

## Recent pharmaceutical excessive pricing cases in context

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*Baker McKenzie global antitrust head **Fiona Carlin**, assisted by Washington, DC, partner **Creighton Macy** and Johannesburg partner **Nick Altini**, examines international trends in excessive pricing enforcement against high generic drug prices - and considers whether the recent spike in activity could be a sign that enforcers are expanding the definition of the infringement.*

In May 2017, the European Commission launched its first investigation into excessive pricing in the pharmaceutical sector, targeting several Aspen generic oncology products. It covers the entire EU with the exception of Italy, where Aspen was fined more than €5 million in 2016 for price hikes of between 250% and 1,500%; a court recently rejected an appeal against the Italian decision. The European Commission's intervention follows a number of recent investigations in the UK, and the announcement of a sector inquiry in France in July 2017. Whilst the parameters are not yet defined, the inquiry may look into regulatory pricing mechanisms as well as alleged instances of excessive pricing.

Is this recent flurry of activity a sign of emboldened authorities expanding the nebulous concept of unfair pricing that is expressly prohibited by article 102 of the Treaty on the Functioning of the European Union? Probably not. It is more likely an effort to correct market and regulatory failures that are enabling conduct that directly harms already strained national healthcare budgets. Understanding the context should ensure that these recent developments in Europe do not have undesirable international spillover effects.

### Context

Although high prices of innovative pharmaceuticals have made political headlines in recent years, competition authorities, for good reason, are reluctant to be arbiters of whether a price is reasonable - all the more so when it comes to the pricing of innovative medicines, so long as there is no "plus factor" of exclusionary conduct that evi-

dently does not meet the “competition on the merits” standard laid down by the European Court of Justice (ECJ) in *AstraZeneca*.

The launch of Gilead’s Sovaldi several years ago - at the time a breakthrough cure for hepatitis C - attracted negative press for its initial \$84,000 per patient price tag. But in 2014 and again in 2015, the European Commission declined to investigate complaints of excessive pricing. In its view, EU member states were using their economic bargaining power and their regulatory powers to contain the prices of Sovaldi and market forces would do the rest; several new antiviral products were at the time in advanced stages of development. EU competition commissioner Margrethe Vestager recognised the need for caution: “...when we do take action against excessive prices, we need to make sure we’re not taking away the rewards that encourage businesses to innovate”.

The Commission’s position has not fundamentally changed. Recent investigations, at least in Europe, stick to a consistent pattern of tackling generic price gouging - exploitative increases in the prices of off-patent medicines treating limited patient populations where it may be difficult to attract market entry. Such conduct signals a market failure and is fair game for competition authorities, and in line with stated policy. The Commission’s 2011 submission to the Organisation for Economic Cooperation and Development (OECD) made clear that: “[E]nforcement against excessive prices is generally only contemplated in markets with an entrenched dominant position where entry and expansion of competitors cannot be expected to ensure effective competition in the foreseeable future, that is markets where high prices and high profits do not have their usual signalling function to attract entry and expansion.”

## The legal test

The ECJ in *United Brands* established that a price is unlawfully excessive where “it has no reasonable relation to the economic value of the product supplied”. The legal analysis involves two steps. The first is a cost-price analysis: is the difference between the costs incurred and the price charged excessive? If so, is the price either intrinsically unfair, or unfair when compared to competing products? This is an alternative, not a cumulative test: the intrinsic economic value analysis identifies those cases where the unfairness of a price is readily apparent without the need to make any comparison with similar or competing products.

Some variation of this test is applied in most jurisdictions around the world. It requires a detailed analysis of the specific circumstances of each case. It appears straightforward in theory, but as the ECJ has recognised, it is complicated - but not impossible - to apply in practice.

The fact that a price generates a high margin is not conclusive of abuse. Measuring cost plus a reasonable profit margin may represent a baseline below which a price will not be considered excessive. But a price above that baseline is not necessarily abusive.

Several scenarios may be relevant for comparison purposes depending on the specific features of each case. These include: a comparison of the prices charged by the dominant company for the same product in other geographic markets, as in *Deutsche Post*; a comparison with prices that rivals charge in other markets, as in *Corinne Bodson v Pompes Funèbres*; and a comparison of prices charged by the dominant company over time if there are no good explanations for price increases.

The UK’s Office of Fair Trading applied this multi-faceted approach in its 2001 *Napp* decision. ECJ advocate-general Nils Wahl most recently confirmed in an April 2017 opinion that there is no one single method, test or set of criteria by which to judge whether pricing is excessive. He recognises that a cost-price analysis may not be suitable in relation to the supply of intangible goods such as copyrighted musical works, which were the issue in the case at hand. He recommends “combining several methods among those which are accepted by standard economic thinking and

which appear suitable and available in the specific situation”. When applied with rigour and objectivity, any convergence of results from the different tests may be taken as an indicator of a reasonable benchmark price.

Checking whether the price imposed is unfair when compared to competing products can be a “sanity check”. While theoretically any deviation from the benchmark competitive price may warrant intervention, this would “neither be realistic nor advisable”. A price should only be deemed excessive when it is both “significantly and persistently above the benchmark price”. This requires a case-specific analysis and an authority should intervene “only when it feels sure” that “almost no doubt remains” as to the abusive nature of pricing.

Wahl concludes that “...it is only when no rational economic explanation - other than the mere capacity and willingness to use market power even when abusive - can be found for the high price applied by a dominant undertaking that that price may be qualified as abusive.” This sets the bar for intervention at a high level, predicated on the existence of such significant entry barriers that profitable opportunities do not attract new market entrants.

The case law does not identify what the right level of pricing should be. Controversially, the UK’s Competition and Markets Authority came close to doing so in the recently published *Pfizer/Flynn* decision in which it indicated that a mere 6% return on sales would be a reasonable benchmark.

## **Pfizer/Flynn**

The CMA fined Pfizer £84.2 million and Flynn Pharma £5.2 million in late 2016, after concluding that they had increased pricing for phenytoin sodium capsules - an anti-epilepsy medicine - by as much as 2,600% without any apparent justification. It ordered the companies to lower their prices.

Pfizer had manufactured and marketed the medicine in the UK as Epanutin until it sold the UK distribution rights to Flynn Pharma in 2012. Pfizer continued to manufacture the medicine and sold it to Flynn at prices between eight and 17 times higher than its historic resale price. Flynn de-branded the medicine, which took it entirely outside of any price regulation. It subsequently resold the product at prices between 25 and 27 times higher than Pfizer’s historic price. Shortly thereafter, a new entrant (NRIM) entered the market and rapidly achieved a 30% share. The fact that the parties lost sales to NRIM was viewed as insufficient to constrain their pricing conduct given the reluctance of pharmacies to switch patients stable on their existing treatment.

The CMA’s application of the *United Brands* “economic value” test on a narrowly defined market is unsatisfactory since it equated economic value to such a low measure of cost plus that almost all pricing risks being categorised as abusive. 6% was the measurement of return that, at the time, companies were allowed to earn on their portfolio of branded medicines (both in-patent and off-patent) sold to the national health service under a voluntary price regulatory scheme. This approach takes no account of the value of the drug for patients and, although the CMA did not mandate a 6% return, its suggestion that this is a satisfactory benchmark leaves the door wide open to regulatory intervention.

The CMA also found that Pfizer’s prices were unfair in themselves, as well as in comparison to Pfizer’s Epanutin prices in other EU member states. It declined to conduct a full analysis of whether there were sufficiently similar competing products that would serve as a meaningful benchmark. It ruled out parallel imports and NRIM’s prices as suitable benchmarks on the grounds that they were set directly or indirectly by reference to Flynn’s (excessive) prices. It ruled out a comparison with Teva’s pricing of phenytoin sodium tablets on the grounds that those prices were not cost-justified and were also likely excessive even though it chose not to investigate Teva on administrative priority grounds.

The CMA declined to take into account any additional costs that would have been incurred by the NHS had Pfizer discontinued production, as this would allow companies with licences for essential or important treatments to charge supracompetitive prices under threat of withdrawing their products. The CMA also rejected Pfizer's claim that recovering its very high R&D costs required maximising profitability on all products, including off-patent products. It accepted that companies may properly seek to recover substantial R&D overheads through higher prices during the period of patent protection, but said it does not follow that manufacturers can demand or expect to sustain significantly supracompetitive prices afterwards.

The fact that Flynn's activities were limited to placing orders for the products with Pfizer and setting its own prices was also relevant. Flynn was not in physical receipt of the products at any time and had contracted out of many of its responsibilities as the holder of the marketing authorisation. For the CMA, there was no objective justification to explain the price hikes. It did, however, recognise that in other circumstances where substantial investment is made or substantial capital employed, or where there are significant commercial risks, a rate of return greater than 6% can be fully justified for the purposes of calculating the relevant measure of cost plus.

*Pfizer/Flynn* is a rare foray by a competition authority into pricing deemed intrinsically unfair in circumstances where the national health service had limited power to regulate the price of generic medicines and relied on competition to constrain prices; recent changes to the UK legislative regime have closed that particular loophole.

The ongoing UK investigation into Actavis also involves withdrawal from the voluntary price regulatory system with the effect that the public bill for generic hydrocortisone tablets increased from £522,000 in 2008 to £70 million in 2015.

The latest EU investigation into *Aspen* is a case of generic product price increases (up to 1,500% in Italy) without any ostensible cost justification. In the Italian case, Aspen was condemned for excessive pricing as well as the separate infringement of engaging in pricing negotiations with abusive intent in the form of threats to withdraw the products from the list of reimbursable medicines (which would have required patients to pay a high price for their life-saving treatment), or to withdraw the products from the market altogether if the Italian medicines agency did not agree to the price increases, as well as the simultaneous reduction of the availability of products in the market while the negotiations were ongoing. Similar threats of withdrawal triggered a preliminary investigation by the Spanish competition authority, which has now been subsumed into the EU investigation. These plus factors will no doubt weigh equally heavily with the European Commission.

### **Spillover beyond abusive generic pricing is unlikely**

There is a clear distinction to be made between patented and off-patent pharmaceutical products. Society legitimately expects to benefit from lower prices after patent expiry. However, reference to a benchmark of 6% return on sales in *Pfizer/Flynn* is worryingly low even in a generic context. It would clearly be an inappropriate benchmark for in-patent medicines, in line with advocate-general Wahl's opinion as to the inappropriateness of a cost-price test in relation to musical works.

When it comes to the innovative pharmaceutical sector, the European Commission recognises that the cost of capital is relevant, as is the fact that there are substantial R&D investment risks involved in developing products that may or may not reach the market (see its 2011 contribution to the OECD's excessive pricing roundtable). Consumers' perception of the economic value of a product is another legitimate part of the analysis (an element that was ignored in *Pfizer/Flynn*). A proper assessment of the economic value of innovative pharmaceutical products will take into account factors such as cost savings resulting from superior efficacy, fewer side effects and reduced overall treatment costs.

For these reasons, competition authorities in Europe are unlikely to investigate high originator prices, absent an obvious plus factor of regulatory abuse or some other manifestly harmful conduct.

## The international picture

The unilateral charging of excessive prices is not in itself an antitrust violation under US law, where there is a long-held view that denying a lawful monopolist the fruits of its monopoly can diminish its incentives to innovate in the first place. Despite continuing political calls to tackle high pharmaceutical prices in the US, initial probes into alleged excessive pricing have focused on off-patent products and have recently shifted to investigate alleged collusion and regulatory rather than pricing abuses. Unlike in the UK, there is no single regulatory loophole to close in order to resolve the issue of generic price gouging, and multiple attempts to find legislative solutions have so far been unsuccessful.

Outside of the US, most laws identify exploitative prices as problematic where high barriers to entry allow dominant companies to command excessive profits. But excessive pricing cases have been rare, and have mostly focused on semi-regulated sectors where incumbents enjoy infrastructure advantages over smaller rivals. Competition authorities universally seem to agree that excessive prices will ordinarily be self-corrected by the market. Intervention on competition grounds has been a measure of last resort, in the absence of other regulatory mechanisms better able to address an obvious market failure.

Until recently, Israel was a notable exception to the rule. Its antitrust enforcer adopted guidelines in 2014 that signalled it would not intervene against monopolies where the gap between cost and price did not exceed 20%. It has since returned to the fold, abandoning the questionable 20% threshold, and confirming that enforcement against alleged excessive pricing will be the exception rather than the rule.

Today, the one true outlier appears to be South Africa, which recently announced investigations into Aspen, Pfizer and Roche. The Competition Commission has no doubt taken its cue from the EU investigations into Aspen, but it is troubling that the authority appears to be targeting a yearly price tag of €35,000 per patient for Roche's innovative oncology product Trastuzumab, and an unspecified "unaffordable" price for Pfizer's innovative oncology product, xalkori.

The South African authority has taken on several other excessive pricing investigations. It has prosecuted only one such matter before the courts, which the Competition Appeal Court ultimately dismissed. While the authority remains without a winning precedent in excessive pricing, that has not prevented it from extracting settlement commitments in other cases - including a requirement to license generics in one pharmaceutical case.

The most recent investigation takes place in the context of the enforcer's long-running inquiry into the state of competition in the broader private healthcare market. Its objective is to find ways to lower the cost of private healthcare in an economy where the vast majority of the population currently cannot afford such care. The healthcare market is labelled a "priority sector" for the South African authority, and both it and government have been clear that competition regulation in South Africa, as a matter of policy, can and will be used to engineer socio-economic equality.

China's National Development & Reform Commission has also entered the fray. On 14 August, it published two decisions sanctioning local pharmaceutical companies for excessive pricing in relation to off-patent products, and issued draft pricing guidelines aimed at the pharmaceutical industry for public consultation. Its evolving approach to determining when prices are "excessive" is based on benchmarking to the price of competing products, as well as comparing price increases to increases in manufacturing costs. These developments take place in the context of wide-ranging drug price liberalisation, and concerns that this pricing freedom may be being abused.

## Conclusions

While social policy objectives may be laudable in the context of a developing economy facing significant affordability challenges, even in this context, competition authorities should be wary of harming innovation incentives and indeed the very availability of innovative medicines in their markets.

In developed markets, attempts to negotiate the best prices for truly innovative products are unlikely to attract scrutiny, even if they come with a stiff price tag, absent an evident plus factor that lowers the bar for regulatory intervention. Alleged abuses of the patent system and gaming the regulatory system are by now established examples of such plus factors; there is potentially a risk of this category expanding.

Companies divesting off-patent products need to think carefully about the risks inherent in mechanisms that link future revenue streams from continued manufacturing and supply arrangements to the purchaser's onward sales price.

The floodgates have not opened. But the sector is on notice that pricing scrutiny by competition authorities is not a passing fad.