August 25, 2015

Pharmaceutical companies should be aware of the risk that competition authorities in Europe may challenge their prices as 'excessive'. For the first time, the UK competition regulator is challenging a company's medicine prices as a violation of competition law on these grounds.

The UK Competition and Markets Authority ('**CMA**') announced on 6 August that it had issued a **statement of objections** to pharmaceutical suppliers Pfizer and Flynn Pharma, alleging infringement of EU and UK competition law. The CMA's provisional view is that each company has abused its dominant market position by charging 'excessive and unfair prices' for Pfizer's anti-epilepsy drug, phenytoin sodium capsules.

According to the CMA's press release announcing this development, having initially marketed the drug to UK wholesalers and pharmacies under the 'Epanutin' brand, Pfizer subsequently sold the UK distribution rights in September 2012 to Flynn Pharma, which de-branded or 'genericised' the drug for UK sale. The CMA asserts that, from that point, Pfizer's prices increased to between 8 and 17 times the previous wholesale price for branded Epanutin, whereas Flynn Pharma's price for onward sale was between 25 and 27 times higher. As a result, annual expenditure on the drug by the UK National Health Service (**NHS**) went up from £2.3 million prior to September 2012 to £50 million in 2013 and £40 million in 2014.

The CMA's predecessor enforcement authority, the Office of Fair Trading ('**OFT**'), opened an investigation into this conduct in May 2013, with the CMA taking over the case on its creation in April 2014. The CMA has now reached the provisional conclusion that each of Pfizer and Flynn Pharma holds a dominant position on a relevant market (presumably for the manufacture and supply of phenytoin capsules, respectively) and that each abused its dominant position by charging prices that were so high as to be abusive.

Excessive pricing as an abuse of dominance

It is generally accepted that profit maximisation is a legitimate commercial objective that should not be constrained by competition law, in the absence of additional wrongful conduct. This principle is particularly important in the pharmaceutical sector, where the ability to recoup development costs across a portfolio of products by charging prices for the small number of successful products that exceed the cost of production is viewed as necessary to support future research. The ability to earn high profits for a certain period remains an important driver of innovation in the sector.

The EU competition law prohibition of abuse of dominance has, at the same time, been interpreted to mean that prices set by a dominant company may be viewed as abusive, and hence unlawful under Article 102 of the Treaty on the Functioning of the EU ('**TFEU**'), if they are 'excessive'. Indeed, Article 102 itself explicitly lists charging "unfair selling prices" as a specific form of prohibited abuse.

According to the European Court of Justice in the leading judgment in this area, prices may be viewed as (unlawfully) excessive if they have "no reasonable relation to the economic value of the product supplied".[1] This requires, in turn, proof that the difference between the costs incurred in supplying the product and the price is 'excessively high' and that the price is 'unfair in itself' or when compared with competing products.

Notwithstanding this long-standing precedent, competition authorities have been understandably reluctant to bring such cases in practice. This is because determination of whether a price is excessive under this test involves consideration of nebulous and

subjective concepts such as a product's 'economic value' and 'unfair' pricing. In order to determine when a price is so high as to be excessive, a competition authority bringing such a case is necessarily called on to consider what a 'non-excessive', and hence lawful, price would be, with the result that the authority risks becoming a *de facto* price regulator. Outside of regulated utilities, this is a role that does not sit comfortably with modern competition law enforcement. It is therefore unsurprising that this case marks the first time that a UK competition authority has brought a formal competition enforcement case based purely on an allegation of excessive pricing since the Competition Act 1998 came into force in March 2000.

While the OFT included a finding of excessive pricing in its 2002 infringement decision in *Napp Pharmaceuticals*,[2] this did not amount to a free-standing abuse in that case. Rather, the abuse arose from Napp's operation of a discriminatory discount policy for the supply of sustained release morphine that combined predatory price cutting in one segment (hospital supply) with higher prices for the same drug when supplied to a different segment (community supply). In other words, it was not the excessive pricing as such that was the problem but rather its combination with predatory prices in a system that facilitated exclusionary price discrimination.

It is nevertheless worth noting that the OFT's conclusion that Napp's prices for community supply were excessive rested on a comparative analysis of the profit margins the company earned on community sales of its drug with its margins on other products and sales to other segments. In other words, the OFT was not required to establish whether the prices were excessive in absolute terms but rather adopted a relative approach. On appeal, the Competition Appeals Tribunal ('**CAT**') supported the OFT's approach, highlighting that there are various methods which can be used to determine whether a price is excessive including consideration of the price of identical products in other markets or during different time periods.[3]

In contrast, it is notable that, in its 2007 judgment in *Attheraces v. British Horseracing Board*,[4] the UK Court of Appeal overturned a High Court excessive pricing finding[5] on the grounds that it was insufficient to consider only the costs of supplying a product and the supplier's reasonable margins (a 'cost plus' test). Rather, as well as considering the supplier's costs, it was necessary to consider the value of a product to the *purchaser*. In the Court of Appeal's opinion, if the purchaser valued a product enough to pay the price demanded by a supplier, however high, and provided that downstream competition was not adversely affected by this, then the price was unlikely to be abusive. The Court stressed that competition law exists to protect competition and consumers (not purchasers) and, as a result, Article 102 TFEU should not be viewed as "a general provision for the regulation of prices".

Any abuse of dominance finding is relatively rare in the UK, with only seven infringement decisions having been issued since the birth of the modern regime in March 2000.[6] This reflects the general reluctance of the CMA, and the OFT before it, to intervene in the unilateral conduct of companies, in the absence of exceptional circumstances. Notwithstanding this generally cautious policy approach, the authorities have been relatively active in the pharmaceutical sector, with three of these seven infringement decisions concerning the supply of medicines.[7] Looked at in this light, the CMA's intervention in this case is perhaps less surprising.

The CMA's decision to bring a straight excessive pricing case, as well as alleging abuse of dominance by two companies at different levels of the supply chain based on an allegation of independent dominance at both levels, is striking. It may be that the CMA felt compelled to act here, given the level of the price increases.[8] While the surrounding facts are not apparent from the CMA's press release, the fact that the parties were apparently able to sustain such rises, notwithstanding de-branding, appears to have raised suspicions. The CMA may also have been put under pressure by the UK government to act, given that the costs of NHS drugs are ultimately borne by the taxpayer. In an environment of ever-increasing medicine bills, this is an area of significant political interest that the CMA may have felt unable to ignore.

Next steps

The companies will now have an opportunity to rebut these charges before the CMA reaches a final decision. If the CMA confirms

its preliminary view that the parties infringed UK and/or EU competition law, it is likely to impose a (potentially substantial) financial penalty. The companies may also face 'follow-on' damages claims before the courts by purchasers of the affected drug.

As the largest purchaser, the NHS would be the most likely claimant and indeed has a track record of bringing such claims. For example, a number of High Court actions have been brought by the Department of Health (on behalf of the NHS), including claims against Servier following the European Commission's investigation and subsequent decision that the company had unlawfully delayed the generic entry of the cardio-vascular drug perindopril. (That litigation remains ongoing at the time of writing).

Based on previous cases, a final infringement decision by the CMA in this case may be up to a year away, if it comes at all. Since Pfizer and Flynn Pharma are likely to appeal any infringement finding by the CMA to the CAT, and potentially beyond, it may well be even longer before we see a final determination of this matter.

Notes

1. Case 27/76 *United Brands v Commission* [1978] ECR 207, 1 CMLR 429, at paragraph 250.
2. OFT decision of 30 March 2001 [2001] UKCLR 597
3. Case No 1000/1/1/01 *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1
4. Judgment of 2 February 2007, [2007] EWCA Civ 38.
5. In *Attheraces v British Horseracing Board* [2005] EWHC 3015 (Ch), judgment of 21 December 2005 (Etherton J).
6. Not including CAT judgments overturning competition authority non-infringement decisions and replacing them with infringement findings.
7. In addition to the *Napp* decision already mentioned, the OFT issued fining decisions for abuse of dominance against *Genzyme* in 2003 (for abusive bundling and margin squeeze) and *Reckitt Benckiser* in 2011 (for abuse of process). It is notable in this context that the CMA currently has an ongoing investigation into suspected anticompetitive agreements between GlaxoSmithKline and a number of generic manufacturers, concerning the supply of an antidepressant medicine. A decision in that case is expected soon.
8. The CMA will no doubt also have found it helpful to be able to use the earlier (lower) pricing as a benchmark for assessment of whether the higher pricing was excessive, following the approach approved by the CAT in *Napp*.