ESTABLISHING UNFAIRLY HIGH PRICES: THE IMPLICATIONS OF THE CAT'S JUDGMENT IN *FLYNN AND PFIZER v COMPETITION AND MARKET AUTHORITY*

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Introduction

On 7 June 2018, in *Flynn and Pfizer v Competition and Market Authority*,[1] the UK Competition Appeal Tribunal (CAT) partly set aside the Competition and Market Authority (CMA)'s decision[2] fining Pfizer and Flynn nearly £90 million for charging unfairly high, or excessive, prices for phenytoin sodium capsules (an anti-epilepsy drug) in breach of EU and UK competition law – Article 102 of the Treaty on the Functioning of the European Union (TFEU) and Chapter II of the Competition Act 1998. The CAT's judgment, and decision to remit the matter to the CMA,[3] is a significant blow for the CMA which, whilst assessing the wider implications of the ruling for this and other similar cases[4] it is in the process of investigating, has been granted leave to appeal against it.

The CMA's decision in *Pfizer and Flynn* was controversial. Even though both Article 102 and Chapter II[5] expressly prohibit the imposition of 'unfair purchase or selling prices' by dominant undertakings, and the European Court of Justice (ECJ)'s 1978 judgment in *United Brands*[6] confirmed that it is illegal for a dominant firm to charge a price which is excessive because it has no reasonable relation to the economic value of the product supplied, there has been relatively little enforcement against such conduct in the EU. Indeed, the question of whether, and if so when, competition law should intervene to control exercise of significant market power purely through exploitative behaviour and the extraction of rents through excessive or unfairly high pricing, is keenly contested.

In some jurisdictions, there is reluctance to condemn monopoly prices at all, unless accompanied by some exclusionary or deceptive conduct.[7] In the United States, for example, high prices are ordinarily seen as providing the incentive for competition and innovation, the reward for winning the competitive battle and a signal for new entry into a market.[8] The basic premise of this 'laissez faire' or 'hands-off' approach is that 'most markets are competitive and monopoly tends to be self-correcting. But even when markets are not competitive, it is believed that the costs of regulation are likely to outweigh its benefits'.[9]

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1) Cases 1275–1276/1/12/17 [2018] CAT 11.

2) Case CE/9742–13, December 2017.

3) Cases 1275–1276/1/12/17 [2018] CAT 12.

4) For example, it has issued a statement of objectives to Actavis for allegedly de-branding and increasing the price of 10 mg hydrocortisone tablets by 12,000 per cent and is investigating Concordia International's alleged practice of buying licences to patented drugs, de-branding them and raising prices by up to 600 per cent.

5) Chapter II is modelled on Article 102.

6) Case 27/76, *United Brands v Commission* EU:C:1978:22, para 250. See also, more recently, Case C–177/16, *AKKA/LAA* EU:C:2017:689, para 36.

7) 'Under this approach, competition authorities can address the acquisition of dominance under the exclusionary abuse provisions and merger control rules, but cannot call into question the high prices charged by what may be called a "pristine monopolist"', OECD Policy Roundtables, Excessive Prices, DAF/COMP(2011)18, 11.

8) Purely exploitative conduct through high pricing is not prohibited by Sherman Act 1890, section 2 (monopolization laws), *Verizon Commc' ns, Inc v Law Offices of Curtis V. Trinko*, LLP 540 U.S. 398 (2004). An important question, however, is the extent to which the Federal Trade Commission Act, section 5, which provides the Federal Trade Commission (FTC) with a broad mandate to prohibit '[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce', applies beyond the reach of practices prohibited by the Sherman (and other antitrust) statutes. Indeed, the FTC previously manifested concern about excessive pricing (i) in the sphere of IPR (*In the Matter of Motorola Mobility LLC and Google Inc* (FTC 23 July 2013) (Decision and Order)) and/or (ii) where combined with some deceptive/exclusionary conduct (see, for example, *In the Matter of Negotiated Data Solutions LLC* (FTC 23 September 2008), *Rambus, Inc.* (FTC 6 August 2006), reversed by *Rambus Inc. v Fed. Trade Comm' n* (D.C. Cir. 2008) (US)).

9) M Gal, 'Monopoly Pricing as an Antitrust Offense in the US and the EC: Two Systems of Belief about Monopoly?' (2004) 49 *Antitrust Bulletin* 343, 358 and see Note 13 below.

Even in jurisdictions, such as the EU and the United Kingdom,[10] where exploitative pricing is expressly prohibited,[11] a cautionary approach is adopted; prosecutorial discretion is frequently exercised not to take excessive pricing cases and instead resources are focused on exclusionary conduct which damages the structure of competition on the market. In particular, there is concern that it is extremely difficult to identify unfairly high prices through the application of a clear, accurate and administrable competition law test. Further, competition agencies and courts may not be best placed to detect, control and remedy such conduct[12] and that in attempting to do so, errors may occur,[13] and uncertainties created, which reduce incentives for investment and new entry; price regulation, the antithesis of the free market, might distort entry, efficiency, investment and pricing incentives. The European Commission has generally, therefore, not wished 'to act as a price regulator' under Article 102[14] and in 2007, for example, Philip Lowe (then Director General for Competition at the European Commission) noted that although high prices harm consumers in the short run, intervention by a competition authority might deter new entry which spurs competition in a way that is good for consumers in the longer term.

> *There is much more for consumers to gain through increased competition than a mere decrease in prices: competition brings more choice, scope for differentiation in quality, innovation, etc.*[15]

There is also 'the risk of competition authorities overstepping their legitimacy in light of political pressures'.[16]

Competition agencies thus generally tend, where possible, to leave these issues to be resolved by regulators, or the market,[17] and to consider investigation as a last resort only where a market is unlikely to self-correct at all or within a reasonable timeframe, for example, where: a firm has a position of monopoly or super-dominance protected by high, non-transitory barriers to entry; a firm's position of dominance has been acquired through exclusionary conduct or the conferral of special or exclusive rights; no timely regulatory solution seems likely (no regulatory regime, or a regulatory gap, exists, or regulatory failure has occurred); intervention is unlikely to have negative effects on incentives to innovate; and/or exploitative behaviour has been combined with exclusionary or deceptive conduct.[18] Even then, competition authorities may 'prefer to address the causes of the abuse – that is, the market circumstances that allow the excessive pricing to occur – rather than using price regulation to address the symptoms. Such interventions arguably have more in common with consumer policy than with traditional competition policy, but the objective is the same; to improve the functioning of competition, to the benefit of consumers.'[19]

At first sight the arguments against competition intervention might seem to be compelling in the pharmaceutical sector. Not only is it a dynamic industry where healthy profits (often extracted initially through patent protection) may be necessary to incentivise investment in research and development (R&D)[20] (including failed R&D, which constitutes a large part of the costs), but dominance in pharmaceutical

10) Exploitative conduct is also prohibited by competition laws in, for example, China, South Africa, India, Korea and Japan.

11) After all, excessive pricing has the clear potential for consumer harm. 'As such, there is a good fit between a law against excessive pricing and the overarching objectives of competition policy'. Contribution of the United Kingdom, OECD, Excessive Prices, Note 7 above.

12) See also the opinion of the Supreme Court in *Trinko*, Note 8 above.

13) Especially the harmful impact of Type I errors, resulting from the risk of conduct that sometimes is competitively benign or beneficial being condemned. Type II errors, in contrast, result where the rules or their enforcement are under-inclusive in the sense that they sometimes tolerate conduct that in fact is competitively destructive. See OECD Background Note, Excessive Prices in Pharmaceuticals, 2018, https://one.oecd.org/document/DAF/COMP(2018)12/en/pdf and F Jenny, 'Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment', in F Jenny and Y Katsoulacos (eds) *Excessive Pricing and Competition Law Enforcement* (Springer: forthcoming), stressing the importance of weighing relatively high Type I risks in excessive pricing cases against lower cost Type 2 risks.

14) European Commission, *XXVIIth Report on Competition Policy* (1997), 29, but see Note 57 below and text.

15) P Lowe, 'Consumer Welfare and Efficiency – New Guiding Principles of Competition Policy?', 13th International Conference on Competition and 14th European Competition Day, 27 March 2007.

16) OECD Policy Roundtables, Excessive Prices, 2011.

17) See Case C–177/16, *AKKA/LAA* EU:C:2017:286, Opinion of AG Wahl, para 3 ('there is simply no need to apply [a rule against excessive prices] in a free and competitive market: with no barriers to entry, high prices should normally attract new entrants. The market would accordingly self-correct').

18) See, for example, D Evans and J Padilla, 'Excessive Prices: Using Economics to Define Administrable Legal Rules' (2005) 1(1) *Journal of Competition Law and Economics* 97; Jenny Note 13 above; and OECD Background Note (2018), Note 13 above.

19) Contribution of the United Kingdom, OECD, Excessive Prices, Note 7 above, at 288.

20) In an excessive pricing case, *Napp* Note 18 above, the UK competition agency, upheld by the CCAT (now the CAT), held that prices charged by Napp for MST were excessive and rejected Napp's argument, among others, that the price was calculated so as to provide an appropriate incentive to Napp and other companies to invest in R&D, and to secure a new generation of drugs for supply to the NHS.

markets is usually achieved on the merits, is limited in time (patents rarely protect against a better medicine and few barriers to entry ordinarily exist once patent protection has ended), and behaviour of firms is frequently monitored by regulators which have built a deep understanding and knowledge of the industry.

Nonetheless, spurred on perhaps by a wave of populism and a growing desire to ensure that competition law addresses 'unfairness' and inequalities in the system,[21] interest in high pricing, especially in the healthcare (and technology)[22] sector, has been mounting. In November 2018, the OECD Competition Committee convened hearings on 'Excessive Prices in Pharmaceutical Markets'[23] and an increasing number of competition agencies have become concerned about the impact on consumer welfare, public funds and health of sudden hikes in the prices of pharmaceutical products, especially where the drug is well established on the market (without recent developments in R&D) and is being commercialised by an entity other than the originator. For example, in 2018, the Danish competition authority condemned price increases of 2000 per cent for the drug Syntocinon;[24] in 2016, the Italian competition agency fined Aspen for increasing prices for cancer drugs;[25] and in 2017, the European Commission opened proceedings in relation to Aspen Pharma's pricing of cancer medicines following significant and potentially 'unjustified prices increases of up to several hundred percent, so called "price gouging"'.[26] Commissioner Vestager stated that:

> *When we get sick, we may depend on specific drugs to save or prolong our lives. Companies should be rewarded for producing these pharmaceuticals to ensure that they keep making them into the future. But when the price of a drug suddenly goes up by several hundred percent, this is something the Commission may look at.*[27]

In *Pfizer and Flynn*, the CMA's investigation was triggered when the price for phenytoin sodium capsules had, to the anger of the Department of Health (DH), increased dramatically over a short period of time, following steps to debrand and genericise the product, actions which took it outside of the relevant voluntary pricing regime applying to branded products, the Pharmaceutical Price Regulation Scheme (PPRS).[28]

These cases and the proceedings in *Pfizer and Flynn*, have reignited the debate as to whether, and if so when, an investigation into seemingly unfairly high prices is justified and how such prices can be identified by agencies, and firms, and remedied when found to violate competition law. Given the broad interest in this issue, the approach adopted by the UK courts is likely to be being closely watched and scrutinised by competition agencies and courts across the world.

This piece commences by looking at the background to the CMA proceedings and its decision before considering why the CAT annulled the finding of abuse. It concludes by noting that the important and contentious issues raised by the case are now likely to be reviewed by the Court of Appeal. A crucial matter in any appeal may be how high the bar should be set for competition agencies intent on protecting consumers from unfairly high prices imposed by dominant firms.

21) See, for example, J Baker and S Salop, 'Antitrust, Competition Policy, and Inequality' (2015) Geo LJ Online 104 and Speech of Commissioner Vestager, 'Protecting consumers from exploitation', Chillin' Competition Conference, Brussels, 21 November 2016.

22) In a number of jurisdictions, there is also concern about pricing by holders of SEPs; see, for example, European Commission Decision, COMP/38.636, *Rambus*, 9 December 2009; *Qualcomm* NDRC Press Release (10 February 2015) and *Qualcomm Inc v Korea Fair Trade Commission* (KFTC, 2009). But see also the Commission's commitments decision in Case AT.39816, *Upstream gas supplies in Central and Eastern Europe*, 24 May 2018 and the French competition authority's indication that it is considering investigations of excessive pricing by online hotel platforms (December 2018).

23) See http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP(2018)12&docLanguage=En hearing on 27–28 November 2018.

24) Decision of 31 January 2018, *aff'd* Danish Competition Appeals Board, 3 December 2018. The DCC also submitted the case to the Danish State Prosecutor for Serious Economic and International Crime; see https://www.en.kfst.dk/nyheder/kfst/english/decisions/2018-cd-pharma-has-abused-its-dominant-position-by-increasing-their-price-by-2-000-percent/.

25) Decision 26185 of 29 September 2016.

26) Press release, 15 May 2017.

27) Ibid. See also Note 57 below and text.

28) See further Note 31 below and text.

The CMA's Proceeding

Background and Context of the Case

The *Pfizer and Flynn* case concerned the pricing of phenytoin sodium capsules. Phenytoin sodium is the international non-proprietary name of an anti-epileptic drug. Because of the particular characteristics of the drug (including its narrow therapeutic window[29] and the differences in pharmacokinetics between brands), clinical guidance in the United Kingdom recommends that patients stabilised on a particular manufacturer's phenytoin sodium capsule should be maintained on that capsule and should not be switched to another manufacturer's capsule ('continuity of supply').

Until September 2012, Pfizer manufactured all phenytoin sodium capsules supplied in the United Kingdom under the brand name 'Epanutin'. In 2012, however, it transferred its UK marketing authorisations to Flynn Pharma Limited (Flynn) and agreed to manufacture and exclusively supply phenytoin sodium to Flynn in accordance with stipulated quality and manufacturing specifications. Flynn then genericised Epanutin, by removing its branding, and marketed it under the name Phenytoin Sodium Flynn. Pfizer stopped selling Epanutin in the United Kingdom and Flynn sought to rely on its trade mark rights to prevent parallel imports into the United Kingdom.[30] At the same time, unconstrained by the PPRS (which applies only to branded products) or another statutory scheme, Flynn significantly increased (by more than 2,000 per cent) the price of phenytoin sodium capsules to the DH.[31] This led the DH to complain to the CMA, which launched an antitrust investigation into the conduct.

The CMA's Decision

The CMA found that:

(i) Pfizer and Flynn held dominant positions in narrowly defined markets for, respectively, the manufacture and distribution of Pfizer-manufactured phenytoin sodium capsules; and

(ii) Pfizer and Flynn had abused their dominant positions by charging unfairly high prices.

Dominance

A key finding, preliminary to the finding of abuse, was that both firms were dominant. Although the CMA found that the ability of both Pfizer and Flynn to maintain significantly inflated prices provided prima facie evidence both that neither party was subject to effective pricing constraint (confirming its view that the relevant markets should not be wider), and that each was able to exercise significant market power,[32] it relied on a range of evidence to establish the relevant markets and dominance on them. For example, the CMA found that, principally because of the continuity of supply principle, rival generic products were not in the same market. Further, it concluded that a finding of dominance was supported by the parties' consistently high market shares, the existence of high barriers to entry and a lack of countervailing buyer power – no such power had been exercised by the DH or the National Health Service.

Abuse

In *United Brands*, the ECJ clarified that one way of establishing unfairly high or excessive prices which bear no reasonable relation to the economic value of the product supplied, is to demonstrate both that:[33]

(i) the difference between the costs actually incurred and the price actually charged is *excessive* – that is, there is a significant and persistent[34] difference between the price actually charged by the dominant firm and that which it would hypothetically have charged had there been effective competition (the benchmark price). EU case law indicates that this screening exercise to assess whether the price is 'suspiciously high'[35] can be done by making a comparison between sale price and cost of production and establishing that it exceeds a satisfactory margin,[36] and/or by making a comparison between the price charged and meaningful comparators, for example the prices charged by non-dominant undertakings in the market, the prices charged by the

29) This means that there is only a small difference between the level of phenytoin sodium in the blood which is toxic, and the blood level of the drug which is required for therapeutic efficacy, Case Nos 1275–1276/1/12/17, *Flynn and Pfizer v CMA* [2018] CAT 11, para 16.

30) *Flynn Pharma Limited v DrugsRUs Limited and Tenelol Limited* [2017] EWCA Civ 226.

31) Pfizer's prices to Flynn were also dramatically higher than its previous prices on the market.

32) Paras 4.180–4.190.

33) Case 27/76, *United Brands v Commission* EU:C:1978:22, para 252.

34) Case C–177/16, *AKKA/LAA* EU:C:2017:689, para 55.

35) Case AT.39816, *Upstream gas supplies in Central and Eastern Europe*, 24 May 2018, para. 65.

36) This may not be feasible in all cases, for example where data is not available.

dominant firm at a different point of time or the prices charged in other geographic markets;[37] *and*

(ii) a price has been imposed which is *unfair* either in itself (the price is so high it obviously reveals an abuse) or when compared to competing products. This requirement, which is not entirely easy to distinguish from the excessive requirement, indicates that a finding of excessive prices cannot be judged simply by reference to supply-side costs and may require account of demand-side considerations; it thus provides a 'sanity check' of the assessment made with regard to the benchmark price – 'there may be relevant factors which were either overlooked in that context, or were consciously not taken into account because they were not easily quantifiable in financial terms'.[38]

Although the ECJ also made it clear that there is no single methodology for identifying unfairly high prices and that '[o]ther ways may be devised … of selecting the rules for determining whether the price of a product is unfair',[39] in *Pfizer and Flynn* the CMA relied on the two-prong test set out in *United Brands* to support its finding of an abuse.

In finding that the prices were excessive it utilised a 'cost plus' test to identify a reasonable rate of return with a benchmark based on the 6 per cent return on sales, a target utilised in the PPRS.

It also found the prices to be 'unfair' in themselves, given the substantial disparity between the price and the economic value of the products[40] and placed overall emphasis on the difference in prices in capsules in the United Kingdom compared to other Member States and a price comparison over time, given the dramatic increase in prices which had occurred following debranding. It considered that there were no potential competing products that would provide a meaningful comparison for this purpose. It thus found an infringement, imposed fines of £84.2 million on Pfizer and £5.2 million on Flynn and ordered the companies to reduce their prices.

Following the lodging of Pfizer and Flynn's appeals, considerable debate about the robustness of the decision ensued, especially in relation to the appropriateness of the CMA's finding of dominance, the methodology used to establish the abuse and the wisdom of intervening in relation to a case where a regulatory response would, arguably, have been preferable. Indeed, the regulatory loophole that existed, and which did not permit the DH to exercise power under the statutory scheme, was subsequently closed in April 2017 by the Health Service Medical Supplies (Costs) Act 2017.

The CAT's Judgment

The Setting Aside of the Finding of Abuse

On appeal, the CAT upheld the CMA's finding of dominance but set aside its finding of unfair prices. In affirming the finding on dominance, the CAT accepted that narrow markets may be drawn in the pharmaceutical sector based on a lack of demand-side substitution between different forms of medicine[41] and a lack of competitive constraint from alternatives. The CAT did, however, recognise and stress that even products falling outside the relevant market might exercise competitive pressure on those within it;[42] a factor of relevance in assessment of both dominance and abuse.

In relation to abuse, the CAT, despite confirming that 'excessive and unfair pricing' can breach competition law and emphasising that it was not holding that there was no abuse in fact, held that the CMA had not applied the correct legal test and had not established an abuse.

With regard to the excessive limb of the test, the CAT found that the CMA had been wrong in law to restrict its assessment of whether the prices were excessive to a Cost Plus test. Although the Cost Plus approach provided a method for calculating an excessive price and in some cases might be the best way of doing so, it could not be relied on just because it was the 'most favourable to establishing an infringement, to

37) See, for example, Case 395/87, *Tournier*, EU:C:1989:319, para 38; Case C–177/16, *AKKA/LAA* EU:C:2017:789.

38) Case C–177/16, *AKKA/LAA* EU:C:2017:286, Opinion of AG Wahl, para 124.

39) Case 27/76, *United Brands v Commission* EU:C:1978:22, para 253. It was also applied in the Danish CD Pharma case, Note 24 above, by the Danish Authority.

40) The economic value of the capsules was Cost Plus as there were no demand-side or non-cost factors to be taken into account which, in fact, increased their value above that level. Pfizer's and Flynn's prices were unfair in themselves as they bore no reasonable relation to the economic value of the capsules.

41) Although the CAT found that, despite the clinical guidance recommending continuity of supply, prescribing habits were not as equivocal as the CMA's decision suggested, it found that there were barriers to switching products. But see the judgment of the General Court in Case T–691/14 *Servier v Commission* EU:T:2018:922.

42) [2018] CAT 11, para 119.

the exclusion of other methods'[43] if other valid methods existed. It also questioned the relevance of the CMA's heavy reliance on the PPRS 6 per cent rate of return, considering that it should have given greater weight to other comparisons put forward, such as rates of return on other products (both of Flynn and of other generic companies). In this case the CMA should have better identified a benchmark price or range which realistically would have applied in conditions of normal and effective competition.

The CAT also held that the CMA had incorrectly assessed whether the prices were unfair by simply relying on the fact that they were unfair in themselves and without properly assessing the price of the products by comparison with the prices of other meaningfully comparable products (including phenytoin sodium tablets which were priced more highly than capsules).[44] The CMA did not have an unfettered choice between the two alternatives and in this case enough material existed to make the CMA, at the very least, pause to consider whether there was a *prima facie* case of fairness under Alternative 2. 'It cannot be right that an authority can simply ignore a *prima facie* valid argument that a price is fair under one Alternative and proceed to find an infringement of Article 102 solely on the basis of the other Alternative establishing that prices are unfair.'[45]

It also found the CMA to be mistaken in finding that there were no non-cost related factors which would increase the economic value of the products beyond Cost Plus and that the sudden price increase (the price comparison over time) did not provide a stand-alone ground for finding unfair prices.

The CAT thus concluded that the correct application of the two-limb legal test involves:

(i) the establishment of a proper benchmark price or range for deducing a reasonable rate of return that reflects the price that would pertain under conditions of normal and sufficiently effective competition. In establishing the hypothetical counterfactual, it is necessary to consider all valid methods unless one method is the only, or overwhelmingly the best, one. The criteria for selection and application of a benchmark must be objective, appropriate and verifiable. The analysis must also be done on a consistent basis;

(ii) a careful assessment of whether the prices charged were excessive in relation to that benchmark/range and considering whether the differential was sufficiently significant and persistent in the light of factors such as: the absolute size and stability of that differential; the reasons for it, taking account of the fact that the conditions for excessive pricing will only usually occur where the market is one where regulation, or some similar feature, or other barriers to entry, protect it from competition; previous decisions finding other differentials excessive, weighted for the markets applicable in those cases; and the wider market conditions, including the evolution of pricing over time;

(iii) an assessment of unfairness in itself or unfairness compared to competing products. Although factors such as the increase in price, the selective nature of price changes, the impact on the buyer, the lack of any independent or objective justification, or the commercial purpose of the agreement, could all be relevant to the application of the unfair in itself test, it is also necessary to give due consideration to arguments that pricing is actually fair under either alternative;

(iv) a finding overall that the price charged bears no reasonable relation to the economic value of product. Assessment of economic value is highly fact specific and essentially a matter of judgment but can include factors on both the supply and demand side, the costs of production and other elements of value to the purchaser (in this case, for example, deriving from the therapeutic benefit to patients);

(v) a consideration of any objective justifications advanced; and

(vi) whether the undertaking is reaping trading benefits that it would not reap under conditions of normal and sufficiently effective competition.

Implications of the CAT's Judgment

The CAT appeared keen in its judgment to ensure that the law in this area does not deter crucial R&D and innovation through the application of an uncertain and potentially over-inclusive test. In particular, it stressed the importance of

43) Ibid., para 314.

44) Ibid., see especially paras 374–398.

45) Ibid., para 367.

the law being set out clearly and providing a good and sound legal foundation for similar actions in the future, competition assessments being made rigorously, and counter-arguments being carefully assessed, tested and rejected if they are to survive full judicial review.

The CAT emphasised the importance of the CMA in this, and any future excessive pricing case, identifying an appropriate benchmark and the 'competitive price'. In determining an excessive price in future cases, the CMA is therefore likely to have to make comparisons not only with cost and previous regulated prices, which might have been set at artificially low levels, but also with, for example, mark-ups achieved by other similar products, even if they do not operate on the exact same product market. Indeed, the CAT[46] was unhappy that the CMA had so hastily rejected the parties' arguments that a comparison should have been made to the price of tablets which contained the same drug as the capsules and which were also purchased by the DH at a bespoke negotiated price.[47] This suggests that, as price or margin comparison may be problematic or have methodological weaknesses, it will be prudent for the CMA to apply several different methodologies, for example, profitability analysis,[48] margin analysis, and historic or geographic comparisons, and proceed on the basis of a 'predominance of evidence'.[49] Although complex, cases are likely to exist where excessive pricing is sufficiently extreme that it is possible to demonstrate, based on a variety of different measures.[50]

Further, the CAT made it clear that any comparison with prices in other Member States will have to be carefully conducted. Although the CMA relied on the fact that Pfizer had not increased the price of its capsules in any other Member State to anywhere near the same extent as it had in the United Kingdom, as some evidence that Pfizer's prices were unfair in themselves,[51] the CAT concluded that insufficient evidence had been adduced to determine whether the five EU Member States in the CMA Decision could be taken into account as comparators. In line with the ECJ's judgment in the *Latvian Copyright* case,[52] it held that prices across different EU Member States could not be compared unless account was taken of other relevant factors that might affect pricing there, such as the impact of governmental measures, economic or regulatory conditions on prices.

Finally, it set out a particularly challenging factor for the CMA to satisfy – by stressing the overarching requirement that the price charged be shown to bear no reasonable relation to the 'economic value' of product at issue. One complication with this obligation is that, arguably, if the economic value of the product is simply what the buyer is willing to pay for it, then pushed to its logical conclusion a finding of excessive pricing seems difficult to make in any case where the buyer has actually bought the product (it might define excessive prices under competition law out of existence).[53] The CAT recognised in this case that attributing a monetary value on patient benefit would not be straightforward. Nonetheless, it held that the difficulties did not mean that a qualitative assessment was not possible and did not need to be attempted. It criticised the CMA for relying too heavily on a supply-side cost plus approach and paying insufficient attention to the product's value on the demand side;[54] the restricted ability to switch decreased patient benefit, but patient reliance on the capsules did not mean that zero value could be attributed to the demand side.[55]

Conclusions and the Future

Even though Pfizer and Flynn's appeals led to the setting aside of the finding of abuse, it seems clear that pharmaceutical companies should still take the possibility of their conduct infringing Article 102 and Chapter II seriously.

46) Ibid., para 379.

47) Ibid., para 374.

48) Examining the firm's return on capital to determine whether it is earning profits that differ from a normal return on capital to be expected in a competitive market.

49) OECD, Excessive Prices, Note 7 above.

50) Contribution of the United Kingdom to OECD, Excessive Prices, Note 7 above, 294, citing *Napp*, Note 18 above, as an example of how one can sometimes observe clear water between 'excessive' and 'competitive' pricing. In this case the OFT benchmarked Napp's prices in several different ways: price-cost margins were compared both across activities and with those of competitors; prices were compared across countries and over time. Napp's prices and margins were found to be high – and by some margin – relative to all of these different comparators.

51) CE/9742-13, para 5.452.

52) Case C–177/16, EU:C:2017:689.

53) Contribution of the United Kingdom to OECD, Excessive Prices, Notes 7 and 13 above, and OECD Background Note (2018), Note 13 above.

54) See also the Court of Appeal's decision in *Attheraces (UK) Limited v The British Horseracing Board Limited*, Case No: A3/2006/0126. February 2007.

55) Ibid., para 406.

First, by upholding the CMA's finding on dominance, the CAT confirmed that narrow markets may be drawn in the pharmaceutical sector, especially where there is a lack of demand-side substitution between different forms of medicine and a lack of competitive constraint from alternatives. Competition authorities are therefore likely to continue to apply narrow market definitions to the activities of pharmaceutical manufacturers and distributors; they may also seek to apply competition laws to a wide range of distribution, pricing and other activities, especially conduct designed to exclude actual or potential competitors from the market,[56] on this basis.

Secondly, despite the finding on the facts, the complexities involved in identifying unfairly high prices and the closing of the regulatory gap for pharmaceutical products in the United Kingdom, the CAT appeared receptive to the idea that high pricing may be problematic in properly identified circumstances. Although it set the finding of abuse aside, it remitted the issue back to the CMA for further consideration.

Thirdly, the Court of Appeal has given leave to appeal against the CAT's decision. An important issue on appeal is likely to be whether the CAT has been too concerned about Type 1 errors, set the burden on the CMA too high (in particular given the difficulty of assessing the economic value of a drug) and, consequently, created an unacceptable risk of Type 2 errors.[57] Indeed, the CMA contends that the CAT has not correctly applied the legal test for finding prices were unfairly high and was wrong to find that the CMA should have attributed further economic value to Pfizer-Flynn Capsules based on demand-side factors.

Fourthly, despite the challenges involved in bringing excessive pricing cases, competition agencies may, as the OECD's discussion on excessive pricing in pharmaceutical markets indicates, feel strong political and public pressure to pursue them, particularly in the pharmaceutical sector where significant sums of public funds are at stake and the impact of the price rises on citizens' health may be severe. Indeed, in its written contribution, the European Commission reminded EU agencies to be 'mindful of their obligation to effectively enforce … the prohibition of unfair pricing', stressing that it will continue to promote 'access to affordable medicines for European citizens, whilst safeguarding the incentives for innovation, research and development'.[58] It remains to be seen how the CMA will rise to the criticisms made of its approach when reconsidering Pfizer and Flynn (subject to the appeal) and considering the other healthcare cases it is investigating.

If further cases do ensue, a crucial matter will also be how an unfair pricing infringement is to be remedied. In Pfizer and Flynn, the CMA had imposed fines and ordered the parties to reduce their prices. Ensuring compliance with such an order, or any price or profit cap imposed, however, is onerous and requires an agency to engage in monitoring and adjustment functions which are regulatory and time-consuming in nature. In this case, such problems would have been avoided as the Health Service Medical Supplies (Costs) Act 2017 now allows for the regulation of the prices even outside the PPRS. Future cases may, however, if appropriate explore whether other remedies,[59] or an Enterprise Act 2002 market investigation,[60] might be alternative mechanisms which would also allow the CMA to address the causes of the market failure directly rather than simply seeking to alleviate its harmful effects.

The increasing attention being focused on high prices is understandable. After all, supracompetitive prices directly harm consumer welfare, the very conduct the competition rules are designed to prevent. At a time when many competition agencies are considering how competition law can be used to rebuild faith in markets and rebalance the benefits of the competitive process, prioritisation of cases widely seen as gross examples of unfair practices may seem to be one mechanism of achieving it. It has been seen nonetheless that the complexities involved in excessive pricing cases are manifold. In particular, an acute challenge is to draw the line between an approach which protects consumers' interest against unfairly high pricing, without imposing measures and creating uncertainties which discourage innovation and new entry essential to the introduction of new products and, in the health sphere, the development of new blockbuster treatments.

56) See, for example, the issues raised by the pay for delay cases such as, COMP/39.226, 9 June 2013, *aff'd* Case T–472/13, *H Lundbeck A/S v Commission* EU:T:2016:449, Case C–591/16 P (judgment pending) and COMP/39.612, *Périndopril (Servier)* 9 July 2014, IP14/799, Case T–691/14, *Servier SAS v Commission* EU:T:2018:922 (and see Note 41 above).

57) See Note 13 above.

58) See https://one.oecd.org/document/DAF/COMP/WD(2018)112/en/pdf.

59) Including structural remedies ordering separation or measures to increase transparency or induce customer-switching.

60) The Enterprise Act market investigation provisions are specifically designed to allow for a holistic examination of markets which do not appear to be working well for consumers, and to examine both causes of the problems as well as their symptoms. It also allows the CMA to impose a wide range of remedies designed to enhance competition; in certain circumstance these may be more effective in encouraging competition through, for example, new entry, expansion or customer switching, than price regulation.