach, to the exclusion of other methodologies and the evidence more widely available. In doing so, the CMA focused its analysis on *"a theoretical concept of idealised or near perfect competition, than to the real world".* The correct approach, according to the Tribunal, was to identify a benchmark price or price range, which would have applied in conditions of *"normal and sufficiently effective competition"*.

In respect of the 'unfair' limb, the CAT found that the CMA wrongly examined only if the Pfizer/Flynn price was unfair in itself, thereby failing to adequately assess the possible impact of phenytoin tablets (the price of which was 25% higher than that of capsules), as meaningful comparators.

In light of the misapplication of the test on excessive pricing, the CAT concluded that the CMA's findings on abuse of dominance were defective and set aside that part of the decision. In terms of

remedy, the Tribunal has indicated that its provisional view is to remit the case back to the CMA for further consideration, noting that the correct application of the test on excessive pricing will require detailed examination of the facts, which the CMA is better placed to carry out.

Cases of pure excessive pricing are very rare in competition law and notoriously difficult to establish. The Tribunal's judgment illustrates the practical issues that competition authorities face when intervening in such cases, notably the lack of a single methodology to determine that a price/profit margin is excessive and the inherent complexity of establishing an appropriate benchmark price. The structure and specificities of the pharmaceutical market, in particular national pricing regulations, compound the complexity of the legal analysis and increase the likelihood of errors.

Despite these difficulties, competition authorities across the EU, including the European Commission, have been in recent years actively pursuing excessive pricing cases in the pharma sector, in particular cases involving significant prices increases.

Shortly after the Pfizer/Flynn decision, the CMA issued a Statement of Objections to Actavis UK in the context of its investigation into excessive pricing of hydrocortisone tablets – involving price increases up to 12,000%. The authority is also currently investigating alleged excessive pricing with respect to liothyronine tablets, a drug used to treat hypothyroidism.

In 2016, the Italian competition authority imposed a €5 million fine on Aspen for charging excessive prices (through increases up to 1,500%) for a suite of off-patent cancer drugs; the fine has been recently upheld by the Italian Administration Court. The company is currently under investigation by the European Commission for having allegedly implemented excessive prices in several EU Member States on five cancer drugs and for having threatened to withdraw those drugs in some other EU Member States.

Earlier this year, the Danish competition authority found that CD Pharma abused its dominant position by charging excessive prices for the drug Syntocinon, an off-patent drug used by public hospitals in Denmark in connection with childbirth. The authority found that in 2014 CD Pharma increased the price on Syntocinon from €6 to €127, corresponding to a price increase of 2,000%. The case has been submitted to the Danish State Prosecutor for Serious Economic and International Crime, who will be deciding on prosecution and financial penalties.

In addition, the French competition authority has recently launched a sector-wide investigation into healthcare, targeting specifically the distribution of pharmaceuticals and their price regulation mechanism, while the president of the Dutch competition authority has published a working paper regarding enforcement of competition law in the pharma sector, where it is noted that *"excessive pricing cases addressing patented products are bound to follow".*

These developments highlight that cases of excessive pricing will continue to remain high on the agenda of competition authorities across the EU in the coming years and suggest that the EU could be moving towards establishing a comprehensive framework for pursuing excessive pricing cases – the CAT's judgment was the first step in that direction.

[1] In assessing the 'plus' element, the CMA considered that an ROS (return on sales) of 6% was a reasonable rate of return, as the maximum permissible ROS for a portfolio of branded medicines under UK pharma pricing regulation. This was one of the most controversial elements of the CMA's decision, raising doubts about the appropriateness and probative value of a regulatory price cap for a portfolio of products as an indicator of a reasonable rate of return for a single generic product.

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