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The Competition Appeal Tribunal's judgment in Pfizer/Flynn—when is a high price unfair?

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Introduction

Excessive pricing cases have traditionally been rare. However, at least in the pharmaceutical sector, this has changed in recent years. In December 2016, the Competition and Markets Authority (CMA) found that Pfizer and Flynn had each abused a dominant position by charging the National Health Service ("NHS") unfair prices for the capsule form of an anti-epilepsy drug ("AED") called phenytoin sodium. The CMA ordered them to lower their prices and imposed record fines totaling nearly £90 million.

Moreover, the *Pfizer/Flynn* case was the tip of the iceberg. The CMA issued a statement of objections to Actavis in late 2016 and one to Concordia in late 2017 relating to unfair prices for generic pharmaceuticals. The CMA's website also indicates that in 2017 it launched further investigations relating to "suspected abuse of dominance in relation to the supply of certain generic pharmaceutical products". The pricing of generic drugs has also been investigated by other competition authorities, with the European Commission opening a similar investigation in 2017 into Aspen Pharma.

Pfizer and Flynn both appealed to the Competition Appeal Tribunal ("CAT"). In June 2016, whilst the CAT upheld the CMA's finding that each firm held a dominant position, it concluded that the CMA had not correctly applied the legal test for finding that prices were unfair.

This article focuses on several key parts of the CAT's judgment, namely:

- **Market definition:**

  The evidence that the CAT relied on to conclude that NRIM, a new supplier of chemically identical phenytoin sodium capsules, should be excluded from the relevant market. This conclusion naturally implied that the parties would have a dominant position by excluding all other alternatives (bar limited volumes of parallel imports), absent any other countervailing factors.

- **Dominance and buyer power:**

  Why the CAT concluded that the NHS did not have countervailing buyer/regulatory power, which might otherwise have meant that the parties were not dominant. In particular, the CAT rejected arguments that the government already had the power to require prices to be reduced.

- **Abuse and analysis of pricing:**

  Why the CAT concluded that the CMA had not demonstrated that Pfizer's and Flynn's prices were either excessive or unfair. Both of these points needed to be established for an abuse finding to be sustained. This was notwithstanding that NHS expenditure on phenytoin sodium capsules rose from about £2 million a year in 2012 to about £50 million in 2013 due to large prices increases. For example, the Drug Tariff price of 100mg packs of the drug increased from £2.83 to £67.50.

This article also considers the wider relevance of the judgment, both in the pharmaceutical sector and more generally. In particular, the CAT's judgment also raises broader questions about the scope of the CMA's investigations—including its willingness to ask detailed questions of third parties.

Market definition

Concepts

Before addressing the specific points raised on appeal, it should be noted at the outset that the CMA's decision accepted that the product market definitions it had applied were "very narrow".

The CMA excluded all other AEDs. This was notwithstanding that the capsule version of the drug had lost sales to other AEDs, and it is typically not prescribed to new patients. The CMA also excluded the tablet version of the same drug. In short, there was no evidence that substitution to these alternatives constrained the parties' prices (more on this below).

The appeal relating to market definition focused on the narrow question of whether the CMA was correct to exclude phenytoin sodium capsules supplied by a new entrant ("NRIM"). NRIM had launched another generic version of the capsule in April 2013. The CMA argued

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that NRIM should be excluded entirely, or (on the basis of the CMA's alternative market definitions) after November 2013.

The issue of market definition was potentially relevant to the duration of any finding of dominance as the infringement period found by the CMA was from 24 September 2012 to at least the date of the CMA's decision on 7 December 2016. However, the CMA found that Pfizer and Flynn had dominant positions over the entire period, including after NRIM's entry.

In other situations, competition authorities have found that the relevant market included other drugs that were used to treat the same condition. For example, in a merger control context, competition authorities might be concerned about the loss of rivalry due to mergers between actual and potential suppliers of alternative drugs that are used to treat the same condition, and typically are likely to start from the premise that at least versions of the same molecule of the drug compete.[1] However, this was not the factual background here for two reasons.

First, the conceptual issue on which market definition is based is whether a hypothetical monopoly supplier could profitably increase prices by a small but significant non-transitory amount (which is commonly referred to as the SSNIP test), which is usually considered to be 5–10 per cent. In the present case, Pfizer and Flynn had collectively increased prices very sharply (as noted in the introduction). This suggested that substitution to alternatives was not a sufficient competitive constraint.

Secondly, a key feature limiting substitution was the importance of stabilised patients staying on the same AED for medical reasons, which both limited substitution to other AEDs and (subject to a consideration of the facts) even substitution to another manufacturer's phenytoin sodium capsules. This feature was highly relevant to the degree of rivalry from NRIM, with the CMA considering that any (limited) competition from NRIM reduced sharply after November 2013. This is because, in November 2013, the Medicines and Healthcare Products Regulatory Agency ("MHRA") issued new guidance (the "MHRA Guidance") that emphasised the importance to patients of "Continuity of Supply" in the sense that patients stabilised on one manufacturer's phenytoin sodium capsules should not be switched to another manufacturer's capsule.

These points supported the concept that market definitions may be very narrow indeed—excluding even chemically identical NRIM capsules.

Evidence v concepts—how much competitive interaction is sufficient to define a market more broadly?

However, the CAT's approach to assessing these issues focused in some detail on the underlying factual evidence in terms of:

(a) to use the CAT's words, "what pharmacists actually did"; and
(b) evidence of overall switching and price rivalry from NRIM.

The CAT's emphasis on these points is noteworthy. In a range of competition investigations, competition authorities typically solicit the views of customers on the market, the products and services they choose between, and the nature and importance of rivalry between different suppliers. However, a fair question to ask is what weight should be attached to customers' general responses and what sort of testing of these responses should be carried out. In particular, even in responding to authorities' formal legal notices, customers' views may be expressed in high-level terms, without necessarily also providing detailed factual information that confirms the completeness and accuracy of their answers. In other words, there may be a gap between customers' descriptions of how they behave, and their choices and reality.

This seemed a highly pertinent issue in this case for two reasons. First, the CAT noted that even after the publication of the MHRA Guidance, which is aimed at doctors (not pharmacies), the proportion of prescriptions for phenytoin sodium capsules in England that were "open" (i.e. do not specify a particular brand or manufacturer's product) increased from 62 per cent in the first eight months of 2012 (before Flynn began distributing phenytoin sodium capsules in the UK) to 91 per cent over the period April 2014 to March 2015. Secondly, pharmacies have a strong commercial incentive to dispense the cheapest drug in response to an open prescription.

In considering pharmacists' behaviour, the CAT observed that the CMA's decision gave the impression that pharmacies complied with the Continuity of Supply principle, based on the policy statements that certain pharmacy chains made in response to the CMA's s.26 notices. The exceptions to this cited in the decision were Boots and Lloyds, two of the largest UK pharmacy chains. Prior to November 2013 they had switched to dispensing NRIM capsules and together accounted for the majority of NRIM's sales. Both these chains confirmed that *after* the MHRA issued its guidance in November 2013 they reverted to observing Continuity of Supply.

[1] The European Commission's approach to market definition in the pharmaceutical sector has proved to be highly fact specific but also evolving. In the past, the Commission has often referred to the third level of the Anatomical Therapeutic Classification (ATC) as the starting point for the purposes of defining the relevant product market. However, in a number of cases, particularly concerning genericised products, the Commission found that the ATC3 level classification did not yield the appropriate market definition. The Commission has also defined the relevant product market at a narrower level, including at the ATC4 level or at the level of the "molecule" (i.e. active ingredient) or group of molecules that are considered interchangeable from a therapeutic perspective and between which there are proven economic substitution patterns so as to exercise competitive pressure on one another (see, for example, *Pfizer/Hospira* (2015), *Mylan/Perrigo* (2015), *Teva/Allergan Generics* (2016) and *J&J/Actelion* (2017)).

However, the evidence available to the CAT suggested that the situation was more "nuanced" and "mixed". In particular, the CAT cited one example identified by Pfizer relating to Morrisons, which stated in its reply to the CMA's s.26 notice that its wholesaler would supply the cheapest option unless the patient/prescription required a specific brand to be ordered, and this was typically not the case (as noted above). In addition, the CAT referred to a Kantar survey that suggested that 67 per cent of pharmacists surveyed would respond to an open prescription by dispensing the brand that they had in stock. The CAT downplayed this survey result as only 11 per cent of respondents stocked NRIM's capsules.[2]

The CAT concluded that pharmacy chains' statements of policy should be considered "in the round" as part of the overall body of evidence, but they cannot in themselves be conclusive evidence of actual dispensing behaviour.[3]

However, the CAT accepted that this evidence was supported by evidence from the new entrant, NRIM, on its sales and ability to grow its business after the MHRA Guidance was issued. This factual evidence from the only rival would seem highly relevant.

In the round, the CAT concluded that, whilst Continuity of Supply had a significant impact on pharmacy dispensing, the position was more equivocal than suggested by the decision as there was still some switching from Flynn to NRIM after the publication of the MHRA's Guidance.

The CAT appeared to attach greater weight to whether NRIM imposed a competitive constraint overall across the whole market. To this end, the CAT considered trends in Pfizer's and NRIM's prices and sales over time. Overall, the CAT concluded that their competitive interaction was "limited in scope and effect", with Continuity of Supply limiting actual switching and NRIM did not seek to compete with Pfizer beyond a certain point (e.g. as NRIM only supplied one capsule size and targeted a certain market share level). Ultimately, the CAT agreed with the CMA that the market should be defined to exclude NRIM's capsules.

The CAT is not explicit about what degree of competitive interaction would have been sufficient to include NRIM with the market, but it stated explicitly that the volume of switching observed was not sufficient itself and there was only relatively limited price interaction after entry. In particular, NRIM's average selling price at launch was well below Flynn's, but Flynn did not respond until nearly a year later and this price reduction was (at best) only in part in response to price competition from NRIM.

As regards the volume switching to NRIM, this would certainly seem to be material. Whilst there seems to be uncertainty as to market shares, NRIM is reported in the CAT's judgment as having increased its volume market share from entry in April 2013 to 12 per cent overall (and 17 per cent of 100mg capsules) by the end of Q3 2013 and to 21 per cent overall (and 28 per cent of 100mg capsules) by the end of Q2 2014. Accordingly, there was no dispute that NRIM won sales from Pfizer/Flynn. In addition, these figures rather suggest that NRIM had grown its market share *even after* the MHRA Guidance was issued that emphasised the importance of Continuity of Supply. Accordingly, it is surprising that the CAT attached little weight to the actual switching observed.

Turning to the CAT's assessment of price competition post-entry, this raises the question of what should be expected. The CAT rejected evidence that the pattern of volume and price changes observed was similar to that observed when drugs come off patent, asserting that this is not analogous to the case at hand. Even if this is correct, there is no simple economic benchmark as to what pricing response (if any) should be observed from an incumbent supplier following the entry of substitutes. This is particularly where such entry was anticipated by the incumbent supplier, as was the case here.

A more direct way of considering what degree of competitive responses would be sufficient would be to return to the conceptual question of whether a hypothetical monopoly supplier would find a small price increase to be profitable. In this regard, the CMA had clear documentary evidence that in assessing the large price increase Pfizer planned, it expected to lose material sales to new generic entry and parallel imports, but that this would not be sufficient to render the price increase unprofitable. However, these high prices are likely to have influenced NRIM's entry decision. Moreover, high-priced branded suppliers might not find it profitable to cut their prices substantially even in response to large-scale entry.

One of the consequences of this approach to market definition is that potentially NRIM is also dominant, notwithstanding its low overall market share. It could be observed that it is a price taker (i.e. discounted off Pfizer/Flynn's prices), but this is arguably not conceptually different to Pfizer/Flynn setting their revised capsule prices by reference to the more expensive tablet prices.

Dominance

Turning to the issue of dominance, on appeal, one point put forward and assessed by the CAT was whether the Department of Health had sufficient countervailing buyer power in the form of regulatory power to prevent Pfizer/Flynn from possessing dominant positions. However, before addressing this point, it is appropriate

[2] It is understandable that the CAT downplayed the survey result since the majority of the pharmacies surveyed did not stock NRIM's capsules. However, it would have been interesting to explore why the pharmacies did not stock NRIM's capsules. Given NRIM's 17–28 per cent share of 100mg capsules (depending on the time period considered), it may be the case that more UK pharmacies stocked them than was the case as regards the survey respondents.

[3] The CMA also considered detailed evidence on sales by a leading pharmaceutical wholesaler, Alliance. However, the value of this data is reduced as in May 2014 Flynn ceased to supply Alliance, and thus Alliance's sales cannot be informative as to possible switching after this date.

to consider the CAT's overall assessment of the issue of dominance, since this puts the assessment of countervailing buyer power in context.

The overall context of the dominance finding

Given the approach taken to market definition (as described above), Pfizer and Flynn each had a virtual monopoly position in the manufacture and distribution of Pfizer's phenytoin sodium capsules over the whole period, bar some limited parallel imports (with these supplies being uncertain). Accordingly, it was straightforward for the CAT to observe that, save for exceptional circumstances, high market shares are in themselves evidence of a dominant position.

The CAT also accepted the CMA's finding that Pfizer's and Flynn's pricing behaviour of substantially increasing prices indicated that they were not constrained to an appreciable extent by their customers and competitors. In reaching this conclusion, the CAT emphasised that it was not prejudging whether Pfizer's and Flynn's prices were excessive and unfair so as to infringe competition law.

The CAT indicated that it attached less weight to profitability as an indicator of dominance, but accepted that Pfizer's and Flynn's profits were high following the price increases.

As regards competition from NRIM, the CAT observed that NRIM did not operate in the same market and it offered only limited competition due to its commercial strategy.

The CAT accepted that the Continuity of Supply principle created high barriers to entry.

Did the Department of Health have countervailing buyer power?

The points discussed above set into context the CAT's analysis of the only point considered on appeal as regards dominance, namely whether the Department of Health had sufficient countervailing buyer power such that Pfizer and Flynn were not dominant.

The CAT could have simply observed that the parties had implemented a very large price increase. However, the CAT's analysis was more nuanced. The CAT indicated that the relevant legal standard for finding sufficient countervailing buyer power was not merely "theoretical" capability, "but there has to be a real possibility that this pressure will be excised in practice and to a sufficient constraint". Accordingly, the CAT expressed the issue in terms of "real possibility", not requiring actual evidence of buyer power already being exercised—albeit that actual observed behaviour would obviously be compelling evidence.

In the present case, the substantive issue was whether the Department of Health had buyer power through regulatory power, such as by the ability to impose or threaten to impose price controls, notwithstanding that the capsules were a generic drug outside the scope of the PPRS. In support of this point, Pfizer referenced what had happened when another supplier, Teva, had increased by approximately 67-fold the price of its phenytoin sodium tablets in October 2007.

The CAT discussed the fact that Teva had initially increased the price of a pack of its phenytoin sodium tablets sharply from £1.70 (when they were subject to price caps) to £113.62. However, around this time, Teva had a meeting with the Department of Health, and following this the pack price was gradually reduced to £30. This raised several follow-up questions that the CAT did not address, namely precisely the regulatory or legal mechanism that the Department of Health could have applied (by extrapolation) to reduce the price of Pfizer's/Flynn's phenytoin sodium capsules, and whether the reduced prices for tablets were fair or otherwise reasonable.

Instead of addressing these issues, the CAT focused on the actual discussions between the Department of Health and Pfizer and Flynn concerning the price increases for Pfizer/Flynn's phenytoin sodium capsules. In this regard, the CAT observed that there was no evidence that Pfizer/Flynn's conduct was in practice constrained by actual or anticipated intervention from the Department of Health. This seems a reasonable conclusion since the price increase was not moderated in any way following these discussions, and no regulatory intervention was implemented by the Department of Health despite its concerns.

Does the Department of Health now have countervailing buyer power?

The CAT did not need to address this issue. However, it may be the case that the Department of Health would now have countervailing buyer power, because its statutory powers to impose price controls for health service medicines have been extended by the Health Service Medical Supplies (Costs) Act 2017. Indeed, in commenting briefly on fines, the CAT also observed that it would have closely scrutinised the CMA's large uplift in Pfizer's fine that was imposed for deterrence purposes given these new price control powers granted to the Department of Health.[4]

[4] The CAT also observed that the uplift for deterrence imposed on Pfizer was inconsistent with the CMA's Guidance on penalties.

Analysis of abuse and pricing

The CAT started its analysis of unfair pricing by setting out what it considered to be the key legal principles to be taken from the European Court of Justice's (ECJ) judgment in *United Brands*, and the further elaboration of these principles by Advocate General Wahl in *Latvian Copyright*.[5]

In summary, the CAT broke down these issues into a number of principles.

First, the dominant undertaking must have "reaped trading benefits" that it would not have earned under conditions of "normal and sufficiently effective" competition. The CAT emphasised that that the ECJ does not refer to perfect competition as the benchmark.

Secondly, the price complained of must bear "no reasonable relation" to the "economic value" of the product supplied. To assess this issue, the ECJ set out a two-limb test:

1. The price must be "excessive". In *United Brands*, the ECJ said that this could be calculated as the difference between the cost of production of the product and the selling price (which the CAT defined as the "Excessive Limb"), but in principle this could also include a consideration of the prices of other benchmark products; and
2. The price must be "unfair" either in itself (which the CAT defined as "Alternative 1") or when compared to competing products (which the CAT defined as "Alternative 2") (which the CAT overall described as the "Unfair Limb").

The CAT also emphasised that the ECJ noted that unfair pricing could be determined in "other ways", and the CAT argued that there also needed to be "an over-arching assessment".

Whilst the CAT is careful to make clear that it has made no finding as to whether there has been an abuse by Pfizer or Flynn, it disagreed with the CMA's legal analysis relating to both the Excessive and Unfair Limbs. This is notwithstanding that the CAT had regard to the magnitude of the price increases and the parties' high profits in drawing its conclusions that the parties had dominant positions.

The Excessive Limb (1)—the PPRS is not a sufficient as a benchmark of normal competitive prices

Considering first the Excessive Limb, the CAT was critical of what it described as the CMA's "Cost Plus" approach where it takes the costs of Pfizer and Flynn and adds a return on sales or capital employed based on certain returns permitted under the PPRS relating to a supplier's portfolio of branded drugs. In short, the CAT advanced two objections:

- A Cost Plus approach is not necessarily sufficient to establish the excess under the Excessive Limb "if other methods are available and, particularly, if they suggest different results". Here, the CAT was clearly referencing the prices of tablets as being a potentially relevant benchmark.
- There must be a benchmark for normal competitive prices, and this benchmark was not idealised or perfect competition. The CAT appears to envisage the CMA examining various possible comparator companies and products (attaching more or less weight to certain comparators, as appropriate) and relying less on returns permitted under the PPRS. The CAT considers that it is sufficient for the authority to establish a range from "available and informative benchmarks" and see if such a comparison of prices or profits "points clearly" to there being excessive pricing.

Already at this juncture it is clear that the CAT considers that the CMA's findings on the Excessive Limb are unsound, which is sufficient to compromise the CMA's overall case. Nevertheless, the CAT considered further whether the PPRS was a suitable benchmark within the scope of the CMA's Cost Plus analysis. In particular, the CAT observed that the PPRS appears to have decreasing relevance as the pharmaceutical industry becomes less UK orientated, and the Department of Health itself had expressed reservations about the 6 per cent return on sales figure being an appropriate benchmark.

The CAT observed that the PPRS applies to a portfolio of products, rather than any individual one. However, the CAT considered that phenytoin sodium capsules should be at the lower end of return of this portfolio, no doubt reflecting that this was an old product first commercialised in 1938 and has been superseded by newer AEDs for the treatment of new patients.

[5] The CAT also separately addressed Pfizer's argument that it could not have abused a dominant position by virtue of its vertical arrangement with Flynn. The CAT rejected this line of argument for a number of reasons. In particular, as a factual matter, Pfizer's input pricing to Flynn set a price floor below which Flynn would not go, and this line of argument would suggest that dominant firms could avoid claims of excessive pricing by appointing a distributor to sell their products. However, this was clearly an ancillary line of argument to the fundamental issue of what constitutes unfair pricing.

The Excessive Limb (2)—prices in other countries and previous prices under the PPRS are not a suitable benchmark of normal competitive prices

The CMA argued that, notwithstanding that other European countries had their own specific regulatory regimes, prices in other European countries were so much lower that it was "unlikely" that these prices differences were justified.

The CAT rejected this view as the CMA had not considered at all whether prices were low in other European countries due to government measures, or different economic or regulatory conditions. This would seem logical as if the PPRS is not a sufficient benchmark for normal competitive prices in the UK, then it is far from obvious that regulated prices in other countries would be an appropriate benchmark for normal competitive prices.

The CAT also dismissed the magnitude of the price increase as providing any basis to assess whether prices were excessive, even if this may be indicative of an abuse of a dominant position that may warrant investigation. In particular, the CAT emphasised that the CMA had not argued that the "before" price reflected normal competition, and it should be borne in mind that Pfizer claimed that its "before" prices under the PPRS were not profitable.

Both of these points were particularly emphasised by the CAT in its analysis of whether prices were unfair.

The CMA's overall conclusions on the Excessive Limb

Overall, the CAT tentatively concluded that the CMA's theoretical approach "may understate" the appropriate benchmark price for Pfizer and thus the assessment of whether its price was excessive, but it cannot determine whether this is the case based on the information available to it.

Turning to Flynn, the CAT considered, and rejected, Flynn's criticisms of the CMA's cost allocations that were used to assess Flynn's profitability. However, the CAT held that the CMA should have placed less weight on the PPRS for identifying an appropriate return on sales and should have considered "more closely the comparator companies identified by Flynn, amongst other factors, appropriately weighted, to establish the right benchmark price".

The CAT also highlighted that any assessment of whether Flynn's prices were excessive based on reasonable comparisons would need to have regard to the fact that Flynn's input price (i.e. Pfizer's price to it under its supply agreement) was "very high". This is important as any return on sales calculation will suggest lower percentage returns for distributors, such as Flynn, as their drug input prices increase.[6]

The Unfair Limb—the presumption of innocence means that potentially relevant alternative comparisons should be explored

The CAT emphasised that it found that the CMA wrongly relied on Alternative 1 (unfair in itself) in assessing unfairness under the Unfair Limb and did not properly consider the possible impact of meaningful comparators (in particular, the tablet version of the same drug) under Alternative 2 (unfair compared to competing products) to assess whether prices were unfair.

The CAT found that the authority must consider whether a prima facie case of fairness under one alternative undermines the basis for the finding of unfairness under the other alternative. The CAT accepted in some cases a cost-plus methodology or only one alternative may be feasible or overwhelmingly superior, but that the authority could not disregard other valid methods to determine counterfactual, normal competitive prices. The CAT stated that:

> "This is necessary not only as a matter of logic but also in order to accord with the burden of proof and the presumption of innocence".

The CAT's view is consistent with Advocate General Wahl's opinion in *Latvian Copyright*[7] that, in order to avoid false negatives and positives, a competition authority needs to consider which approach, or combination of approaches, is more appropriate for the market it is considering and the relevant facts. He added that the method applied and other indicators must give the authority a complete and reliable set of evidence that all points in one direction: the existence of a significant and persistent differential between the hypothetical benchmark price and actual prices.

The CAT's focus was on whether tablets might be a suitable comparator, and it considered that this issue should have been explored further. This was notwithstanding that the CMA accepted that tablet prices might themselves be excessive due to Teva's price increase (and tablet prices were also affected by the Continuity of Supply principle). Indeed, the CAT stated that if prices and market conditions between the product in question and the comparators are similar, then this "might suggest either that all of the prices are unfair, or that none are". The CAT also accepted the CMA's point that cost information may be required to compare tablet and capsule prices, but rejected the CMA's view that it should not bear the burden of obtaining this information. The CAT observed that undertakings accused of abusing

[6] For example, if a distributor faces an input price of £1 for a drug and achieves a 10 per cent margin then its margin in absolute terms is only 10p. However, if the input cost of this drug increases to £10, then a 10 per cent distribution margin (of £1) may be high.

[7] *Biedriba Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome* (C-177/16) EU:C:2017:286.

a dominant position cannot be expected to obtain information on other companies' costs. This seems entirely reasonable.

At this juncture, there would appear to have been a relevant piece of evidence missing. Pfizer and Flynn emphasised that the Drug Tariff Price (i.e. the key price which determines what the NHS pays for drugs) for their capsules was deliberately set materially below the Drug Tariff Price for Teva's tablets. However, the CAT appeared to consider that average selling prices (ASP) (i.e. the net prices that Flynn and Pfizer receive) would seem a more appropriate basis for comparisons, and recent new entry in the supply of tablets might have reduced the ASP of tablets below Flynn's ASP. The CAT was clear that it did not have sufficient information to reach a conclusion on this point. However, it seems reasonable for the CAT to observe that this information could have been relevant to inform the assessment of the benchmark price of normal competition and whether prices are unfair, but this is a matter for the CMA.

The CAT concluded that the case for meaningful comparisons with other AEDs is less compelling than for tablets as they differ as products and the CMA had no data on their costs. In our view, if tablets did not exist, then we would speculate that other AEDs—particularly off patent AEDs—could potentially be relevant comparators.

The CAT also emphatically rejected price comparisons over time and across Member States as indicators of unfairness for the reasons discussed above.

The CAT's conclusions on abuse—the unanswered question of what is economic value

The CAT concluded that the issue of whether prices bore no reasonable relationship to economic value was most appropriately addressed after the assessment of unfairness, with this being part of the overall abuse assessment.

Pfizer criticised the CMA for relying solely on supply-side factors, based solely on cost considerations, to assess economic value, and thus ignoring anything to do with the demand side. In this regard, in *Scandlines* the European Commission specifically envisaged that the economic value of port services also included the economic value to customers of the ports being able to make the shortest/fastest journeys.[8] Similarly, in *AttheRaces* the English Court of Appeal envisaged that prices could exceed cost without being unfair.[9]

The CAT was critical of the CMA asserting that there was no economic value to the products beyond that captured by the CMA's Cost Plus calculation (with the CAT adding that it was "irrelevant" in this regard that the drug had been off-patent for a long time), with the CMA seeking to justify this view based on patients' dependency on the drugs (following the Opinion of Advocate General Jacobs in *Tournier*, albeit in the context of assessing different issues).[10]

The CAT was explicit that the CMA cannot re-present its findings under the Excessive Limb to justify a finding of unfairness. Such an approach would render "largely otiose the clearly separate Unfair Limb". This conclusion is entirely consistent with Advocate General Wahl's opinion in *Latvian Copyright* that the Unfair Limb is a separate test, and requires an objective assessment of the dominant undertaking's behaviour and its motives.

The CAT's view was there is some economic value from the capsules treating patients, even if this is reduced by some patient dependency on the drugs. The CAT envisaged that a "qualitative" assessment should have been attempted by the CMA. The CAT indicated that comparators may be informative as a guide to what products are worth in economic value terms. However, the CAT rejected the argument that it should somehow award all of the economic value to Pfizer (and none to Flynn). It also rejected the argument that the economic value could somehow be proxied by the saving the NHS makes by capsule patients not buying more expensive tablets. This seems reasonable as economic value cannot simply be what customers are willing to pay, since even absolute monopolists will have regard to this in setting their prices.

However, this leaves unanswered how economic value should be assessed.

In this regard, Advocate General Wahl envisages Alternative 2 as a "sanity check" of the Excessive Limb, particularly where there are elements that cannot be factored into the Excessive Limb or where economic value would be higher than the benchmark. This line of argument might suggest that economic value exists where firms have added more value to consumers than suggested by simply considering their costs of supply plus a normal profit margin, *and* where such higher prices may be observed in normal competitive markets. In this regard, even in normally competitive markets, prices can (and will) exceed costs in a wide range of circumstances. For example:

- prices for intellectual property will typically exceed the actual cost of delivering that property. For example, the horse racing data that was the subject of the dispute in *Attheraces* was the product of considerable investment across the whole racing supply chain;
- high prices may be a reward to innovation and/or risk taking;
- high profits may be a reward to superior efficiency;

[8] *Scandlines Sverige AB v Port of Helsingborg* (COMP/A.36.568/D3) [2006] 4 C.M.L.R. 23.
[9] *Attheraces Ltd v British Horseracing Board Ltd* [2007] EWCA Civ 38.
[10] *Ministère Public v Tournier* (C-395/87) EU:C:1989:215.

- in competitive markets, high prices are part of the price mechanism to signal that new entry and expansion is profitable. Entry does not necessarily mean that the incumbent's prices fall immediately to the competitive level. Instead, over time, the competitive process leads to customers switching to lower-priced sources of supply; and
- similarly, prices may be high at a specific point of the business cycle to reward firms for their investments in capacity that will not be fully used at times of low demand.

A relevant consideration in the present case is what pattern of prices is "normal" in small and declining markets, and should this be part of assessments of economic value? In some markets, firms will exit small and declining business segments for strategic reasons, and management want to focus on larger core businesses and where there are risks associated with these declining markets. Pfizer was clearly reluctant to exit, not least as this would have had reputational and patient consequences. However, it does raise the question of whether some uplift above costs and a normal competitive margin would be appropriate to reflect such considerations.

A broader approach to economic value than simply Cost Plus would appear to be consistent with Advocate General Wahl's view that price will only be abusive under art.102 if it is significantly above the benchmark price and there is no rational economic explanation for the high price other than capacity and willingness to exploit market power.

Future developments

The CAT's provisional view was that it should remit the issue of abuse back to the CMA for further consideration. Unsurprisingly, the CMA expressed disappointment in the CAT's judgment (including that the CAT would not take its own decision), and on 28 June 2018 the CMA applied to the CAT for leave to appeal to the Court of Appeal. The CMA emphasised that this case has wider implications, because it has several active investigations related to excessive generic drug pricing that may now be "severely delayed". Accordingly, this case will be of wider relevance, both in the pharmaceutical sector and more generally.

On 25 July 2018 the CAT refused all parties leave to appeal and remitted the issue of abuse and other consequential matters to the CMA for consideration. The CAT's judgment also makes clear that the CAT considers there is no reason why other CMA cases should be delayed pending possible hearing of the *Pfizer/Flynn* case before the Court of Appeal. Should the Court of Appeal hear the case, the CMA would need to win on both the Excessive and Unfair Limbs for the CMA's original decision to stand. This would appear to be challenging for two key reasons. First, it is not obvious that the PPRS provides a good measure of normal competitive prices for generic phenytoin sodium capsules.

Secondly, the CAT also clearly saw the potential appeal of considering whether the tablet version of the same drug might be an informative comparator, and also considered that the presumption of innocence suggested that the CMA should explore various comparisons further to assess whether prices are unfair. Addressing this point would require the CMA to obtain detailed information from suppliers of other comparators on their prices and profit margins.

Both of these points will also need to be considered carefully by the CMA in the context of its other pharmaceutical investigations.

Johannes Laitenberger, Director-General of Competition at the European Commission, gave a speech on 22 June 2018 at the Florence EUI Competition Workshop in which he expressed alternative views of the legal standard for unfair pricing set out in the CAT's judgment. In particular, he considers that the CAT has gone further than the *United Brands* test for unfair pricing by appearing to require thorough benchmarking at both stages of the test (excessiveness and unfairness), including a detailed explanation as to why certain potential benchmarks are not considered. This point will no doubt be actively debated on appeal. However, as discussed above, on the facts of the case, the CAT had reservations as to the weight that should be attached to the PPRS as a good benchmark to determine normal competitive prices, which raises an obvious question as to whether other benchmarks might be appropriate and the CAT considered in some detail why such comparisons may be relevant.

This leads to two final legal, economic and policy questions: namely how high should the bar be for an authority to sustain a finding of unfair pricing, and what degree of investigation is sufficient to address the legal presumption of innocence.