Neutral Citation Number: [2026] EWCA Civ 765

Case Nos: CA-2025-000637 & 000637A & 000638 & 000638A

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM COMPETITION APPEAL TRIBUNAL
Mr Justice Marcus Smith, Mr Eamonn Doran & Professor Michael Waterson
[2024] CAT 65

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 19/06/2026

Before :

LORD JUSTICE GREEN
LORD JUSTICE SNOWDEN
and
LORD JUSTICE ZACAROLI

- -

Between :

CA-2025-000637 & 000637A

Pfizer Incorporated **Pfizer Limited** **(together, "*Pfizer*")** **- and -**	**1st Appellant**
The Competition and Markets Authority	**Respondent**

CA-2025-000638 & 000638A

Flynn Pharma Limited **Flynn Pharma (Holdings) Limited** **(together, "*Flynn*")** **- and -**	**2nd Appellant**
The Competition and Markets Authority	**Respondent**

- -

Mark Brealey KC, Robert O'Donoghue KC & Tim Johnston (instructed by **Clifford Chance LLP**) for the **1st Appellant**
Jemima Stratford KC, Tom Pascoe & Alastair Richardson (instructed by **Macfarlanes LLP**) for the **2nd Appellant**
Joshua Holmes KC, Prof. David Bailey KC, Jennifer MacLeod & Alexandra Breckenridge (instructed by **Competition and Markets Authority**) for the **Respondent**

Hearing dates: Tuesday 27th - Thursday 29th January 2026

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Approved Judgment

This judgment was handed down remotely at midday on Friday 19th June 2026 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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Lord Justice Green, Lord Justice Snowden & Lord Justice Zacaroli:

A. Introduction : Overview and summary of conclusions

Introduction / the context

1. This is the single judgment of the Court to which we have all contributed.

2. The appeal is from a decision dated 20th November 2024 of the Competition Appeal Tribunal ("*CAT*"). The CAT's decision was itself made on appeal from a decision of the Competition and Markets Authority ("*the CMA*") entitled "*Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*" (21st July 2022) ("*the Decision*"). The CMA had found that the appellants, Pfizer and Flynn, were guilty of abuse of dominance for unfair pricing contrary to section 18 of the Competition Act 1998 ("*CA 1998*"). The abuse consisted of increasing the price of the generic, anti-epilepsy drug, phenytoin, to unfair levels over the 4 year period, September 2012 - December 2016 ("*the Relevant Period*"), without there being any justification for that increase. The CAT set aside the Decision, but then remade the decision similarly concluding that Pfizer and Flynn were guilty of abuse of dominance.

3. It is relevant to place the issues into context.

4. Pfizer acquired the Marketing Authorisations ("*MA*") for four strengths of phenytoin sodium capsules in 2000, at which point they had been off patent for several decades. Pfizer sold capsules under the brand name "*Epanutin*". As a branded product it was subject to the price control regime set out in the Pharmaceutical Price Regulation Scheme ("*PPRS*").

5. In September 2012, Pfizer and Flynn entered into an exclusive distribution agreement. Flynn became the exclusive distributor for Pfizer's capsules in the UK. On 23rd September 2012 Flynn purchased the MA from Pfizer for £1. Thereafter, Pfizer continued to manufacture capsules and supplied them to Flynn. Flynn debranded Epanutin, removing it from the PPRS, so that it was now supplied as a generic. From then it was priced in accordance with "*Scheme C*", which applied to generic drugs and which, because it was based upon the premise that generic drugs are priced according to competitive market conditions, allows suppliers to sell to the NHS at market prices.

6. The capsules supplied by Pfizer to Flynn pursuant to the distribution agreement remained identical to Epanutin save for the name. The only change to the supply chain was that Flynn was inserted and placed orders with Pfizer on a weekly basis. Pfizer continued to manufacture the capsules in Germany and continued to deliver them to the same pre-wholesaler in the UK that it had previously used.

7. The distribution agreement heralded immediate and dramatic increases in prices. Flynn's average selling price ("*ASP*") to the NHS was up to 2,682% higher than Pfizer had charged before the agreement.

8. Over the Relevant Period: the price for the most widely sold pack of 100mg capsules, accounting for about 75% of demand, rose from £2.21 to £59.53; the price increases generated profits of £57m for Pfizer and £36m for Flynn; and, annual spend on capsules

by the NHS, which had been at £2.3m in 2012, rose to £50m in 2013, £42 million in 2014, £37 million in 2015, and £35 million in 2016.

9. The increases were not justified by any change in costs or any improvement, innovation, investment, or additional benefits for patients having been created, and they were not needed to ensure the commercial viability of the product.

10. In the Decision, the CMA set out a lengthy analysis of the internal, contemporaneous, documents disclosed during the proceedings which recorded the commercial strategy of the parties. A summary is set out at paragraphs [51] – [65] below. The motivation was to increase profitability. Pfizer was clear that if it sought, unilaterally, to increase prices by the magnitude contemplated it would be constrained by the PPRS and otherwise would meet resistance from the NHS, and it would fail. The solution was to sell the MA to Flynn for a nominal sum, agree that Flynn would be the exclusive distributor for Pfizer's capsules in the UK, de-brand the drug and withdraw it from the PPRS, charge Flynn a very high wholesale price, and then leave it to Flynn to push through the price increases to the NHS. The documents record internal debates about the ethics of the strategy, a recognition that pushing prices up risked adverse health consequences for patients, and a concern on the part of Pfizer as to reputational risk. By interposing Flynn into the distribution chain Pfizer sought to deflect criticisms from itself.

11. When the price increase strategy was introduced, it was met with immediate opposition from the Department of Health ("*the Department*" or "*DHSC*") who, on 28th September 2012, complained to the Office of Fair Trading ("*OFT*", the statutory predecessor to the CMA). On 23rd October 2012 the Department contacted Flynn for information relating to its costs and, on 6th November 2012, met with Flynn and made clear its serious concerns about the new pricing structure. On 16th November 2012 Flynn wrote to the Department offering further information and intimating that they would welcome discussions. At a meeting on 10th January 2013, Pfizer told the Department that it had sold Epanutin to Flynn as it was no longer economically viable. It could give no further information. On 26th February 2013 Pfizer sent a follow-up email stating that it would not be appropriate to comment upon Flynn's pricing strategy, as Pfizer no longer held the MA.

12. This is the second occasion when this case has come before this Court. On the first occasion (see paragraph [20] below) the then Chancellor, Sir Geoffrey Vos, observed that, whilst the facts needed to be thoroughly considered, a "*stark reality*" needed to be kept in mind:

> "…literally overnight, Pfizer and Flynn increased their prices for phenytoin sodium capsules by factors of between approximately 7 and 27, when they were in a dominant position in each of their markets. That did not, of course, abrogate the need for a rigorous reasoned approach to the legal and factual questions before the CAT, but it was important to keep in mind."

AEDs / Phenytoin capsules

13. AEDs are anti-epileptic drugs. Phenytoin sodium is an AED. It was originally synthesised in 1908 and was first commercialised by Parke-Davis in 1938. Phenytoin

sodium capsules are long off-patent. Phenytoin sodium is sold in capsule and tablet form (of 25mg, 50mg, 100mg and 300mg). There is a very small difference between the level of the drug necessary to achieve therapeutic efficacy and the level which, if exceeded, risks adverse side effects. This feature of the drug is termed its "*narrow therapeutic index*" ("*NTI*"). Clinical guidance recommends that patients stabilised on a particular manufacturer's phenytoin sodium capsule should therefore be maintained on that drug in capsule form and not switched to another manufacturer's product and this includes in tablet form. This is referred to as "*continuity of supply*".

14. In relative terms phenytoin (whether in capsule or tablet form) is a third-line treatment and has been long superseded by other first-line AEDs. This assessment of relative value was in place before the Relevant Period and was recognised in NICE guidance published in 2012. This categorised AEDs by reference to their relative benefits to patients. Phenytoin's categorisation as a third-line treatment indicated that, whilst of course it still provided medical benefits to those for whom it was prescribed and for whom the first or second line treatment did not work, it was inferior to other AEDs in term of efficacy, side effects, adverse drug interactions, and/or relative ease of clinical use. This is also reflected in prescribing practices. It is a prescription of last resort and was "*only very rarely*" prescribed during the Relevant Period: see generally Decision paragraphs [6.90ff].

The first CMA Decision, 7th December 2016 ("the First CMA Decision")

15. In 2013 the CMA opened an investigation into the price increases following the complaint by the DHSC. The CMA adopted a decision on 7th December 2016 finding an abuse of a dominant position by Pfizer in the market for manufacture of phenytoin capsules and by Flynn in the market for distribution of the capsules. Following the decision the price of 100mg capsules fell from £54 per pack in December 2016 to £9.14 per pack in April 2017.

The first appeal to the CAT: [2018] CAT 11 ("the First CAT judgment")

16. Pfizer and Flynn appealed to the CAT which upheld the CMA's Decision on issues of market definition and dominance but found that the CMA had erred in relation to its analysis of certain categories of evidence which were relevant to whether prices could be set at above Cost Plus: (i) tablets as comparators and in particular the prices of phenytoin sodium tablets as comparators and (ii) medical benefits.

17. The CAT did not say that after a more detailed analysis the CMA was bound or required to arrive at a different conclusion, but it did say that the existing analysis was insufficiently detailed to arrive at that conclusion.

18. In relation to tablets the CAT said:

> "379. It is apparent from the above that the CMA clearly gave some consideration to the suitability of tablets as a comparator. However, it is not clear to us that it did so in sufficient depth. We emphasise that the purpose of a comparison at this stage of the analysis is to see whether what has been found to be a price influenced by market conditions where competition is restricted is unfair in the context of comparators. If the prices, and market

> conditions, are similar, it might suggest either that all of the prices are unfair, or that none are. Given the inherent difficulty in making assessments in this area of competition law it is all the more important to conduct a full and proper examination."

19. In relation to medical benefits the CAT (judgment paragraphs [411] – [419]) accepted that specific guidance on ascertaining economic value was limited and was "…*essentially a matter of judgment with appropriate weight being given to factors on both the supply and demand side*". The issue was whether the CMA was correct, "*on the facts of this case*", to reject outright the uncontested evidence that "*phenytoin remains a useful and effective treatment for a significant number of patients*". The CAT accepted that benefit and value were discrete issues. The mere fact of the existence of benefit did not, by that fact alone, mean that a premium over that recognised in the Plus of Cost Plus was always justified. It recognised that there was a real issue arising from "*dependency*" i.e. that because there was only one supplier of the product, patients were dependent. It did not accept that this implied that there could never be incremental value (over Cost Plus) attributable to medical benefit. On the contrary it was a question of degree not a binary yes/no. The CAT required the CMA to conduct a more detailed analysis:

> "417. We therefore do not think this is a binary issue but more one of degree. We of course accept … that charging what the market will bear does not automatically point to abuse of a dominant position. There is clearly some economic value to be derived from the significant contribution of phenytoin to treating epilepsy in a significant number of patients. Some allowance must be made for the extent to which the choice of switching from phenytoin may be restricted, which decreases the value as measured in terms of patient benefit.
>
> …
>
> 419. In light of the above, our finding is that the Decision was defective in its treatment of the economic value that may be derived from patient benefit. Placing a precise monetary value on patient benefit is not straightforward but it appears to us that a qualitative assessment would be possible and should have been attempted by the CMA rather than simply assessing this value as nil."

The first judgment of the Court of Appeal: [2020] EWCA Civ 339 ("Phenytoin I")

20. The CMA appealed to the Court of Appeal which upheld certain of its grounds of challenge but upheld the CAT on its central conclusion that the CMA had failed adequately to examine the evidence relating to tablets and medical benefits. The Court considered that these were, quintessentially, findings of fact made by the CAT which it was within its jurisdiction to make: judgment paragraphs [165] and [166]. The case was remitted for the matter to be re-determined in line with the judgment.

The second CMA Decision, 21st July 2022 ("the Decision")

21. The CMA conducted a new investigation. It focused only upon abuse since the prior findings of product market and dominance had been upheld. It addressed the issues found by the CAT to require more detailed investigation. On 21st July 2022 the CMA adopted the Decision once again finding abuse by Pfizer and by Flynn upon the basis that the price increases were unfair and abusive. Penalties were imposed. A summary of the Decision is set out at paragraphs [50] – [109] below.

The second appeal to the CAT: [2024] CAT 65 ("the Judgment")

22. Pfizer and Flynn appealed the Decision to the CAT. The Judgment can be divided into three parts. The first, from paragraphs [20] – [282], addresses the appeals of Pfizer and Flynn against the Decision. The second, from paragraphs [283] – [287], is where, having decided that the Decision was flawed and should be set aside, the CAT decided to retake the decision itself in accordance with its powers under Schedule 8(3) CA 1998. The third is found between paragraphs [288] – [321] and sets out reasons for the CAT's new decision that Pfizer and Flynn had abused their dominant positions and that the prices charged were unlawful.

23. In the first part of the Judgment, the CAT found that the CMA erred in a range of substantive and procedural respects, including that it was guilty of bias in that it predetermined the outcome and focused only upon inculpatory evidence and ignored exculpatory evidence. According to the CAT, the CMA had reversed the burden of proof and the presumption of innocence, made a series of other legal errors and adopted unsustainable positions not fairly or transparently set out in the Decision. The CAT held that, individually and collectively, these failings were "*fundamental*" and material.

24. In the second part of the Judgment, the CAT recognised that it had a choice. It could remit the matter to the CMA to retake (for a third time) the decision; it could bring the proceedings to a complete and definitive end; or, it could take a new decision itself.

25. The CAT adopted the latter course and, on retaking the decision, found once again, that Pfizer and Flynn had acted unlawfully. The CAT concluded (Judgment paragraph [342]) that the infringements alleged by the CMA against Flynn were made out and, as against Pfizer, all save one (in relation to 25mg capsules) were made out. Subject to a minor downward adjustment in Pfizer's penalty (reducing it from £63,000,000 to £62,370,000) the CAT affirmed the penalties imposed by the CMA for the reasons given in the Judgment and in Chapter 9 of the Decision.

26. In paragraphs [333(7)(iii)] and [333(8)] the CAT encapsulated its reasons for holding that the prices were unfair and abusive:

> "Pfizer and Flynn were aware that they were able to price independently of cost and independently of competitive constraints. As successful Enterprises, they will have been well-aware of why this was the case. They were in a dominant position because of the need for Continuity of Supply, which was not something they delivered to the market, but rather something that they took advantage of. In short, they priced not because demand exceeded supply … nor because of any particular innovation … but because there was a basic human need for the Capsules, which only they could satisfy. The human need was not as stark

> as it might have been – the State intervened to pay – but that does not disguise the fact that both Pfizer and Flynn were gouging the market in a manner that can only be characterised as unjustifiable or opportunistic or – in a word – unfair.
>
> This is something that Pfizer and Flynn intended. They did not accidently or negligently overprice. They had market power given them; and they abused it."

27. The CAT held that the violations were intentional, that they harmed the healthcare system by the extraction of "*monopoly rents*" and were "*extreme*". The reasons could be "*shortly stated*":

> "340 … we are in no doubt that these were intentional infringements, which harmed the healthcare system in this country by extracting from a limited budget monopoly rents. Although this is rightly a long judgment – competition law infringements must be established to the proper standard and the reasoning fully set out, particularly where the decision under appeal is materially flawed – the infringements in this case are extreme and can be shortly stated in the manner that we have just done."

The position before the Court of Appeal

28. The CAT granted permission to appeal to Pfizer and Flynn. They submit that the Judgment in relation to the retaken decision is flawed and should be set aside, because it was made by a procedurally unfair process and contains multiple substantive errors. They do not challenge the first part of the Judgment wherein the CAT acceded to their appeals.

29. The CMA seeks permission to appeal the Judgment as a whole upon the basis that, in allowing the appeals of Pfizer and Flynn, the CAT wrongly rejected the original Decision. The CMA contends that if the Judgment in this regard is defective, then the Decision should be restored.

30. The CMA originally contended that if the Court was not minded to restore the Decision, then the retaken decision should be upheld. However, at the start of the appeal, the CMA modified its position. It accepted that there was force in Pfizer and Flynn's submissions that the retaken decision was vitiated by procedural unfairness. As explained below (paragraphs [316] - [333]), we agree that the retaken decision was vitiated by procedural unfairness. This meant that the heart of the appeal concerns the CMA's challenge to the setting aside of the Decision.

B. A summary of the law relating to unfair, abusive, pricing.

The test of fairness

31. The parties are in agreement as to the applicable principles of law, but they all raise concerns about their application to the facts by the CAT. It is helpful to recapitulate the basics.

32. Section 18(1) CA 1998, entitled "*Abuse of dominant position*", provides that any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the United Kingdom. Section 18(2) lists various examples of abuse. Section 18(2)(a) stipulates that conduct may amount to an abuse if it consists in: "…*directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions*". There is no statutory definition of fairness in the CA 1998, or in equivalent treaty provisions at EU level, but it is common ground that jurisprudence under the EU regime is relevant, though not binding.

A summary of case law

33. The *locus classicus* of the test is found in the CJEU judgment in Case C-27/76 *United Brands v Commission* EU:C:1978:22 ("*United Brands*"), in particular at paragraphs [248] – [253]. The Court of Appeal, in *Phenytoin I*, taking *United Brands* as its starting point, summarised the various approaches to evidence endorsed in case law. The underlying premise is that no single category or type of evidence is necessarily dispositive or relevant, or indeed irrelevant. The guiding principle is weight, not admissibility: *Phenytoin I* paragraphs [97(iii)-(vii)], and [105]. Whilst all evidence is capable of being admitted its individual probative worth will be for the CMA and CAT, on an appeal, to assess. In *Phenytoin I* the Court of Appeal pulled together nearly 50 years of jurisprudence:

> "97. …
>
> (i) The basic test for abuse, which is set out in the Chapter II prohibition and in Article 102, is whether the price is "unfair". In broad terms a price will be unfair when the dominant undertaking has reaped trading benefits which it could not have obtained in conditions of "normal and sufficiently effective competition", i.e. "workable" competition.
>
> (ii) A price which is "excessive" because it bears no "reasonable" relation to the economic value of the good or service is an example of such an unfair price.
>
> (iii) There is no single method or "way" in which abuse might be established and competition authorities have a margin of manoeuvre or appreciation in deciding which methodology to use and which evidence to rely upon.
>
> (iv) Depending upon the facts and circumstances of the case a competition authority might therefore use one or more of the alternative economic tests which are available. There is however no rule of law requiring competition authorities to use more than one test or method in all cases.
>
> (v) If a Cost-Plus test is applied the competition authority may compare the cost of production with the selling price in order to disclose the profit margin. Then the authority should determine whether the margin is "excessive". This can be done by

> comparing the price charged against a benchmark higher than cost such as a reasonable rate of return on sales (ROS) or to some other appropriate benchmark such as return on capital employed (ROCE). When that is performed, and if the price exceeds the selected benchmark, the authority should then compare the price charged against any other factors which might otherwise serve to justify the price charged as fair and not abusive.
>
> (vi) In analysing whether the end price is unfair a competition authority may look at a range of relevant factors including, but not limited to, evidence and data relating to the defendant undertaking itself and/or evidence of comparables drawn from competing products and/or any other relevant comparable, or all of these. There is no fixed list of categories of evidence relevant to unfairness.
>
> (vii) If a competition authority chooses one method (e.g. Cost-Plus) and one body of evidence and the defendant undertaking does not adduce other methods or evidence, the competition authority may proceed to a conclusion upon the basis of that method and evidence alone.
>
> (viii) If an undertaking relies, in its defence, upon other methods or types of evidence to that relied upon by the competition authority then the authority must fairly evaluate it."

The Cost Plus test

34. Many grounds of challenge concern the application of the Cost Plus test by the CAT. For now, it suffices to identify, in broad terms, some key terminology. In an excessive pricing case, a central method for determining abuse is known as "*Cost Plus*". Under this test the cost of production, the "*Cost*", together with a reasonable rate of return ("*the RRoR*") of providing the good or service (the "*Plus*"), is established. The calculation of the Plus can take a number of forms. Two common tests are the return on capital employed ("*ROCE*") and return on sales ("*ROS*"). In determining a reasonable ROCE a decision maker might look for evidence as to what the weighted average cost of capital ("*WACC*") is. The resultant Cost Plus figure is then compared against the ASP (or some other appropriate measure of final price) to determine a differential which is then assessed for fairness.

The simplified approach of the CAT in Le Patourel

35. Case law suggests that the margin of selling price over Cost Plus is a measurement of the extent to which the final price is "*excessive*": see paragraph [97(v)] of *Phenytoin I* cited above. Care, however, is required. At one level the differential between the ASP and Cost Plus may be described as the "*excess*" of price over Cost Plus. As a noun the term does not import adverse connotations. But used as an adjective "*excessive*" bears negative implications and refers to something which exceeds a normal, usual, standard or reasonable level of something. In the context of the test for abuse, both meanings are relevant since at some point the margin of selling price over Cost Plus must be both (i) determined and (ii) evaluated.

36. An issue that has been debated in case law is whether the adjectival test for excessiveness is different or the same as that for fairness, which after all is the sole statutory test. Seeking to circumvent this issue, the CAT in *Justin Le Patourel v BT Plc* [2024] CAT 76 ("*Le Patourel*") at paragraph [53] applied a simplified two-stage approach:

> "53. For our part, and notwithstanding the flexibility open to a court or competition authority as to where to take into account the question of economic value, we consider the approach taken by the parties to be a helpful one. This is for two reasons. First, it enables the Limb 1 exercise, complex and challenging as it may be, to focus on the linear process of deciding (a) the relevant competitive benchmark, (b) the excess of the price (if any) over that benchmark, and (c) whether such excess is significant and persistent …. One would perhaps hesitate to describe such a process as "mechanical" where the underlying questions can be the subject of hotly contested expert evidence and where they involve various value judgments, and moreover where there is a margin of appreciation afforded, at least to a competition authority. Nonetheless, we consider that it is, from an analytical point of view, "cleaner" and more efficient if the question of economic value can be considered as part of the Limb 2 unfairness exercise which, on any view, is clearly less "mechanical" than the Limb 1 exercise, and where a multiplicity of different factors can be taken into account."

At the first stage, the computation of Cost Plus and the determination of the margin of ASP above Cost Plus was hence treated as an accountancy led evidential exercise. The principal evaluative exercise occurred at the next stage, during which the justification offered for the margin was evaluated in a single overall exercise to decide whether there was a reasonable relationship between the price charged and the economic value of the goods or services in issue (see paragraph [97(ii)] of *Phenytoin I*). This approach was endorsed as "*sensible*" by this Court in refusing permission to appeal: [2025] EWCA Civ 1061 at paragraph [7]. We also endorse that approach, which enables the decision maker to evaluate all evidence which might be relevant to the statutory test of fairness without having to worry about which box it fits into.

The CMA's formal confirmation - no presumption that prices above Cost Plus are abusive

37. Case law makes clear that, in relation to alleged unfair excessive prices, the floor threshold for determining whether a price might be abusive is Cost Plus. But this does not imply that prices above that threshold are unlawful or deemed or presumed to be so. It is clear from case law that not every price above Cost Plus is abusive; otherwise, there would be no point in assessing whether the increment or excess above Cost Plus was justified.

38. As we explain below, the CAT concluded that, contrary to the above, the CMA took the position in the Decision that <u>any</u> price above Cost Plus was *per se* illegal. Before us, however, Mr Holmes KC, for the CMA, explicitly confirmed that it was the CMA's formal position that prices above Cost Plus were <u>not</u> *per se* illegal or even presumed to

be so. It was also explicitly confirmed that if, in a hypothetical excessive pricing case, a decision maker could identify no specific evidence of benefit in a product or service that consumers would value and pay an increment above Cost Plus for, but that there was credible evidence that in a genuinely competitive comparable market prices were materially above Cost Plus, then a dominant undertaking (in the index market) which sold at prices on a par with those in the comparable market, would not necessarily be engaging in abuse. This was because the essence of the test for abuse was whether the impugned price would be charged in conditions of workable competition and evidence of this could derive from pricing in comparable competitive markets. This might be "*proxy evidence of economic value*": see Decision footnote [1155] citing *Phenytoin I* paragraph [172].

39. This issue was considered in *Cinven Capital Management and others v CMA* [2025] EWCA Civ 578 ("*Cinven*"). That case bears similarities to the present. The CMA issued a decision in which it found that a supplier abused a dominant position by increasing the price of a generic, long out of patent, drug designed to treat thyroid deficiency to unfair and abusive levels in sales to the NHS. The average Cost Plus over the period of the infringement was calculated at £4.63 per box. Between 2009 and 2017 the price rose to £247 per box. In percentage terms the highest price charged, of £247 per box in 2017, was c.6000% higher than the calculated Cost Plus. The CMA held that there was no objective justification for these price increases and imposed penalties exceeding £100m. For administrative reasons instead of taking a baseline of Cost Plus for determining breach and penalties it took the higher and more conservative price of £20.48. In arriving at its final conclusion, the CAT considered evidence of how the same drug was priced in other European states where, the evidence showed, it hovered at or around the UK Cost Plus price. The undertakings adduced competing evidence of how the prices in the UK changed after the infringement period, when new entry had occurred and prices had fallen. They argued that these were superior comparators because they concerned the self-same product in the self-same UK market charged at a time when, on their case, the market was workably competitive. These new prices however were substantially above Cost Plus. The CMA rejected these as valid comparators. Appeals by the undertakings to the CAT and then to this Court were unsuccessful. The Court held as follows in relation to the evidential relationship between Cost Plus and evidence of pricing in comparable markets said to be workably competitive:

> "76. … . It is important to be clear about the implications of different phrases which are used in the case law. The term "*workable competition*" is a short hand for the language used in *United Brands* (*ibid*) paragraph [249] of "*normal and sufficiently effective competition*" and this, itself, is a shorthand for fairness, which is the legislative test. The concept of "*workable competition*" was formulated … as an antidote to the economic concept of "*perfect competition*" which emerged in the late 19th century literature in which paradigm markets were described as in optimal equilibrium where output was equal to marginal cost. It was early understood, however, that the use of perfect competition as a tool for understanding how markets really operated, or for determining regulatory policy, was

> unrealistic and attention turned to workable competition as a practical alternative. … .
>
> 77. …there is agreement that competition law regulation does not proceed upon some theoretical, laboratory, model of perfect competition but upon the real world and focuses upon achieving the acceptable or adequate as opposed to the paradigmatic. Evidence of how a market reflecting "*normal and sufficiently effective competition"* or *"workable competition*" operates might therefore be relevant, and even important, evidence in a case but it is not a mandatory test. There is no rule that a regulator or Court *must* seek out evidence of what might happen in an actual market said to exhibit the features of workable competition as a benchmark. … The case law, as summarised in *Phenytoin* at paragraph [97] … describes practical approaches to determining fairness as the legislative test. It is understood that, to make the law practicable, there must be evidential proxies for determining what a fair price would be if generated in sufficiently effective, workably competitive, market conditions. It also makes clear that there is a wide range of economic and accounting models, as well as a variety of sources of evidence (e.g. comparables), that can be used to this end. As observed this does not mean that evidence of a broad nature about market structure is irrelevant but it does mean, contrary the applicants submissions, that in an appropriate case Cost Plus, is a valid and sufficient way of establishing whether prices are "*fair*" and, to this extent, can be said to reflect those that would be generated in a sufficiently effective, workably competitive, market: *United Brands* paragraphs [248]–[252] and *Phenytoin* paragraph [97(i) – (v)]. This is notwithstanding that a Cost Plus exercise is performed in relation to a dominant undertaking operating in a market which is not workably competitive."

Some basic principles about the approach to be adopted on an appeal

40. Between them Pfizer, Flynn and the CMA launch multi-faceted, all-encompassing, challenges to the Judgment.

41. The CMA argues that the Judgment is based upon a flawed and unfair reading of the Decision. It argues that the statutory task of the CAT upon a merits appeal is to decide, taking into account all the evidence before it, which might well go beyond that which had been before the CMA, whether the impugned decision was right. But a merits appeal is not a hearing *de novo*, and so, argued the CMA, the CAT had to consider, carefully and fairly, what the CMA actually found in the decision under challenge. In this context the CMA's argument invites a close comparison by this Court between what the CMA *actually* did or did not do in the Decision, and what the CAT *said* in the Judgment the CMA did or did not do. We agree that an error on the part of the CAT in interpreting a CMA decision would amount to an error of law over which this Court has jurisdiction.

42. This Court, however, only has jurisdiction over appeals on points of law. Challenges to findings of primary fact or findings based upon an evaluation of evidence can in principle amount to a point of law, but the threshold for success in such a challenge is high. It must be established that the decision maker's conclusions were outside the margin of appreciation that a specialist body, such as the CMA or CAT, has over the facts. In relation to appeals arising from complex issues of accountancy and economics, which are said to raise points of law, the Court in *Le Patourel* stated:

> "12. The Court of Appeal has jurisdiction in appeals of this sort only on points of law: section 49(1) CA 1998. Where an issue focuses upon an evaluation of evidence it is, at least in principle, capable of amounting to an error of law in some circumstances: see e.g. *Airwave Solutions Limited v CMA* [2025] EWCA Civ 54 at paragraphs [88] and *Cinven* (*ibid*) at paragraphs [161], [242]-[243]. Classic illustrations are where the CAT acted irrationally in its findings in the sense that no CAT could, acting reasonably, arrive at the conclusion that it did, or failed to address relevant considerations, or took into account irrelevant considerations. However, this Court has to ensure that it does not, without good and proper reason, interfere in the exercise of the legitimate discretion of the CAT to find facts and draw inferences from those facts. Both the nature of the evidence and the institutional composition of the CAT are factors affecting the breadth of the margin of discretion that must be accorded to the CAT and this impacts upon the sorts of alleged errors that the Court will recognise as amounting to viable grounds of appeal:
>
> i) First, many issues to be decided about the computation of Cost-Plus and the justification for the differential with selling prices are incapable of precise measurement or quantification. The complexity of the task is multiplied because many cases resemble large multi-piece jigsaws. The CAT has to form conclusions based upon data exhibiting varying degrees of accuracy and completeness which may also be based upon assumptions of uncertain precision and authenticity meaning that routinely it must make judgment calls about the reliability of multiple strands of divergent and inconsistent evidence. In doing this the CAT has to use its powers of informed, skilled, guesstimation, or, to use the more colourful analogy deployed in other cases, wield the broad axe.
>
> ii) Secondly, the CAT has an institutional ability on the Bench to meld legal, financial, business and economic experience, a range of skills not systemically replicated in an appeal Court, but which are especially important in cases such as the present given the nature of the evidence. Where a finding concerns how to identify relevant costs, or as to their attribution once identified to a line of business or, assuming it is to be attributed, as to the extent of the allocation, or as to the assessment of the value to consumers of various features of a good or service both in the

> index market and/or in a comparable market, or as to the relationship between value and final selling price, the appellate court is in a materially weaker position to form a fair and rounded conclusion, than is the CAT. This is why its jurisdiction is limited to points of law and why, where disputes over evidence and fact are said to amount to appealable points of law, the Court exercises considerable reticence before interfering in the CAT's evaluative judgment."

43. Accordingly, given that the CAT has a merits jurisdiction, we accept that if all the CAT did was, after due and careful consideration, disagree with factual findings or evaluative decisions of the CMA as set out in the Decision, and form its own, different, conclusions on the relevant evidence, then the threshold for us to intervene would be high.

44. It is a different matter however if the CAT can be shown to have misinterpreted or misunderstood the Decision of the CMA. In *Phenytoin I*, cf paragraphs [141] – [147] this Court, emphasised that an "…*appeal is not a de novo hearing but takes the decision as its starting, middle and end point. Under section 46 the CA 1998 the appeal is "against, or with respect to," the decision and includes "whether" there has been an infringement"* (Paragraph [141]). The Court went on to explain what that meant in practice and emphasised that it was for the CAT, when it found an error, also to decide whether that error was material to the ultimate conclusion in the impugned decision (Paragraphs [143] – [147]). For present purposes the important point is that our task, when reviewing the CAT judgment, is to see whether the CAT has adhered to its statutory obligation to determine, *by reference to the substance of the Decision*, whether the Decision was right on the merits.

C. A summary of the conclusions of the Court

45. As we have already observed, we consider that the CAT's remade decision was vitiated by procedural unfairness and the heart of this appeal therefore concerns the challenge of the CMA to the setting aside of the Decision. If the CAT was wrong to set aside the Decision, then there was, in any event, no jurisdictional basis upon which it could remake the decision.

46. The CMA's case focuses predominantly upon the reasons why the CAT held that the Decision was flawed procedurally and substantively. In the Judgment the CAT identified multiple errors and failings on the part of the CMA which it said were "*material*" and often "*fundamental*" such that the CAT could not trust any finding of fact in the Decision. The CMA complains that the CAT's criticisms are unfair and do not reflect accurately what the CMA actually did in the Decision.

47. Our conclusion, which takes into account points raised in Respondents Notices, is that the CAT was wrong to set aside the Decision. The CAT found errors in the Decision which, on a fair reading, the CMA did not make. We consider that in material respects the CAT failed to engage with, or mischaracterised, the CMA's decision on critical issues. We conclude, in particular, that the CAT was wrong to find that the CMA predetermined the outcome of the decision making process and examined the evidence in a biased and selective way to confirm a pre-formed conclusion.

48. Accordingly, we grant the application of the CMA for permission to appeal and allow its appeal. In view of that conclusion, and separately from our conclusion about procedural unfairness, there was no basis upon which the CAT could remake the Decision, and the whole of the Judgment must be set aside.

49. We address the issues in the following order:

- First, we summarise the Decision.
- Secondly, we summarise the Judgment: (i) in relation to the appeals of Pfizer and Flynn to set aside the Decision; (ii) in relation to the exercise of discretion by the CAT to retake the decision under Schedule 8(3) CA 1998; and (iii), in relation to the reasons given for retaking the decision and finding infringement by Pfizer and Flynn.
- Thirdly, we determine the application for permission to appeal and the substantive grounds of appeal advanced by the CMA against the setting aside of the Decision.
- Fourthly, we address the complaint of procedural unfairness in relation to the retaken decision.

D. The Decision

The Decision

50. The thrust of the CMA's appeal is that the CAT misconstrued the Decision. Accordingly, to understand the appeal it is necessary to set out the findings made by the CMA in some detail so that they can be compared and contrasted with the CAT's reading of the Decision. For the reasons referred to at [21] above, the Decision addressed only abuse and penalties.

The Pfizer/Flynn distribution agreement

51. An important issue concerns the conclusion of the CAT that the CMA wrongly proceeded upon the basis that the distribution agreement between Pfizer and Flynn was an unlawful cartel and/or abuse of joint dominance and that this unarticulated conclusion of law was critical to many key findings in the Decision: see paragraphs [145] – [160] below. We start with the CMA's findings of fact as to the rationale and *modus operandi* of the agreement and how this related to the CMA's conclusions of law.

- *The First CMA Decision analysis of the agreement*

52. In the First CMA Decision the CMA considered the facts surrounding the coming into effect of the agreement and its operation as evidence supporting its conclusions about the product market being confined to phenytoin capsules produced by Pfizer and as to the market power of Pfizer and Flynn in that market. We treat this as relevant background to the findings in the Decision on abuse.

- *The Tor proposal*

53. Section 2(D) of the Decision, entitled "*Background to the Infringements*", sets out in detail (from paragraphs [2.193] – [2.276]) how the Pfizer/Flynn agreement came about. Before the agreement Pfizer was, from 2009, in negotiation with Tor Generics Ltd ("*Tor*") about the conclusion of a possible agreement whereby Pfizer would license Epanutin to Tor who would change its name and sell it as a generic, at an increased price. Tor's proposal was that the agreement would enable the parties to "*distance ourselves from the price increase*" (Decision paragraph [2.200]). Tor explained that an advantage to Pfizer of using a partner was that "… *there would be no need for PFIZER to answer questions to the [DHSC] in relation to a generic presentation or product price*".

54. In an email in July 2009 a Pfizer employee explained that a rationale for an agreement of this sort was: "…*that we do it via Tor to distance ourselves from the price increase. Clearly, we do not need Tor to do this and could just try to go down this route ourselves, however I believe that we would struggle to get the price increase required with the [DHSC]*". The email concluded:

> "My other concern is just an ethical one – the top line money looks great, however this would increase the price of phenytoin capsules to the NHS drastically and to be frank, doesn't feel right. Clearly we need to make money on the product and therefore, I wonder if a conversation with the DOH [DHSC] with these findings could simply increase our pack price to enable profitability. It would certainly not add £19m to the top line but might sit better? Or on the other hand, maybe I'm just being to [sic] nice!!"

55. Pfizer considered the implications for patients if prices were increased dramatically from a reputational and medical perspective. One concern focused upon Pfizer's "*Trust initiative*" (Decision paragraph [2.202]). Another concern was that a drastic price increase risked increasing switching with other AEDs which could have a "*major impact clinically*", which would not be "*medically safe*" given the narrow therapeutic window (Decision paragraph [2.204]). An internal conclusion (September 2009) was that: "*[t]here seems to be a strong concern/reluctance on the advisability of doing this form [sic] a patient care / Trust perspective. I echo these*" (Decision paragraph [2.206]).

56. Pfizer also considered the possibility of third party entry. The conclusion was that if prices increased there was little risk of a much higher price being challenged by new competitors (Decision paragraph [2.210]).

57. In February 2010 Pfizer was aware that if it pushed through price increases it would be seen as hypocritically fleecing the NHS but it also considered, presentationally, the arguments it might nonetheless use to persuade the DHSC to accept such higher prices if it did go ahead:

> "2.214 In addition, [Pfizer Director 1] raised a concern regarding the 'positioning' of the proposal: 'We need to work out how we can position this as 'no change' with patients & physicians; and at the same time 'change' with [the DHSC] and payers without being accused of hypocrisy by pursuing a trust agenda, yet taking the opportunity to fleece the NHS in [a] time of funding crisis'.

> Finally, [Pfizer Director 1] again raised the possibility of approaching the DHSC directly:
>
> May be a 'no-goer' but as an alternative; is there an opportunity to go to [the DHSC] and have a sensible debate with them about the inequity in the tabs/caps prices, and explain (in the spirit of openness) that we cannot afford to sell it [Epanutin] at this price and that we could implement a scheme such as this (without going in to details). The aim being to obtain a special price increase outside of PPRS; or at least get them to cut the Cat M price of tabs to the same as caps and prevent TEVA making supernormal profits."

58. In Decision paragraph [2.215] the CMA records evidence given about these documents in the course of the First CAT proceedings. In relation to the recognition within Pfizer that Teva was earning "*supernormal profits*" on tablets, which obviously undermined any argument the prices paid by Teva for tablets were a relevant comparable, this was sought to be explained away in oral evidence upon the basis that it was "*clearly not a serious comment*".

- *The Pfizer / Flynn agreement*

59. Pfizer rejected the Tor proposal in April 2010 by which point in time it had been engaged (as from January 2010) in discussion with Flynn about a similar agreement.

60. The Decision records the progress of the negotiations and how they culminated in agreement. In July 2010 Flynn sent Pfizer draft Heads of Terms. As part of a briefing to Pfizer, Flynn outlined future strategy. The Decision states:

> "2.233 In relation to 'pharmaco-political issues', the briefing records:
>
> > Pfizer UK's position would be simple: Pfizer has divested the product to Flynn Pharma Ltd. Flynn would defend its right to make profit within the bounds of the PPRS and generic pricing regulations. The cost implications to the NHS would be preferable, in any event, to the alternative of discontinuing the product in the UK and switching patients to more expensive tablet presentations."

61. Pfizer and Flynn considered how they could defend against parallel imports which might be induced by a possible magnetic effect flowing from high prices (Decision paragraphs [2.265] – [2.276]). They also focused upon how the parties would present the arguments and in particular how Pfizer would address the "*Trust agenda*", an issue the Association of the British Pharmaceutical Industry was concerned with and whose committee on trust issues was chaired by a representative from Pfizer (Decision paragraph [2.240]).

- *The CMA's assessment of the impact of the agreement*

62. In paragraphs [2.258] – [2.259] the CMA concluded that the inclusion of Flynn into the supply chain had a "*limited impact on the route to market*" for capsules. Prior to the agreement capsules were manufactured by Pfizer in Germany and delivered to Pfizer's pre-wholesaler in the UK from where they were distributed to pharmacies by logistics service providers contracted to Pfizer. Following the agreement capsules continued to be manufactured by Pfizer in Germany and delivered to the same wholesaler in the UK. Flynn placed an order with Pfizer upon a weekly basis which was processed and sent to third parties who stored and delivered the capsules to Flynn's customers. Flynn had no warehousing or delivery facilities and at no point took physical receipt of the capsules nor was ever responsible for their dispatch. The agreement brought about a single change to the supply arrangements namely that Flynn placed orders for the product but, otherwise, the route to market was "*largely identical to that which existed prior to September 2012*".

63. The CMA conducted a detailed analysis of the final agreement. It found, as a fact, that Flynn incurred "*very little financial risk*" in relation to the role it performed in the supply chain and that its pharmacovigilance role was essentially administrative. Aside from product purchase and distribution costs, Flynn's other specific costs were limited to marketing activity and customer management (Decision paragraphs [2.262] – [2.264]).

64. In paragraphs [2.282ff] the CMA set out evidence relating to the attempts by Flynn to obtain a price increase from DHSC. In July 2012, the DHSC informed Flynn that, under the terms of the PPRS, it could not agree to Flynn's informal PPRS pricing proposal. In paragraph [2.290] it recorded that Flynn proceeded to de-brand Epanutin and withdrew the product from the PPRS "*…meaning they were no longer subject to any form of profit control*". From 24th September 2012, Flynn distributed the products under the name "*Phenytoin Sodium Flynn Hard Capsules*" at a supply price significantly above the price historically charged by Pfizer under the PPRS. The Drug Tariff ("*DT*") price paid by the NHS was consequently set by reference to Flynn's list price, significantly increasing the costs of the drug to Clinical Commissioning Groups ("*CCGs*") purchasing similar volumes of the same products.

- *The CMA's analysis of the relevance of the agreement to a finding of abuse*

65. The CMA did not analyse the agreement as an unlawful exclusive distribution agreement which had as its object or effect the restriction of competition (under section 2 CA 1998) nor did it examine the case as one of joint dominance and abuse (under section 18 CA 1998). In the first CMA Decision the agreement is analysed as enabling Pfizer to confer its dominant market position upon Flynn in the downstream supply market. In the Decision the agreement is treated as the means or mechanism whereby the parties implemented price increases which were immunised from competition and as such the agreement is part of the factual matrix to the abuses by Pfizer and Flynn. In paragraph [1.16], the CMA held that the high prices were the "*result*" of the agreement:

> "1.16 The high prices that the Parties imposed were the result of an agreement between them under which Capsules were de-branded and removed from the branded price regulatory regime (the Pharmaceutical Price Regulation Scheme (the 'PPRS')), so that they could significantly increase their prices and share the substantial profits generated between them."

In paragraphs [2.256] and [2.257] the CMA's conclusion was as follows:

> "2.256 The arrangements entered into between Pfizer and Flynn had the effect of introducing a second dominant supplier into the supply chain, without the addition of relevant commercial activity or financial investment in that supply chain.
>
> 2.257 The Parties also envisaged that the arrangements themselves were likely to increase barriers to competition from parallel imports."

The calculation of Cost Plus

66. In Chapter 5 the CMA set out the methodology it used to calculate both the Cost and Plus elements of Cost Plus. The first step was to determine the total costs incurred in producing and supplying the product which included costs directly incurred in the supply of capsules and an appropriate apportionment of indirect costs, such as corporate overheads. A RRoR was then calculated and added to total costs, to determine Cost Plus.

- *The RRoR: ROS v ROCE*

67. In paragraphs [5.31] – [5.49] the CMA examined the pros and cons of using ROS as against a ROCE as the appropriate method of determining the RRoR. An important section of the Decision is paragraphs [5.40ff]. This explains when ROS is and is not appropriate and the evidential significance of comparator evidence to this analysis:

> 5.40. ROS is a measure of profit margins. It measures returns relative to revenues, after the deduction of both direct and indirect costs.
>
> 5.41 The ROS approach involves the identification of products or companies that are sufficiently similar to the reference product. Where sufficiently similar comparators can be identified, the authority may infer a reasonable rate of return by applying the comparator ROS to the reference product. In practice, the authority does this by calculating the uplift on costs that results in the required ROS.
>
> 5.42 As ROS measures returns relative to revenues only, it is not directly informative of how returns compare with the capital, activities and risks that are necessary to supply the specific product or service. A ROS cannot be compared directly against the cost of capital for this reason. In fact, a key criticism of the ROS approach is that there is no direct link between the ROS of a company or product and an objective benchmark against which observed returns can be compared.
>
> 5.43 Given this limitation, a ROS analysis is typically only undertaken where:

> 5.43.1 there are significant difficulties associated with the ROCE approach (for example, where the identification and valuation of the capital employed in the relevant activities is uncertain or particularly complex); and
>
> 5.43.2 sufficiently similar products or companies can be identified which allow for reliable and meaningful comparisons to be drawn with the reference product.
>
> 5.44 The critical issue in applying the ROS approach (or any other approach based on profit margin comparisons) is the selection of suitable comparators.
>
> 5.45 The factors that determine appropriate comparators will vary on a case-by-case basis and will be dependent on the particular characteristics and circumstances of the specific product or company under investigation.
>
> 5.46 As explained further below, the characteristics and features of specific products may be expected to affect profitability on a ROS basis considerably. The selection of comparators should therefore be based on good reasons to believe that the comparators are sufficiently similar to the reference product (across all relevant product characteristics). The average returns of selected companies may not provide good comparators for a specific product for this reason (indeed, the profit margins of individual products within one company's portfolio can themselves be expected to vary considerably). Where there are unusual features associated with the reference product, the identification of suitable comparators may prove particularly problematic.
>
> 5.47 Typically, relevant factors may include that other products or companies are sufficiently similar to the reference product in terms of their activities, capital intensity, cost structure and level of risk, and that the chosen comparators are not distorted by ineffective competition."

- *RRoR: The choice of a 10% ROS for Pfizer*

68. For Pfizer, a 10% ROS was applied which was more generous than the 6% ROS used in the First CMA Decision. In the First CMA Decision in 2016 the CMA attributed a 6% ROS based upon a consideration of: (i) Pfizer's internal average ROS; (ii) Pfizer's contribution margin threshold (below which Pfizer would place a product under review); (iii) the CMA's analysis of the capital employed by Pfizer in producing and supplying Pfizer's Products; and (iv), the allowable ROS under the PPRS. In the Decision the CMA used a 10% ROS based upon: (i) the average ROS earned by the business units within Pfizer which managed the supply of Pfizer's Products; (ii) Pfizer's contribution margin threshold; (iii) the allowable ROS under the PPRS; and (iv), the results of an updated ROCE analysis (see paragraphs [5.143] – [5.179]). The CMA held:

> "Conclusion on a reasonable rate of return for Pfizer's Products
>
> 5.177 The CMA considers that a 10% ROS represents a reasonable rate of return for Pfizer's Products.
>
> 5.178 This level of return reflects the average ROS earned by the EPBU, the business unit within Pfizer which managed those products which are most similar to Capsules. The CMA's ROCE analysis also produces a reasonable return which is equivalent to a 10% ROS, supporting that this level of return appropriately compensates the activities and risks associated with the supply of Pfizer's Products.
>
> 5.179 The reasonableness of adopting a 10% ROS for the purposes of the CMA's Cost Plus assessment is also supported by a consideration of how this level of return compares to Pfizer's contribution margin threshold and the allowable ROS under the PPRS."

Pfizer did not appeal these findings.

- *RRoR: The choice of a 10% ROCE for Flynn*

69. In the first CMA Decision in 2016, the CMA held that ROCE was inappropriate for determining a reasonable return for Flynn, due to difficulties in measuring the level of capital assets employed. It therefore adopted the ROS approach. Having identified a relevant ROS benchmark (the PPRS), the CMA assessed the risk and investment profile of capsules against that benchmark. The CMA concluded that Flynn's supply of capsules was less risky and required less investment than the benchmark average. It adopted the benchmark of average ROS as a conservative proxy for a RRoR for Flynn's Products.

70. In the Decision the CMA reversed its earlier position because it now considered that it could adopt a ROCE analysis, calculating the average annual capital employed (at £3.5m) and applying a WACC of 10%. It cross-checked its ROCE analysis against several sensitivities including a RRoR of 6% ROS.

71. In paragraphs [5.102ff] the CMA considered and rejected Flynn's argument that ROS was the appropriate approach which demonstrated that its prices were not abusive. The CMA set out the reasons for adopting the ROCE approach in paragraphs [5.56ff]. The CMA explained:

> "5.61 In view of all of the available evidence, including the evidence obtained after the 2016 Infringement Decision, the CMA considers that the difficulties previously perceived in measuring Flynn's capital base are no longer well founded. In practice, the evidence shows that the ROCE methodology can be applied to Flynn's Products because:

> 5.61.1 the information and submissions provided by Flynn clearly identify the capital that is employed in its supply of Capsules;
>
> 5.61.2 the data provided by Flynn allows this capital to be quantified and valued reliably (and for sensitivities to be applied); and
>
> 5.61.3 the CMA is able to identify a reliable estimate of Flynn's cost of capital.
>
> 5.62 On this basis, the CMA has applied the ROCE methodology to establish a reasonable rate of return for Flynn's Products..."

72. In paragraph [5.63], the CMA explained why ROS was inappropriate:

> "5.63 Conversely, for the reasons explained in paragraphs 5.102 to 5.119, the CMA considers there to be significant conceptual issues which render the use of a ROS analysis problematic in Flynn's case. These conceptual issues include that:
>
> 5.63.1 the high input cost that Flynn agreed to pay to Pfizer as part of the Parties' arrangement suppresses Flynn's profit margins, such that significant profits earned by Flynn can be associated with a low computed percentage margin. Profit margin analysis thus allows Flynn to rely on its position in the supply chain and its arrangement with Pfizer to insulate Flynn's own supply prices from the effective application of Chapter II.
>
> 5.63.2 the combination of a number of product-specific factors (including high sales volumes and a very low level of commercial risk as well as the high input cost incurred by Flynn) result in unusual economics of supply, with the consequence that it is very difficult to identify meaningful ROS comparators for Flynn's supply of Capsules."

73. During Flynn's appeals to the CAT the CMA supported the analysis in the Decision with additional expert evidence benchmarking the reasonableness of the ROS approach. This took into account data provided by: Flynn as part of the 2016 proceedings; evidence provided by Flynn and its experts before the CAT and the Court of Appeal; and, Flynn's representations on the SO. Flynn had adduced evidence: that there was "*very little fixed capital employed by Flynn for phenytoin*"; that it accepted that it had not invested heavily in relation to phenytoin during the Relevant Period; that it had not innovated in relation to the relevant products; and, that it had incurred zero sales and promotion costs during the Relevant Period. In evidence to the CAT (when discussing activities undertaken by Flynn in supplying capsules which thereby entitled it the opportunity to earn a return), Flynn referred only to the need to cover the cost of its working capital and the need to strengthen the supply chain by identifying a second API supplier.

The differential between Cost Plus and ASP

74. The CMA set out the evidence upon which it relied to determine the selling price and explained why it used ASP as the relevant benchmark, as opposed to the Drug Tariff. In an analysis covering over 300 paragraphs (paragraphs [5.123]–[5.428]) and 66 pages, the CMA set out the accountancy and other evidence upon which it relied to arrive at its conclusions.

- *Prices above Cost Plus are not per se illegal*

75. In paragraph [5.30] the CMA stated that a price above Cost Plus was not necessarily abusive:

> "…Where the costs of production or the costs actually incurred, including a reasonable rate of return, can be ascertained, there is no reason why the authority should not be able to use such methodology to ascertain an appropriate counterfactual for the excessive limb of the analysis. For the avoidance of doubt, Cost Plus does not determine the maximum price for a product. It is possible for an undertaking to price above Cost Plus without those prices being either excessive or unfair."

- *Margin - Pfizer*

76. In relation to Pfizer the CMA calculated the margin (excess) of ASP over Cost Plus and summarised the results in Table 1.2:

Table 1.2: Pfizer's excesses on Pfizer's Products, September 2012 to December 2016

	Capsule strength				Total sales
	25mg	50mg	100mg	300mg	
Revenue	£2,406,053	£7,254,162	£37,094,139	£24,532,890	£71,287,245
Cost Plus	£1,935,870	£3,792,624	£4,834,151	£3,259,203	£13,821,849
Excess (revenue)	£470,184	£3,461,538	£32,259,988	£21,273,687	£57,465,397
Excess (per pack)	£0.88	£3.20	£32.67	£32.10	N/A
Excess (%)	24%	91%	667%	653%	416%

Source: CMA analysis in Section 5 (Excessive).

- *Margin - Flynn*

77. In relation to Flynn the equivalent tale is Table 1.3:

Table 1.3: Flynn's excesses on Flynn's Products, September 2012 to December 2016

	Capsule strength				
	25mg	50mg	100mg	300mg	Total
Revenue	£7,499,989	£15,317,886	£52,700,832	£35,881,444	£111,400,152
Cost Plus	£3,132,759	£8,643,336	£38,602,169	£25,286,634	£75,664,898
Excess (revenue)	£4,367,230	£6,674,550	£14,098,664	£10,594,810	£35,735,253
Excess (per pack)	£8.26	£6.27	£14.55	£16.30	N/A
Excess (%)	139%	77%	37%	42%	47%

Source: CMA analysis in Section 5 (Excessive).

78. The CMA took the (high) input price charged by Pfizer to Flynn as the relevant Cost Plus benchmark against which to measure Flynn's margin. This meant that Flynn's Cost Plus was significantly higher than Pfizer's and that accordingly Flynn's percentage margins were (in general) less than Pfizer's. But Flynn's margins were, in absolute terms, significant for each capsule strength.

79. The CMA found that the excess for both Pfizer and Flynn was material, having been sustained over a period of years.

Application of the test of fairness

- *The approach of the CMA*

80. In Chapter 6 the CMA considered whether the prices were unfair in themselves and whether they were fair by reference to comparators. It concluded:

> "6.2 First, the CMA finds that Pfizer's Prices and Flynn's Prices were unfair in themselves (see section 6.B).
>
> 6.3 Second, the CMA finds that the comparators relied upon by the Parties do not demonstrate that Pfizer's Prices or Flynn's Prices were fair when compared to competing products or undermine the CMA's conclusion that the Parties' prices were unfair in themselves. In coming to this conclusion, the CMA has evaluated relevant evidence and arguments advanced by Pfizer and Flynn and gathered and evaluated a large body of additional evidence (see section 6.C)."

- *Summary of reasons why the prices were unfair in themselves*

81. The CMA examined (at this stage without having regard to comparables) whether features of the products justified the price increases and took into account that: (i) the capsules were long off patent; (ii) they were in the third stage of the drug life cycle where competition should have driven prices down; (iii) there was no improvement to the products, their production or distribution; (iv) there was no innovation, investment or commercial risk-taking activity which could be associated with the price increases; and (v), in qualitative terms the capsules suffered from significant limitations and compared poorly to other AEDs.

82. Pfizer's ability to increase capsule prices to 783% - 1,601% higher than had been charged until September 2012 was made possible by its dominant position. Equally, Flynn's ability to charge pharmacies and wholesalers (i.e. Pfizer's previous customers) prices which were 2,361% - 2,686% higher than Pfizer's pre-September 2012 prices, was also made possible by its dominant position which it had acquired by virtue of its exclusive distribution agreement with Pfizer. The undertakings understood that they possessed market power and chose to exploit it. In July 2010 Flynn gave a presentation to Pfizer highlighting that even if the then proposed increase in price triggered parallel imports which gained a 50% market share, the planned price increases would still generate in excess of £20m in additional profit. An internal Pfizer email agreed: *"…[t]he incremental revenue will be approximately £20M / year – and as nothing else changes significantly, this goes straight through to the bottom line*".

83. The CMA also took into account that the commercial objective behind the arrangements between Pfizer and Flynn was to remove capsules from PPRS constraints with a view to increasing prices and that the reason Pfizer brought Flynn into the supply chain was to create a reputational shield from criticisms that would arise from the anticipated adverse impact on the NHS when prices were, abruptly, increased.

84. The reasons were summarised in Decision paragraph [1.47] and more fully in paragraphs [6.5ff]:

    (i) The price increases imposed over time by both Flynn and Pfizer were significant, resulting in very high prices relative to costs which went well beyond the level that might have been required to ensure the drug was commercially viable or sustainable: Decision paragraphs [6.6.1], [6.7] – [6.8], [6.9] – [6.16] (in relation to Pfizer), and [6.17] – [6.26] (in relation to Flynn).

    (ii) The price increases were "*selective*" since it was only in the UK that Pfizer entered into arrangements of the type agreed with Flynn and significantly increased prices above the level of prices that Pfizer charged for identical capsules in other European jurisdictions. Capsules supplied in EU Member States were manufactured by Pfizer in the same facility in Germany as capsules supplied to Flynn in the UK: Decision paragraphs [6.6.2], [6.27] – [6.37].

    (iii) Pfizer and Flynn deliberately exploited their market power. Prices reflected substantial market power arising from the absence of effective constraints and very high barriers to entry. The markets were incapable of functioning to produce a reasonable relationship between price and economic value. The Parties knowingly exploited this market power to impose significant overnight price increases on the NHS which they maintained for over four years. They wilfully ignored customer concerns: Decision paragraphs [6.6.3], [6.38] – [6.71].

    (iv) The features of capsules provided no justification for the price. Capsules were long off-patent and in their third stage of the drug life cycle where competition could normally be expected to drive prices down and result in ongoing low prices even whilst they continued to deliver benefits for patients. There had been no improvement to the products, or their production or distribution, or any innovation, investment or commercial risk taking activity justifying the new prices. Capsules suffered from significant limitations and compared poorly

relative to other AEDs which explained their position as a third line treatment for patients. Demand was sustained predominantly by barriers to switching patients to other treatments, not because of the therapeutic benefits relative to other AEDs: Decision paragraphs [6.6.4], [6.73] – [6.100].

(v) Pfizer and Flynn gamed the regulatory system in order to increase prices. The purpose behind the agreement was to remove capsules from the constraints of the PPRS in order to increase prices thereby generating substantial profits for Pfizer and Flynn. Flynn was brought into the supply chain to provide reputational protection for Pfizer from the criticism that would otherwise arise from the impact on the NHS. The prices had significant and adverse effect on Pfizer/Flynn Customers and Pfizer/Flynn Patients: Decision paragraphs [6.6.5], [6.101] – [6.117].

Comparator evidence

85. In addition, the CMA considered comparator evidence:

> "1.49 However, the Parties have argued that the £30 Drug Tariff price of phenytoin sodium tablets ('Tablets') and the prices of certain other AEDs demonstrate that their prices were fair by comparison. For the purposes of assessing the Parties' arguments, the CMA has gathered and carefully evaluated evidence relating to the following potential comparators:
>
> 1.49.1. the £30 Drug Tariff price of Tablets;
>
> 1.49.2. upstream ASPs of Tablet suppliers; and
>
> 1.49.3. the prices of other AEDs."

The CMA also examined the prices paid for phenytoin capsules in other EU states. We summarise the analysis of the CMA in relation to each below.

- *The DT as a non-comparable mechanism/price*

86. As set out above, the first time around the CAT set aside the decision upon the basis that there was an insufficiently detailed analysis of tablets as potentially relevant comparators. In particular the CAT, and then this Court on appeal, recognised that a key issue that required further investigation was whether the prices charged by Teva, as the main supplier of tablets, were affected, adversely, by market power such that they were super-competitive and not reflective of the prices that would be paid in a genuinely competitive market.

87. The analysis in the Decision of tablets covers two main issues: (i) the DT price for tablets of £30 paid to Teva; and (ii) the upstream prices paid for tablets. The analysis is granular and detailed. It covers 70 pages (pp 284 – 354) of text and nearly 300 paragraphs from Decision paragraphs [6.164] – [6.457].

88. As to the DT itself the CMA held that, as a mechanism, it was not a comparable. This was because the £30 DT price was not a like-for-like comparison with the parties' prices, which were at different levels of the supply chain. It was significantly above the

upstream selling prices charged by tablets suppliers during the Relevant Period, which would be much closer comparators with Flynn's prices. Pfizer's prices were even further upstream from the DT price rendering them even more remote and distant comparators: see summary at Decision paragraph [6.192.1].

- *The £30 DT reflected the exercise of market power*

89. Pfizer and Flynn benchmarked capsule prices by reference to the prevailing DT tablets price of £30 (28x 100mg Tablets) and argued that this was appropriate because the £30 price had been implemented following arm's length discussions between Government ("*DHSC*") and the supplier Teva UK Limited ("*Teva*"). This represented a price the DHSC was prepared to pay for tablets taking into account its true value and therefore was a valid comparable.

90. The CMA disagreed. Tablet prices were characterised by market power on the part of Teva and were not useful comparators. It carried out a detailed, chronological, analysis of the evolution of prices over time and asked whether, and if so to what extent, fluctuations in prices were affected by market power held by Teva. The Decision considers the evidence under four headings: (i) product characteristics and usage of tablets; (ii) regulatory regime; (iii) the evolution of the DT price for tablets; and (iv), market entry and upstream supply prices.

91. In relation to product characteristics and usage, capsules and tablets were both in the third stage of the drug's lifecycle. They were a third line AED very rarely prescribed to new patients. They were subject to the same clinical guidance as capsules which discouraged switching between different manufacturers' products. Tablets were prescribed to a smaller set of patients than capsules and they were sold at a dosage strength of 100mg only whereas capsules were also sold at strengths of 25mg, 50mg, and 300mg.

92. In relation to price increases imposed by Teva over the Relevant Period the CMA started its analysis in March 2005 when, as the monopoly supplier of tablets, Teva was charging £3.87 per pack. Over the period to October 2007, it increased the price to £113.62. The Decision records that DHSC levelled criticism at Teva as a result of these increases. This culminated in a meeting between Teva and the DHSC in October 2007 which then led to a reduction from £51.25 to £29.50 in October 2008. Subsequently tablets were removed from the quarterly adjustment mechanism which determined the DT price which remained at £30 thereafter. In evidence to the CMA the DHSC explained that the continuation of a DT price at £30 was an "*oversight*": Decision paragraph [6.183].

93. The CMA gathered evidence as to the evolution of tablet prices following market entry when Teva was no longer a monopolist. Prices fell to significantly below the £30 DT: Decision paragraphs [6.190] – [6.214]. The CMA took account of internal documents obtained from Teva which were construed as reflecting a recognition by the company that it was able to use market power to extract high prices. At the time the DHSC had no alternative source of supply and patients could not be switched to alternative treatments. Between 2005-2007 Teva increased the price substantially, by a factor of 8 relative to the price paid by the DHSC in April 2005 at the commencement of Scheme M, and by a factor of 18 relative to the price of £1.70 paid by the DHSC in March 2005: Decision paragraph [6.192.2].

94. To address the argument that the DHSC was a willing purchaser prepared to pay the high DT price the CMA examined at length the evidence of relations between Teva and NHS stakeholders: Decision paragraphs [6.125] – [6.266]. It held that there was unequivocal opposition on the part of the DHSC to Teva's pricing. It rejected as "*unsustainable*" the argument that Government had been a willing payor and considered £30 to be value for money. It took into account what it described as "… *the substantial volume of evidence which shows that the Parties knew that the DHSC (and many CCGs and other stakeholders) objected to their prices and did not consider that the benchmarking against the Tablets Drug Tariff price was justified and that these reservations were communicated unambiguously to the Parties*".

95. In relation to capsules, to decide whether the evidence shed light upon the issue, the Government sought explanations for the cost increases from Flynn and Pfizer who "… *refused to provide their costs information to the DHSC. Instead, they continued to impose their high prices*".

96. Upon the basis that the DT price did not afford useful comparator material the CMA also examined the upstream prices of tablets. It did this across over 150 paragraphs ([6.304] – [6.457]) between pages [317] – [354]. It examined the evolution of prices over the period and linked this to changes in the degree of market concentration. The CMA tracked prices when Teva was a monopolist, when the market was duopolistic, and when it was oligopolistic. It benchmarked its analysis of price movements by reference to the internal documentation of Teva and the new entrants (Wockhardt and Milpharm) to see whether that evidence reflected an appreciation upon the part of the suppliers that they were able to price at levels reflecting high degrees of market concentration. The CMA found that this evidence corroborated the conclusion that upstream tablets pricing was affected by high degrees of market power. During the period when there were three suppliers, which reflected the most competitive period under review, prices reduced but not to a level the CMA considered reflected prices that would have been charged in a genuinely competitive market (Decision paragraphs [6.307ff]).

- *Other non-Phenytoin AEDs*

97. In relation to other AEDs the CMA evaluated evidence submitted by Pfizer concerning the pricing of 5 AEDs. These were in their solid form and, it was said, thereby the most similar to phenytoin sodium capsules (Decision footnote [1486]). These were: (i) branded topiramate (known as Topamax); (ii) branded lamotrigine (known as Lamictal); (iii) branded levetiracetam (known as Keppra); (iv) branded oxcarbazepine (known as Trileptal); and (v), generic ethosuximide. Pfizer's case was based upon conclusions about the characteristics of AEDs relative to capsules. It argued that these were relevant benchmarks because they were similar to capsules, treating the same condition, and with similar levels of efficacy and a comparable lack of serious side effects. It was also argued that because they were not subject to continuity of supply their pricing was more consistent with that emerging from workably competitive conditions.

98. The CMA rejected this evidence as not "*meaningful*". It compared and contrasted the characteristics of these AEDs relative to the Pfizer capsules including: the existence of "*undesirable product characteristics*" not present in the other AEDs; whether the other AEDs were used to treat different seizure types and patient groups; whether the AEDs

were equivalent in terms of their line of treatment; clinical guidance and relative benefits; whether they were branded or not; and, as to the impact of de-branding on their price and volume of sales when it occurred.

99. In Decision paragraphs [6.73] – [6.100] and in Annex E (pages [491] – [517]) the CMA considered possible commercial justifications for the high prices by reference to other AEDs.

100. The CMA considered: (i) the position of phenytoin capsules and other AEDs in the drug life cycle; (ii) whether each drug was viewed internally by the parties as a "*commodity*" driven market; (iii) whether, if that were so, one would expect to see prices driven down towards cost; (iv) what the likely response of the DHSC would have been to an application to push prices up; (v), whether there was any improvement, innovation or investment in the product or in the levels of commercial risk undertaken by the parties which could justify the price increases; and (vi), whether there was any change in manufacturing or the route to market which justified price increases. It concluded that there were no possible justifications for the price increases.

101. The CMA also examined evidence submitted by Flynn in relation to: steps taken to implement the agreement with Pfizer and to maintain existing positions with patients including continuity of supply; risks and responsibilities assumed by Flynn as the MA holder; savings in costs incurred brought about by conclusion of the agreement; expenditure on buffer stocks; risks said to have been accepted by Flynn; and activities in relation to products unrelated to capsules. The CMA observed (Decision paragraphs [6.85]-[6.86]) that where such factors resulted in costs incurred these were accounted for as part of the RRoR. The CMA concluded, on the facts, that Flynn undertook limited commercial activities carrying a low level of commercial risk. Nothing in the arguments advanced by Flynn justified the prices it charged.

102. Later in the Decision (paragraphs [6.87] – [6.100]) the CMA addressed evidence concerning the medical value of phenytoin capsules relative to other drugs including other AEDs. It performed a comparative analysis from a medical and pricing perspective. It asked whether capsules generated "*additional benefits*" or "*particular enhanced value*". The evidence, which took into account independent evaluations by NICE, showed that relative to other AEDs, capsules were materially inferior:

(i) in terms of patient benefit and continuity of supply;

(ii) as a third line treatment relative to other AEDs which were first line treatments;

(iii) in terms of side effects, adverse drug interactions and ease of clinical use; and,

(iv) in respect of the rate of prescribing of third line capsules during the Relevant Period which indicated that prescriptions for capsules were a legacy matter relating to long standing patients only.

The CMA referenced its conclusions on relative inferiority against the parties' internal documents and found that this corroborated the conclusion.

103. The CMA also analysed capsules pricing against movements in prices for AEDs after they became generic. It observed (Decision paragraph [6.499]) that evidence of generic

competition had resulted in lower prices for four of the five AEDs reviewed, a trend not seen in relation to capsules. A more detailed analysis is found in Decision pages [360] – [377], paragraphs [6.482] – [6.531]. The CMA analysed the relative performance of generic capsules against the four branded AEDs put forward as evidence by Pfizer. The price of these branded versions had been maintained at high levels even though the vast majority of market volume had switched to the generic version: Decision paragraph [6.499]. The CMA concluded that the price of the branded comparators was not a meaningful comparator. Branded pricing reflected strategic decisions by the suppliers not to compete with generic entry. Branded prices applied to a small and dwindling proportion of the overall volumes and were not the result of price competition in competitive market circumstances: Decision paragraph [6.500].

104. The overall conclusion (Decision paragraph [6.531]) was that because capsules were a generic drug which had maintained high prices and volumes any meaningful comparison had to be against the price of generic entrants who competed for the higher volumes associated with open prescriptions. The price of these generics was reflective of price competition and related to the contestable portion of the market which had the higher aggregate volumes and was materially lower than capsule prices.

- *Comparative prices of phenytoin capsules in the EU*

105. This category of evidence was obtained by the CMA as part of its own investigative exercise and was relevant in addressing the submission of Pfizer that it needed to increase prices in order to secure the commercial viability of capsules. In the First CAT judgment in 2018 (paragraphs [401] – [402]) it was held that evidence of prices in other EU states needed to be treated with care since different regulatory regimes governing price applied and could affect the meaningfulness of that information as a comparable. The comparative data did not demonstrate, in and of itself, that UK prices were unfair. The CAT did, however, think that it was significant that increases in UK pricing, which had been comparable to EU prices prior to 2012, occurred only after the agreement between Pfizer and Flynn.

106. In the Decision the CMA therefore conducted a more detailed analysis which is described in paragraphs [2.339] – [2.355] and [6.28] – [6.30]. It did not rely upon this evidence to demonstrate abuse *per se* but relied upon the substantial differential between EU and UK pricing as supporting evidence. The CMA pointed out that the cost of supply to Pfizer was identical in each state (paragraph [2.339]). In all EU states Pfizer used the method of distribution it had used in the United Kingdom prior to 2012 and the agreement with Flynn. Between 2011 and 2012 Pfizer's ASP to pharmacies in the UK was comparable to prices elsewhere in the EU (paragraph [2.340] and Figure 2.9). In paragraphs [2.341] – [2.342] the CMA recognised that in six out of seven EU states in which the drug was sold it was subject to regulatory constraints. The regulatory regimes across the EU were not the same: "*Across the EU Member States where Pfizer is subject to varying degrees of price control*…" (paragraph [2.350]).

107. Between paragraphs [2.343] – [2.345] the CMA compared and contrasted price increases across the EU with increases in the UK *via* the Flynn agreement. In paragraph [2.346] and Table 2.11 the CMA described the substantial disparity between price rises in the UK and the EU. In paragraph [2.348] the CMA recorded that implementation of the Pfizer/ Flynn agreement led to prices in the UK which were: 24 times higher than

in Spain; 13 times higher than in Greece; 8 times higher than in Cyprus; 7 times higher than in Belgium, Luxembourg, Ireland and Malta; and 6 times higher than in Sweden.

108. In Decision paragraph [6.14] the CMA recorded that Pfizer had argued that the price increases imposed in September 2012 were necessary to ensure the continued supply of capsules to the UK market. A witness before the CAT stated that Pfizer's price increases were "*about putting this product back on a fair sustainable basis for the longer term*" and were the only way Pfizer could bring pricing to a level of profitability that made the product viable. The CMA set out reasons why this argument was unsustainable (Decisions paragraphs [6.15] and [6.16]). In footnote [1011], the CMA set out a calculation that made the point very clearly based upon Pfizer's own data: "*Using Pfizer's own measure of contribution, it incurred losses amounting to £3.5 million from January 2007 up to September 2012. Using the same measure of profitability, Pfizer earned profits of £4.4 million between September 2012 and October 2012 alone, more than covering any losses it claims to have incurred in the preceding five years…*".

109. In paragraphs [2.350] – [2.355] the CMA addressed price increases in Sweden where the regulatory authority permitted a price increase from 23.86 to 79.5 SEK (approximately £7.41) upon the basis that the increase was needed to secure commercial viability. In paragraphs [6.27] – [6.29] the CMA drew inferences from the above facts. It stated that production costs were more or less identical across the UK and EU and across all jurisdictions Pfizer used similar arguments in relation to viability to seek increases in prices. The CMA recognised that because regulatory systems differed "*some caution*" had to be exercised when drawing comparisons. However, the "*selective nature*" of the price increases supported (but did not prove) the conclusion that Pfizer's prices in the United Kingdom were unfair. The CMA considered that, subject to the need to exercise caution, prices in other EU jurisdictions were relevant to fairness and to addressing potential justifications advanced by Pfizer (paragraph [6.33]). In paragraphs [6.34] – [6.36] the CMA considered the position in certain EU states (Sweden and Malta). In paragraph [6.37], the CMA's conclusion responded to the argument about commercial viability:

> "The significant differences in price between the UK and these seven other European jurisdictions illustrate the true scale of the price increases imposed in the UK, as well as the resulting very high prices. They also illustrate further how the price increases in the UK went beyond any level that might have been necessary to ensure commercial viability, given that this is exactly the same drug, manufactured by the same company, in the same facility in Germany, and with similar direct costs."

E. The CAT Judgment

The setting aside of the CMA Decision: Summary of the main criticisms made by the CAT of the CMA

110. We turn now to the Judgment. In setting aside the Decision the CAT largely accepted the appellants' grounds of appeal. A summary of the CAT's conclusions is set out below. These represented the targets of the CMA's challenge to the Judgment in this appeal.

111. There were three overarching findings by the CAT that were relevant to most other grounds of appeal and applied to both Pfizer and Flynn, namely:

(i) **The prior illegality point**: The reasoning in the Decision depended upon a finding, not set out or acknowledged by the CMA in the Decision, that the Pfizer/Flynn agreement was an unlawful cartel prohibited by section 2 CA 1998 and/or an unlawful abuse of joint dominance contrary to section 18 CA 1998. This was because the CMA's case relied upon a finding that Pfizer and Flynn shared profits, which could only be made if there was a cartel or a joint abuse. In the absence of a *formal* finding that the Pfizer/Flynn agreement was unlawful, prices charged by Pfizer to Flynn had to be treated as fair and competitive.

(ii) **The per se approach to Cost Plus**: The CMA erred in adopting the legally incorrect position that any price above Cost Plus was unlawful. In so doing the CMA reversed the burden of proof, ignored the presumption of innocence and failed to consider the evidence tendered by Pfizer and Flynn to justify prices above Cost Plus. The CMA failed to recognise that a "*fair"* price lay somewhere between Cost Plus and the actual selling price and it failed to delineate where on that pricing scale the divide between fair and unfair sat.

(iii) **Bias:** The CMA was guilty of confirmation bias. To justify a predetermined conclusion that Pfizer and Flynn were guilty of abuse it focused only upon inculpatory evidence and ignored exculpatory evidence.

112. In addition, the CAT found that the CMA erred in its calculation of Cost Plus for Flynn. It held that whilst the CMA was correct to use ROCE as the proper measure of RRoR, when determining the ROCE of Flynn the CMA: (i) wrongly determined the cost of production for Flynn by ignoring the input price charged to Flynn by Pfizer for the capsules; (ii) *"grossly underestimated*" the capital required by Flynn to distribute the capsules; and (iii) jumped to "*conclusory*" and unsubstantiated conclusions about an appropriate figure for WACC.

113. In relation to the test of fairness, which applied to both Pfizer and Flynn, the CAT held that the CMA erred in several respects:

(i) **Comparables:** The CMA failed to consider the probative value of comparables and in particular the DT price for tablets, the upstream market price for tablets, and prices of other AEDs. The CMA's finding that features of capsules militated against any justification for above Cost Plus pricing was a "*material*" and "*bad*" point. In summary: (i) the CMA failed to refer adequately to continuity of supply; (ii) whilst the CMA was not incorrect to say that the product had not improved over time this reflected the mindset of the CMA that any price above Cost Plus was presumed unfair which unlawfully reversed the burden of proof; (iii) the conclusion that capsules suffered from significant limitations was incorrect because it suggested that barriers to switching were imposed by the seller as opposed to Medicines and Healthcare Products Regulatory Agency ("*MHRA*") guidance; (iv) the suggestion that capsules were not medically beneficial was fundamentally incorrect and implied criticism of conscientious doctors treating epileptic patients; (v) the finding that there was no economic value or patient benefit was not sustainable and the medical benefits of capsules were given insufficient weight; (vi), the conclusion that economic value sat at

Cost Plus ignored all of the factors that might justify a surplus; and (vii), when considering value and benefits and what might arise in a counterfactual workably competitive market the CMA wrongly used a new test "*sufficiently effective competition*", instead of the proper test which was "*Real World*" competition.

(ii) **Prices in EU states**: The CMA erred in taking into account the price of Pfizer's phenytoin sodium capsules supplied in various member states of the EU because it wrongly assumed that all such prices were competitive even though they were subject to regulatory constraints which made such a conclusion unproven. It also erred because it assumed, without producing relevant evidence, that Pfizer was obliged, for regulatory reasons, to price similarly in all markets and because the CMA treated selective pricing as unlawfully discriminatory, a conclusion which was inconsistent with principles of competition law: Judgment paragraph [228(2)].

(iii) **Changes in prices over time**: The CMA erred in taking into account the irrelevant factor that the prices of phenytoin capsules rose dramatically with the coming into effect of the Pfizer/Flynn agreement. This was "*explicitly"* a Cost Plus factor whereby the CMA had wrongly presumed the excess to be unjustifiable and therefore unfair.

(iv) **Knowing exploitation of market power**: The CMA erred in taking into account its finding that Pfizer and Flynn knowingly set out to exploit their dominant market power which gave them power over price. Because the CMA assumed that any price above Cost Plus was unlawful it had not examined the position fairly by reference to the facts and had "*simply concluded*" that <u>any</u> producer surplus was illegitimate. It was incumbent upon the CMA to articulate "*at least some reasoning in support of the conclusion it has asserted*".

The retaken decision

114. We turn next to provide a summary of the retaken decision. The analysis appears in paragraphs [288] – [321] of the Judgment. We focus upon those findings which relate to the appeals of Pfizer and Flynn concerning procedural unfairness.

- *The need to assess the facts from the perspective of a hypothetical ultimate consumer*

115. In paragraphs [294]–[298] the CAT stated that because the drugs market does not work like ordinary markets where the payor is the consumer it is necessary to create a standard by which to measure the fairness of any price, namely that of a hypothetical "*ultimate consumer*". This was a new test devised by the CAT in its judgment and had not been addressed in the Decision or in the appeals of Pfizer and Flynn.

116. In the CAT's view, the "*ultimate consumer*" had the following characteristics: (i) a diagnosis of epilepsy requiring treatment by a third line phenytoin sodium capsule; (ii) a level of understanding or knowledge about epilepsy, the various medicinal products available and relevant guidance commensurate with that of a GP but not a specialist; (iii) a responsible and reasonably robust attitude towards dealing with the condition embracing an understanding that continuity of supply was intended for psychological

comfort but not medical need; and (iv) an income significantly above the average in the UK implying a person who was well off but not unlimitedly wealthy (see Judgment paragraph [298]).

117. The CAT concluded that such an ultimate consumer would be prepared to pay a premium above Cost Plus for phenytoin capsules because they had significant medical value to those for whom they were prescribed. This value included the continuity of their supply. This value had to be taken into account in determining whether the excess of price over Cost Plus was excessive and/or unfair.

118. The CAT's reasoning (Judgment paragraphs [294] – [298]) was as follows:

(i) In a case of pass-on the intermediate buyer (Flynn), who pays an unfairly high price but then passes it on to the ultimate consumer, does not pay that price itself. To focus upon that intermediate buyer therefore asks the wrong question. The focus needs to be on the ultimate consumer for both Pfizer (who sold only to Flynn) and Flynn.

(ii) In the highly regulated drugs markets, the patient does not pay for the drug but pays a means-tested prescription charge bearing no relationship to the cost or price of the medicine. The party who pays, via the pharmacy and the DT, is the CCG. Neither the patient nor the CCG has agency in what product is prescribed, this being for the clinical judgment of the treating doctor.

(iii) The question is therefore: whose interests are relevant when considering the question of fairness? The ultimate consumer (as defined by the CAT) is a triptych combining the characteristics of doctor, CCG and patient.

(iv) Fairness can only sensibly be evaluated if a particular ultimate consumer is borne in mind. The fact that a person in need of medical treatment is not deprived of treatment because they lack the means to pay and, instead, the cost of treatment is borne or subsidised by the State, is correct but obscures the relationship between price and consumer that is the ultimate driver of competition law.

(v) Because the annual state budget for pharmaceutical products runs to billions "… *how can it sensibly be said that the price of an individual course of treatment costing a tiny fraction of the total budget is or is not fair*?" The criteria by which medicines are admitted into the state system are "… *different to those that inform the Unfair Limb*".

- *The Annex 3 data*

119. In paragraphs [299ff] (cross referring to Judgment paragraph [14]) the CAT referred to the data in Annex 3, which was headed "*Data from the Focal Product Spreadsheets*". This contained data about capsule products, sales volumes, costs and prices for both Pfizer and Flynn during the Relevant Period on a month by month basis. The data had been compiled in "*a static and not a dynamic fashion. The cost of Capsules, and the prices they were sold at, have been captured as a "snapshot" in time (a static measure) and not taking into account the cash flow implications of the sale and purchase of Capsules (a dynamic measure)*".

120. It was not possible to determine from this data Flynn's on-going (dynamic) cashflow requirements for selling or distributing capsules (which a dynamic measure would imply) since this would require a modelling of cost outflows and revenue inflows that has not been undertaken and which would "…*be extremely complex to undertake*". The static model did however enable average capsule costs and prices to be ascertained. In paragraph [299], the CAT held that the data was "*reliable*" and use of a static analysis did not imply any criticism of the CMA:

> "…We stress that this is no criticism of the CMA: but it is important and necessary to understand from the outset the manner in which the CMA has approached the cost and price metrics in this case, for that informs the manner in which the competition law infringements found by the CMA have to be viewed. We cannot, and do not, seek to reinvent the methodological approach that the CMA has chosen to adopt in this case."

- *Summary of cost/price for Pfizer and Flynn*

121. In paragraph [301], the CAT summarised the cost/price data for Pfizer and Flynn as set out in Annex 3 to the Judgment.

Annex 3 values averaged over the Relevant Period	**Capsule Dosage**			
	25mg	50mg	100mg	300mg
(a) Product Unit Cost incurred by Pfizer	£3.27	£3.17	£4.42	£4.44
(b) Volume sold by Pfizer to Flynn	10,282	20,780	18,991	12,746
(c) Pfizer Product Unit Price/Cost to Flynn	£4.50	£6.68	£37.83	£36.67
(d) Product Unit Cost incurred by Flynn	£5.73	£7.93	£39.17	£38.08
(e) Average volume sold by Flynn	10,167	20,456	18,631	12,498
(f) Flynn Product Unit Price	£14.22	£14.43	£52.87	£55.02
	£1.23	£3.51	£33.42	£32.23
(g) Pfizer's Profit Margin	38%	111%	757%	726%
(h) Flynn's Profit Margin	£8.49	£6.50	£13.70	£16.94
	148%	82%	35%	44%

- *Were Flynn's prices abusive?*

122. As regards Flynn's product unit costs, in paragraph [303], the CAT concluded that since there was no basis for finding a Chapter I infringement by virtue of the Pfizer/Flynn agreement, there was no proper basis for suggesting that the price charged by Pfizer to Flynn was not a "*proper competitive price*". That conclusion was not altered even if Pfizer's price to Flynn was abusive: "... *given that there is no Chapter I infringement or abuse of collective dominance as between Pfizer and Flynn, the prices charged by Flynn are reasonably and efficiently incurred. No adjustment to Product Unit Cost is needed*".

123. In paragraphs [305] – [308], under the heading "*The Excessive Limb*", the CAT considered Flynn's RRoR. The CAT explained at [306] that the starting point was to determine the capital employed by Flynn, which it took to be the total cost paid by Flynn for all products sold over the relevant period. The CAT made no adjustment for the fact that in practice the capital actually needed to be employed by Flynn would be significantly less, given that Flynn would be both buying and selling the product over the period. The CAT noted at [306(4)(iii)] that it had "*neither the data nor the benefit of the parties' submissions*" to make such adjustment, but took the view that it was appropriate to proceed on the basis of the total cost "*… because this gives the benefit of the doubt (on an industrial scale) to Flynn, which is the appropriate course given the circumstances in which we are re-making the CMA's decision*".

124. The CAT then explained that it used Flynn's ROS figures for capsules and other pharmaceutical products distributed by Flynn. This suggested a ROS of 35-38% between 2013 and 2016. The CAT used these figures even though it had serious doubts about the evidence (paragraph [306(5)(ii)]):

> "(ii) We entirely recognise the fragility of these figures. They are fragile for a number of reasons. We know very little about the other products distributed by Flynn, in particular their Product Unit Costs and their Product Unit Price. We simply have the percentage ROS figure, from which these values cannot be inferred. The level of the percentage ROS figure varies according to volumes sold: the percentage ROS is significantly lower in the case of higher volume sales. That is unsurprising, given that a Seller will look to absolute revenue not percentage return. The Capsules, as can be seen from Figure/Table 10, are by volume one of Flynn's best sellers, and yet the ROS commanded is at around the average ROS rate, which is high."

125. On this basis, the CAT concluded that 30% represented the "*absolute upper limit*" of a RRoR: paragraph [306(6)]. The CAT then considered what ROCE would represent a normal profit to an entrepreneur conducting the business of Flynn. On the basis that the figure for capital employed was likely to be too high in favour of Flynn (see above) the CAT indicated that it thought that a figure of 15% would represent "*supra-normal profits*". On this basis the CAT concluded that Flynn's profit margins of between 35% and 148% were <u>still</u> "*demonstrably immoderate*" (Judgment paragraph [307]).

126. The CAT then turned to consider what it described as "*The Unfair Limb*". The CAT stated that this was not a case in which demand for capsules exceeded supply (so that a more efficient seller might earn a return above a normal profit), or a case in which Flynn added value to the product (because it was just a distributor of pharmaceutical products generally). As such, the CAT took the view that this was a case in which it was not possible to identify any feature of the services offered by Flynn that would enable it to charge more than a normal profit in circumstances of real world competition: Judgment paragraph [309].

127. In the circumstances, the CAT held that Flynn's prices were unfair and abusive.

- *Were Pfizer's prices abusive?*

128. In paragraphs [311] – [321] the CAT considered whether Pfizer's prices were abusive. It started by setting out in tabular form Pfizer's profit margin based upon the data in the table set out above at paragraph [121]. This showed that, for the highest volume 100mg capsule, the average profit margin was 757%.

129. Pfizer had not challenged the CMA's finding of excess but the CAT decided to undertake its own analysis and "*rigorously consider whether such a finding is justified*". It acknowledged that it had not received factual submissions on the point from Pfizer or the CMA, as it would have done had the point truly been live, and determined to adopt an approach that gave Pfizer the benefit of "*every doubt*": Judgment paragraph [312(2)].

130. In paragraph [312(3)] the CAT rejected the reliance placed by the CMA on the fact that Pfizer's capsule prices were substantially lower prior to the coming into effect of the Pfizer/Flynn agreement in 2012. The "*mere fact*" that prices had increased dramatically did not "*assist very much*" in determining whether the increased prices were excessive or unfair:

> "The fact is that Pfizer contended that its prices before its arrangements with Flynn were put in place were loss-making. Given the judgmental difficulties in ascertaining Product Unit Cost and Product Unit Price, competition authorities need to be confident that the evidence justifies the rejection of such a contention, and in this case, we are not. Similarly, whilst an ability to increase prices dramatically is certainly evidence of dominance, to regard it as evidence of abuse is to prejudge matters without considering the facts objectively."

131. The CAT calculated an appropriate return on capital upon a "*preliminary - and very much broadbrush*" basis (Judgment paragraph [313(2)]). It took the time value for money for a risk free enterprise as a "*generous 5%*" and added a risk loading of 10% on top, giving a 15% RRoR. The CAT thought that this was generous because the capsules were an established product in an established market with inelastic demand generated by the medical needs of those patients who were reliant on phenytoin sodium in general, and such capsules in particular, rather than any other AED: Judgment paragraph [313(3)].

132. The CAT then considered the profit margin in terms of the excess of unit price over unit cost. In paragraph [313(5)] it set out the percentage differentials, which were 38% of the 25mg capsules, over 100% for the 50mg capsules, and 700% in respect of the 100mg and 300mg capsules. The CAT concluded, without more, that these were excessive, albeit that it considered that this conclusion was more marginal for the 25mg capsules.

133. Having concluded that Pfizer's prices were excessive, the CAT then went on to consider whether they were also unfair.

134. In that regard, in paragraph [315] the CAT first explained that it obtained "*only limited assistance*" from a comparison with tablet prices. It rejected the heavy reliance placed by Pfizer on the £30 DT for tablets and the prices at which tablets were sold. In paragraph [315(2)] the CAT rejected the analysis of the CMA coming to the same

conclusion but then stated that there were "*other reasons*" for attaching limited weight to this data. The CAT did not view the DT as a comparator price "*at all*". It was a reimbursement rate that represented, at most, a *de facto* price ceiling under which different sellers of tablets competed and the pharmacies benefitted from such competition.

135. The CAT then conducted an analysis of the benefits to its "*ultimate consumer*" of the capsules. It did so using the twin concepts of "*Consumer Surplus*" and "*Producer Surplus*" that it derived from the judgment of the CAT in *Allergan v CMA ("Hydrocortisone I")* [2023] CAT 56. In that case, at paragraphs [310] – [317], the CAT had defined the two concepts as follows:

> "312. *Consumer surplus* is an economic measurement of consumer benefits resulting from market competition. A consumer surplus arises when the price that consumers pay for a product or service is less than the price they are willing to pay. It is, in short, a measure of the additional benefit that individual consumers receive because they are paying less for something than what they would have been prepared to pay.
>
> …
>
> 316. *Producer surplus* is the difference between how much a supplier would be willing to accept for a product versus how much they can receive by selling the product at the market price. Again, it is a measure that varies according to individual producer. The difference or surplus amount is the benefit a particular producer receives for selling the good in the market."

136. In the instant case, the CAT first held that continuity of supply was a distinctive benefit to an "*ultimate consumer*" having the characteristics that it had defined (see above). The CAT reasoned:

> "316. …The sale of Capsules cannot be said to provide no benefit to the consumer at all. The consumer benefits through the continued supply of Capsules manufactured by Pfizer. This, for reasons articulated, is of objective benefit to patients. This objective benefit is something of economic value for which ultimate consumers, as a class, would be prepared to pay a premium. In other words, the Consumer Surplus is such that, assuming an ability to pay, there will be some willingness to pay over-and-above CMA Cost Plus rates.
>
> 317. We consider … Pfizer is providing distinctive value to the ultimate consumer in the form of a differentiated product. The effect of the Continuity of Supply issue and the MHRA Guidance is to render each phenytoin sodium product different, even though these products are pharmacologically the same. This is a form of distinctive value that a Seller like Pfizer is entitled to charge for."

137. At paragraph [319(2)] the CAT started with the presumption that prices charged by Pfizer were "*defensible*" and this was a case where Pfizer could properly charge "*some*" Producer Surplus so that it was "*wrong in principle*" for the starting point to be "*CMA Cost Plus*".

138. In paragraphs [320(1) and (2)] the CAT outlined two factors that justified some Producer Surplus over and above CMA Cost Plus:

> "(1) We accept that all Enterprises – and in particular, Enterprises engaged in the pharmaceutical sector – rely upon any Producer Surplus that they can charge in order to recover Extraneous Costs. The pharmaceutical sector as a whole is engaged in developing new products and should be encouraged to do so. That means that the costs of failure need to be recovered somehow. The only way to discharge such legitimate Extraneous Costs is by charging a Producer Surplus where such can be maintained.
>
> (2) We also accept that the Capsules manufactured by Pfizer do real good. AEDs that eliminate or ameliorate seizures in epileptics deliver significant and unquantifiable human benefit. They also deliver significant benefit in the form of avoided costs namely: (i) the costs of treating a seizure that could have been avoided through prescription of Capsules; and (ii) the costs to the wider economy in an epileptic being off work or unable to assist in family life, etc. We accept that these benefits vastly outweigh the price of the Capsules, although we are in no position to quantify these benefits (even the economic ones)."

139. Although the CAT identified these factors as justifying some Producer Surplus, it nevertheless found that the prices charged by Pfizer were unfair because there was a "*grotesque mismatch*" between the distinctive value generated by the capsules and the Customer Surplus for the ultimate consumer. The CAT explained this as follows in paragraph [320(3)] as regards the 50mg, 100mg and 300mg capsules:

> "(i) The distinctive value generated by the Capsules is limited to the provision of Continuity of Supply. That has undoubted psychological benefits, which are valuable, but the Capsules deliver no medical benefit that could not equally be delivered by differently manufactured Capsules or Tablets. There was evidence of considerable switching between phenytoin sodium products and – apart from the important psychological aspect – the experts were relaxed about this.
>
> (ii) Turning then, to the ultimate consumer – as we have defined them – we consider that such a consumer would be prepared to pay a premium in order to procure Continuity of Supply to them. Put another way, assuming an ability to pay, there would be a willingness on the part of the ultimate consumer to pay materially above CMA Cost Plus. In short, at the CMA Cost Plus price, there would be very significant Consumer

> Surplus, which would remain significant (although of course less) even if the Product Unit Price were higher so as to accommodate a material Producer Surplus accruing to Pfizer.
>
> (iii) At some point the ultimate consumer (rather than paying 50mg, 100mg or 300mg Product Unit Prices) would either pivot to 25mg Capsules (and simply take more Capsules to achieve the same dosage) or to phenytoin sodium differently administered (e.g., Tablets).
>
> (iv) The reason this movement away from the Capsules does not occur in the real world is because Pfizer has been taking advantage of the noble – but inconsistent – objectives of our health care system. This system wants to obtain value for money, but not at the price of patient welfare. Hence the clear tension between the firm strictures of the MHRA Guidance in regard to Continuity of Supply and the concerns expressed by CCGs as to cost. Because the system needs to consider the aggregate class of epileptics being prescribed Capsules, and cannot consider the individual case, there is an invidious choice between keeping costs under control and maximising patient benefit. In adopting the MHRA Guidance, the latter has been prioritised over the former, thereby giving market power to Pfizer."

140. In paragraph [320(5)] the CAT held that the price for the 25mg capsules, though excessive, was not objectively unfair. The CAT did not explain this conclusion, merely stating the 25mg capsule pricing could be seen as a relevant comparator which highlighted the unfair pricing of other strengths.

F. The CMA's appeal against the setting aside of the Decision: Introduction to the Issues

141. We now consider the CMA's case that the CAT erred in setting aside the Decision. This issue took up the preponderant part of the hearing of the appeal.

The appeal to the CAT by Pfizer and Flynn

142. We start by summarising the arguments put by Pfizer and Flynn to the CAT which it in large measure accepted in the Judgment. Pfizer advanced 4 grounds alleging failure by the CMA: (i) to consider "*real world comparators*"; (ii) to attribute proper weight to therapeutic and economic value; (iii) in the calculation of Cost Plus; and (iv) to guarantee procedural fairness because of bias on the part of the CMA. Flynn put forward 6 grounds alleging failure by the CMA: (i) in the analysis of excessiveness; (ii) in determining returns in the industry; (iii) in relation to prices in the industry; (iv) in analysing the extent of the excesses; (v) in mischaracterising Flynn's role in the supply chain; and (vi) in the determination of economic value.

The position of the parties on the appeal to this Court

143. On this appeal the CMA argues that, at base, the CAT materially misconstrued and misread the Decision and thereby wrongly found that the CMA made errors. For their

part Pfizer and Flynn argue that the CAT was correct and that the Decision was defective. But, in any event, Pfizer and Flynn argue that the point has been reached when this Court should say "*enough is enough*". Finality of litigation and legal certainty mean that there should be no further steps allowed in this overly long and protracted litigation, regardless of this Court's conclusion about the Decision.

Main issues

144. We have summarised the criticisms made by the CAT of the CMA's reasoning at paragraphs [111] – [113] above. These are framed to be consistent with the way in which the CMA now challenges the CAT's reasoning. It suffices to summarise the CMA's main grounds as follows:

(i) **Issue I:** The prior illegality point.

(ii) **Issue II:** The per se approach to Cost Plus.

(iii) **Issue III:** Bias.

(iv) **Issue IV:** The ROCE analysis in relation to Flynn.

(v) **Issue V:** The failure properly to analyse comparables relating to tablets and AEDs.

(vi) **Issue VI:** The wrongful taking into account of prices charged in EU states.

(vii) **Issue VII:** The wrongful taking into account of the fact that prices changed over time before and after the coming into effect of the Pfizer/Flynn agreement.

(viii) **Issue VIII:** The wrongful taking into account of the conclusion that Pfizer and Flynn knowingly exploited their market power.

G. Issue I: The prior illegality point

The CAT's criticisms

145. The CAT held that the CMA found an infringement which went beyond that identified in the Decision. This was that Pfizer and Flynn were guilty of concluding an unlawful cartel and/or engaging in a joint abuse of dominance, although no such findings were set out in the Decision. The CMA thereby closed its eyes to the "*inconvenient*" fact that there might be no breach at all. It disregarded the presumption of innocence, the rights of defence and the burden of proof. It abandoned due process and this unarticulated finding was important proof that the CMA was guilty of confirmation bias. These failings vitiated the Decision against both Pfizer and Flynn and opened the door to the CAT retaking the decision. The CAT relies upon its analysis in this respect of the Decision at numerous points in the Judgment. In paragraphs [129] and [130] the CAT held:

> "129. The reasoning in the Decision is at variance with the findings of infringement actually made in the Decision. The reasoning proceeds on the basis that there was an infringement

> of competition law going beyond that found in the Decision. Thus, the Decision states:
>
> > 'The high prices that the Parties imposed were the result of an agreement between them under which Capsules were de-branded and removed from the [PPRS], so that they could significantly increase their prices and share the substantial profits generated between them.'
>
> 130. We do not see how the statement that there was a sharing of profits can properly be made without a finding of either (i) an infringement of the Chapter I prohibition or (possibly) (ii) an abuse of joint dominance. Neither of these findings have been made by the CMA in the Decision. Whilst, no doubt, the higher prices resulting from the arrangements between Pfizer and Flynn are relevant background, the only permissible conclusion of the fact that Pfizer was charging a high price to Flynn was that this was a cost to Flynn. Anything going beyond this constitutes an implied finding of infringement which is (as we have indicated) an improper abandonment of due process."

146. In paragraph [131(4)] the CAT held that the "*implied finding*" that Pfizer and Flynn had been acting improperly "*infects*" all parts of the Decision including: the CMA's analysis of the scale of the price increases above Cost Plus; the conclusion that the prices were not to ensure "*commercial viability*"; and, the conclusion that the prices charged before the agreement and those charged afterwards were indicative of unfairness. The CAT held:

> "There is, thus, a palpable sense of the Decision reasoning towards the conclusions the CMA wanted to find, without pausing to consider the evidence in the round nor the infringements actually found by the CMA"

147. In paragraphs [133] – [134] the CAT held, in relation to the finding by the CMA that the agreement enabled inflated profits to be shared, that this finding was not "*sustainable without a finding of a Chapter I infringement between Pfizer and Flynn*.". In paragraph [133] the CAT held that the CMA treated the Pfizer/Flynn agreement as a "*ruse to disguise the massive profits that Pfizer and Flynn were jointly making"* which was "*an illegitimate consideration, disregarding the presumption of innocence, the rights of defence and the burden of proof. It has distorted the approach in the Decision*." The CAT gave three examples of such distortion in paragraphs [134(1)-(3)] relating to the calculation of profit margins and the transition from ROS to ROCE in relation to Flynn. In paragraph [135] the CAT held that this error on the part of the CMA undermined its entire analysis against both Flynn and Pfizer.

148. In Judgment paragraphs [134(1) – (2)], [148(3)(iv)] and [148(4)(vii)]) the CAT held that, because of this error, the CMA had wrongly ignored Pfizer's prices charged to Flynn as relevant to determining Flynn's costs. Instead, the CMA treated Pfizer's costs as relevant to a determination of Flynn's margins and the CMA wrongly ignored Flynn's own costs which, of course, included the prices charged to it by Pfizer.

149. In paragraph [215(5)] the CAT held that the CMA failed to square up to the conclusion that the Pfizer/Flynn agreement was an illegal cartel contrary to Section 2 CA 1998. The CAT attacked the CMA's findings (c.f. Decision paragraphs [6.6.5] and [6.101] – [6.117]) that the parties "*gamed the regulatory system in order to increase prices*".

150. In paragraph [303], the CAT held that because it had "*concluded that there is no basis for us finding any Chapter I infringement in the relationship between Pfizer and Flynn*" there was no "*proper basis for suggesting that the price was not, as between Pfizer and Flynn, a proper competitive price*". The CAT asked whether the analysis would differ if it was to hold that "*Pfizer's price to Flynn was unfair and a Chapter II prohibition*". It concluded: (i) the issue was not before the CAT but (ii) in any event it "*would be quite difficult to conclude that the price charged by Pfizer was unfair to Flynn*". Finally, because "*… there is no Chapter I infringement or abuse of collective dominance as between Pfizer and Flynn, the prices charged by Flynn are reasonably and efficiently incurred. No adjustment to Product Unit Cost is needed.*"

151. In paragraph [308] the CAT held that the Pfizer/Flynn agreement was "*unimpeachable in competition law terms*" but, at the same time found Flynn was dominant and had abused its position by charging prices that were "*demonstrably immoderate*" and it was "*…only able to charge a premium in regard to the Capsules because of its exclusive supply arrangements with Pfizer, meaning that it is the only distributor of Capsules in the UK*."

Analysis

152. In view of the above, the thrust of the CAT's criticism of the Decision was twofold. First, that the CMA made an implied negative finding about the agreement between Pfizer and Flynn which amounted – in effect – to it being an infringement of Chapter I, but did so without such an allegation having been put to Pfizer and Flynn and without the CMA acknowledging that it had made such a finding. Second, that this finding infected and undermined all of the CMA's analysis against both Pfizer and Flynn.

153. In our view, on a reasonable and fair reading of the Decision, the CAT's criticisms are not borne out. At no point did the CMA expressly or impliedly find that the agreement was an unlawful cartel or a joint abuse of dominance, nor did the logic of the Decision in any way depend upon any such findings.

154. We have set out the description in the Decision of the Pfizer/Flynn agreement including how it came about, its terms, and the underlying commercial imperatives, at paragraphs [51] – [65] above. The finding of the CMA that, in its conception and operation, the agreement was a device (or ruse) designed to enable Pfizer and Flynn to exploit market power, increase prices to the state, and share the increased profit, were findings amply supported by the detailed analysis of disclosed material in both the First Decision and the Decision. The CAT's Judgment did not examine this evidence, nor gainsay the CMA's analysis of it.

155. We also reject the CAT's view that the CMA's findings about the purpose and effect of the Pfizer/Flynn agreement amounted to an implied conclusion that the agreement was in breach of Chapter I.

156. The only place in the Judgment where we can find an explanation for the CAT's reasoning is in paragraph [130] set out above where the CAT says that the CMA's conclusion that the agreement involved "*a sharing of profits*" could not properly be made without a finding of either (i) an infringement of the Chapter I prohibition or (possibly) (ii) an abuse of joint dominance, neither of which had been made by the CMA in the Decision (see paragraph [145] above). Insofar as the CMA intended the reference to profit sharing to be a broad description of the parties' joint purpose, this does not necessarily imply that there was an unlawful cartel. Numerous joint ventures and commercial agreements involve the sharing of profits in a broad sense without there being even a hint of unlawful conduct and agreements which do include formal profit shares do not, by that fact alone, become unlawful.

157. The CMA's conclusion, based upon the evidence, that the agreement was designed to swell the parties' profits was relevant to the analysis of abuse – as the CAT itself recognised. Whether it might also have founded some different finding of unlawfulness is irrelevant. For regulatory purposes it was unnecessary to "*overload*" the indictment by adding engaging in an unlawful cartel and/or abuse of joint dominance, to the charge sheet.

158. There is also the conclusion of the CAT that *because* the CMA had analysed the case as an illegal cartel between Pfizer and Flynn it had also wrongly calculated Flynn's abusive conduct by reference to Pfizer's costs of production which were then compared against Flynn's sale price (Judgment paragraphs [134(1) – (2)], [148(3)(iv)] and [148(4)(vii)]). This is simply wrong. The Decision is clear that Pfizer's prices to Flynn were taken into account when computing Flynn's cost structure. This can be seen, for instance, from Decision paragraph [5.207.1].

159. Accordingly, we consider that the criticism made by the CAT that to treat the agreements as improper was an "… *illegitimate consideration, disregarding the presumption of innocence, the rights of defence and the burden of proof*" which *"... has distorted the approach in the Decision*", is wrong.

160. We conclude that the CAT was in error.

Issue II: The per se approach to Cost Plus.

The CAT's criticism

161. This is a further point where the CAT found that the CMA was guilty of adopting a false and unarticulated position. The CAT described the argument of Pfizer and Flynn as follows:

> "219. The point taken by the Appellants was simply this: when considering the Unfair Limb, the model that the CMA had in its mind was substantially derived from theory – a kind of dynamic perfect competition model – which accorded no legitimacy at all to the Producer Surplus, but rather regarded it as a badge not merely of excess, but of unfairness also. This is the issue which underlies a number of the Appellants' Grounds of Appeal."

162. The CAT agreed:

> "195. We consider that a state of Real World Competition will not necessarily produce Prices that sit above cost or at the level of CMA Cost Plus, even in the long run. Even though CMA Cost Plus is a consistent theme throughout the Decision, the Decision fails to consider the limits of the proposition. The Decision says:
>
> > 'It is possible for an undertaking to price above Cost Plus without those prices being either excessive or unfair.'
>
> But the circumstances in which prices above CMA Cost Plus might not be excessive or unfair are nowhere considered. Thus, the Decision accepts that a dominant Enterprise pricing at above Cost Plus does not commit a by object or per se infringement of competition law. Pricing at above CMA Cost Plus is not necessarily abusive. The problem is that neither the Decision, nor the CMA's experts, attempted to draw the line between legitimate and illegitimate Producer Surplus. In failing to do so, the CMA's adopted an a priori erroneous view of abusive pricing cases. It is not enough to say that this case was so clear cut a case of illegitimate Producer Surplus that further inquiry is unnecessary. That is just another way of presuming the very conclusion that the CMA was tasked to consider impartially and expertly. Since the line between pro-competitive Producer Surplus and anti-competitive Producer Surplus is key to understanding both the Excessive Limb and – as we shall see – the Unfair Limb, it is necessary to consider that line with some care."

163. Elsewhere, the CAT held that the CMA proceeded upon the basis that any price above Cost Plus was "*per se excessive*" (Judgment paragraph [205]). In paragraph [206], the CAT held: "…*treating every case of Producer Surplus as rendering Product Unit Price automatically excessive defeats the object of the Excessive Limb as a gateway to the Unfair Limb*." In paragraph [228(1)] the CAT held that the CMA had "*presumed*" Pfizer's prices above Cost Plus to be unjustifiable and unfair. In paragraph [245], it held that the CMA nowhere considered whether the margin above Cost Plus "*could have been defended*". This was wrong because, in law, the "… *proper approach … is to see economic value as lying somewhere between CMA Cost Plus and the Product Unit Price actually charged.*"

164. The CAT thus found that the Decision was based upon a concealed premise, which we infer the CAT considered was intentional and deliberate. This way of construing the Judgment is supported by the CAT's related finding that the CMA was guilty of actual bias which reflected a "*single minded desire to bring the case home*" (see Section H below).

Analysis

165. It is difficult to understand the basis of the CAT's conclusion. The Decision does not proceed upon the premise that any price above Cost Plus is *per se* unlawful or even presumed to be unlawful. In fact, in paragraph [5.30] it says the very opposite. The proposition that a price above Cost Plus can be lawful is squarely embedded in nearly

50 years' worth of case law and the Decision devotes a huge amount of text to analysing the evidence put forward by Pfizer and Flynn on justifications for above Cost Plus pricing. It is true that the CMA rejected that evidence, but the idea that this exercise was a smokescreen to shroud the CMA's true position, as opposed to being a conclusion about the evidence, is not credible. We acknowledge the formal confirmation of the position given by the CMA during the hearing and set out at paragraph [38] above.

166. We also do not follow the point, set out in Judgment paragraph [195], that there is a duty upon the CMA, which it failed to observe, to identify a line above Cost Plus which marks the boundary between fair and unfair. This assumes that in every case there will be a justification for above Cost Plus pricing but that assumption is inconsistent with case law.

167. The CAT's erroneous conclusion on this issue coloured its view of the approach the CMA had adopted to the entirety of the evidence. Our conclusion is that the CAT erred in its conclusions about the CMA's approach.

H. Issue III: Bias

Introduction - Pfizer's appeal to the CAT

168. Before the CAT Pfizer argued that the CMA's conduct of the investigation was procedurally unfair. Its Ground 4 pleaded:

> "…This appeal should be allowed because the CMA's conduct of this investigation has been sufficiently unfair and unbalanced that the Tribunal cannot have confidence in the process by which the CMA gathered and disclosed evidence, the objectivity of the CMA's analysis and ultimately the Decision itself."

The criticisms of the CAT

169. In Judgment paragraph [279] the CAT held:

> "Ground 4 is particularised in a number of respects, and most of these we have no hesitation in rejecting. Thus, points are made in regard to the CMA's disclosure of material, the CMA' changes of position in response to Pfizer's probing, and the dilatory nature of the investigation. We do not consider that these are fair criticisms of a decision-making process that clearly has been conducted conscientiously and with every effort being made to achieve due process."

170. The CAT did however uphold the following complaint:

> "The public statements of the CMA, and its approach to the evidence as a whole, displays a clear case of confirmation bias. The CMA's conduct of this investigation has been characterised throughout by a single-minded desire to bring the case home. That is not consistent with its role as a competition authority."

171. The CAT identifies four specific failings it held demonstrated confirmation bias: (i) the failure by the CMA to acknowledge that it treated the Pfizer/Flynn agreement as an unlawful cartel and its overreliance upon that conclusion; (ii) the failure on the part of the CMA to consider why the market was not working and allowed Pfizer and Flynn to increase prices so dramatically; (iii) the failure on the part of the CMA to accept that "Producer Surplus" could ever exist (i.e. the CMA's conclusion that no price above Cost Plus could ever be lawful); and (iv), the "*disregard*" by the CMA of the fact that comparable drugs were being sold at prices similar to capsules during the Relevant Period. These are set out in Judgment paragraph [281]:

> "Ground 4 is made out in this regard for the following reasons, which we have already identified in this Decision. We state them out briefly now:
>
> (1) The CMA has been over-influenced by the arrangements between Pfizer and Flynn, which resulted in the dramatic increases in the prices for the Capsules. Without labelling those arrangements as competition law infringements, the CMA has treated them as such, thereby disregarding the presumption of innocence and reversing the burden of proof. These are fundamental failings.
>
> (2) The fact that price increases – of a dramatic nature – occurred practically overnight is a factor impossible to disregard, and one that should not be disregarded. As the Chancellor put it in Phenytoin 1 (CoA):
>
> > …It was quite easy to lose sight of a stark reality, which was that, literally overnight, Pfizer and Flynn increased their prices for phenytoin sodium capsules by factors of between 7 and 27, when they were in a dominant position in each of their markets. <u>That did not, of course, abrogate the need for a rigorous reasoned approach to the legal and factual questions before the CAT, but it was important to keep in mind.</u>
>
> This was a criticism levelled at the decision in Phenytoin 1 (CAT). It can equally well be made of the Decision itself. The price increases in the Capsules are significant, but no-one has ever said that de-branding products that were (as branded products) subject to the PPRS price controls was illegitimate. Following debranding, Flynn and Pfizer priced to the Tablet price levels, which themselves were informed by the Drug Tariff rate which was (we find) properly set by DHSC. The fact that prices increased is therefore not, of itself, particularly surprising. It was expected that generic competition would subsequently keep prices under control. That did not happen and it may be that this absence of generic competition is an indicator of competition law infringement, in the way that (substantial) price increases are not. It was incumbent upon the CMA to consider the reasons behind the fact that this market was not working and – in light of a true and fair examination of that market –

> understand and articulate the nature of the abuses that may or may not have been taking place.
>
> (3) Dramatic increases in price by dominant Enterprises very likely means pricing at above CMA Cost Plus. That is almost inevitably going to be the case where prices are increasing by factors of over seven. The CMA, as the Decision makes clear, only ever saw this as a CMA Cost Plus case. Whereas this approach may be defensible when considering the Excessive Limb, it is not so far as the Unfair Limb is concerned. The notion that there could be such a thing a legitimate Producer Surplus was mentioned, once, in the Decision but never seriously considered.
>
> (4) Equally, the circumstances pertaining in the real world - the comparators we have described, and the Drug Tariff - were essentially disregarded. The fact that comparable pharmaceuticals were being priced at similar levels to those of the Capsules during the Relevant Period is not determinative, but it is material and it did fall to be considered."

Analysis

172. We reject the conclusion of the CAT that the CMA was guilty of bias. In its case to the CAT, Pfizer did not particularise its objection save in the broadest of terms. The CMA points out that Pfizer's Notice of Appeal to the CAT was 99 pages long and the only argument or reasoning on bias is that quoted above, which at a high level of generality complains about the CMA's public statements and its overall approach. The CMA further submitted that the only other reference made by Pfizer to this issue was in its reply before the CAT where it said: "*Pfizer's considered view, formed after careful analysis and reflected in its NoA, is that the most likely explanation for the CMA's approach to this investigation (including but not limited to divergence from its usual approach to comparators and disclosure) is confirmation bias."*

173. The CAT nowhere explains what it understands by the expression "*confirmation bias*" nor does it set out what test it applied in coming to its conclusion. It simply treats the existence of what it sees as errors in the CMA's analysis as proof of bias. Yet the two are obviously different: see e.g. *British Academy of Songwriters, Composers and Authors v Secretary of State for Business, Innovation and Skills* [2015] EWHC 1723 (Admin) ("*BASCO*") at paragraphs [274] – [281].

174. The test for bias is well known and not in dispute between the parties. It remains that set out by the House of Lords in *Magill v Porter* [2001] UKHL 67 at paragraphs [95] – [103] where, following settled case law, the Judicial Committee reiterated the distinction between a predisposition and predetermination. In any procedure leading to a decision, as the investigation proceeds the decision maker will begin to form a provisional view, i.e. have a predisposition. But the final decision must be taken upon the basis of an open mind and a full and fair examination of the evidence and the arguments. The CMA cites the judgment of Johnson J in *R (QA) v Secretary of State for Foreign, Commonwealth and Development Affairs* [2024] EWHC 3064 (Admin), in which the judge, having set out the position on actual and apparent bias, stated:

> "A decision is also flawed and liable to be set aside if the decision maker approaches the issue with a closed mind, so that the outcome is predetermined. As with bias, that is so both if the outcome is actually predetermined and also if there is an appearance of predetermination… Accordingly, if there is a real possibility that a decision maker has predetermined an issue, in the sense of closing their mind to the merits of the issue that is to be decided, then they are disqualified from making the decision, and if they do make the decision it is liable to be quashed. The test to be applied is the analogue of the Porter test for bias. That is, whether a fair-minded and informed observer, having considered the facts, would conclude that there was a real possibility that the tribunal had predetermined the issue…"

175. The concept of confirmation bias assumes that the decision maker applies a process of evidence collection and evaluation to arrive at an end result or decision which fits a predetermined conclusion as to what the outcome should be. With this mindset the decision maker seeks out and/or relies upon only such evidence as supports its predetermination and ignores other potentially exculpatory evidence or evidential lines of inquiry. A decision maker guilty of confirmation basis will not be conducting a procedure which requires that all evidence be collected and evaluated fairly and objectively.

176. We note that in Judgment paragraph [279] (cited above at paragraph [169] above) the CAT recognised that the CMA's decision-making process had been conducted conscientiously and with every effort being made to achieve due process. The CAT's objection was hence not about procedure but was about mindset. Turning to the CAT's reasons which underpin the finding that there was bias, we reject those reasons.

177. First, the CAT held that the CMA was "*over-influenced*" by the arrangements between Pfizer and Flynn to such a degree that it disregarded the presumption of innocence and reversed the burden of proof. We have rejected this complaint (see paragraphs [145] – [160] above).

178. Secondly, in relation to the nature and extent of price increases on a before and after basis, the CAT says that the CMA misunderstood the Chancellor's position in *Phenytoin I* (set out at paragraph [12] above) and failed to consider the reasons behind the fact that this market was not working. The complaint of the CAT seems to be that the CMA placed too much store in the fact that prices increased suddenly and dramatically which led the CMA to refrain from engaging in "… *a true and fair examination of that market"* and in further consequence the CMA failed to understand and articulate the nature of the abuses that may or may not have been taking place. We have difficulty in following this criticism. We can see no connection between the CMA's reliance upon the nature of the price increases and its understanding of the market. The Decision explains why the market was not working: MHRA guidelines on continuity of supply made switching difficult; there was a very low risk of new entry (including by parallel imports) if prices were increased; Pfizer had dominant market power in the upstream market which it transferred to Flynn in the downstream supply market by the agreement; and, in these circumstances Pfizer and Flynn could raise prices with impunity. The CMA set outs its analysis at great length in the Decision. We

can detect nothing in the CMA's analysis of prices over time which indicates, or is relevant to, a finding of bias.

179. Thirdly, in paragraph [281(3)] the CAT held that the CMA "*only ever saw this as a CMA Cost Plus case*" and then observed that the "*notion that there could be such a thing as legitimate Producer Surplus was mentioned, once, in the Decision but never seriously considered*". We have addressed this already and do not repeat our conclusions. The Decision did not address "*Producer Surplus*" using that expression, because that term was first coined by the CAT in the *Hydrocortisone I* judgment [2023] CAT 56 which post-dated the Decision. However, the CMA devoted hundreds of pages to considering the evidence adduced by Pfizer and Flynn on the justification for the differential between Cost Plus and ASP. But even if the CMA had been in error in this respect, that fact alone does not establish bias.

180. The fourth point made by the CAT is that the CMA "*essentially disregarded*", the "*circumstances pertaining in the real world*" (comparators and the DT). We have addressed tablets and AEDs as comparators above. The CMA did not disregard this category of evidence. It was examined comprehensively but was not found, on the facts, to support the undertaking's case. An example relating to AEDs is found at Decision paragraphs [6.519] – [6.520] where the CMA records that Pfizer argued that the CMA was "*determined*" to find that there was no AED that could shine light on the lawfulness of capsule pricing (i.e. the CMA had predetermined the outcome). In the Decision the CMA responded that its conclusion (that AEDs did not provide meaningful evidence) was based upon the evidence, which is set out over 23 pages of the Decision between paragraphs [6.458] – [6.531]. We have concluded that the analysis of evidence on AEDs was orthodox and persuasive. There is no credible challenge by the appellants to the conclusions of fact set out in the Decision. But even if there had been, the most that could be said is that having grappled with the evidence in detail, the CMA nonetheless erred. That would not be evidence of bias.

181. Finally, when the CAT came to retake the decision it rejected tablets as comparables because suppliers held dominant market power and prices did not reflect *Real World* competition, and it did not consider AEDs at all. The CMA's rejection of evidence the CAT *also* rejected can hardly support a finding of bias on the part of the CMA.

I. Issue IV: The ROCE analysis in relation to Flynn.

The CAT criticisms

182. We turn next to issues concerning the calculation of the ROCE by the CMA in relation to Flynn. The CAT agreed with the CMA that ROS was inappropriate to use to calculate Flynn's RRoR. However, it also found that the CMA erred in its calculation of the proper ROCE.

- *Terminology used by the CAT*

183. We start by commenting upon the terminology used in the Judgment. The CAT used the term "*CMA Cost Plus*". This is defined at Judgment paragraph [62] as the cost to Flynn of producing and selling the capsules, including the amount paid by Flynn to Pfizer, and this is therefore the same Cost Plus as used in other case law, such as in *Phenytoin I*. The CAT's term "*Product Unit Cost*" is the "*Cost*" element of Cost Plus.

The CAT's term "*Entrepreneurship*" (or "*cost of Entrepreneurship*" in Judgment paragraph [62]) is the same as RRoR i.e. the "*Plus*" in Cost Plus (see Judgment paragraph [80(3)(i))]).

184. As indicated above, the phrase "*Producer Surplus*" was used by the CAT to describe the difference between how much a seller would be willing to accept for a product compared to how much they can receive by selling the product at the market price (see Judgment paragraph [61(2)]). It is therefore apparent that Producer Surplus was used to describe the difference between Cost Plus and the price charged for the product: see the diagram at Judgment paragraph [145(2)].

185. The CAT accepted that the analysis by the CMA of the Cost element of Cost Plus was appropriate. It also agreed with the CMA that the RRoR (or cost of Entrepreneurship) was not to be regarded as a cost "*in the traditional sense*", and that it was rightly regarded as constituting the Plus element in Cost Plus (Judgment paragraphs [81]-[82]).

- *The CMA erred when it held that capital employed was £3.5 and not £74m*

186. The CAT held that the CMA committed a fundamental error in concluding that the capital employed, for the purposes of the ROCE analysis, was only £3.5 million. It held that the correct cost of capital employed was the total cost to Flynn, over the relevant period of four years, of acquiring and distributing the capsules, namely £74,156,575 (derived from the Focal Product Spreadsheets at Annex 3 to the Judgment: see paragraphs [119] – [120] above). The CAT arrived at this conclusion by the following route (see Judgment paragraphs [153] – [156]):

(i) The Decision defined capital in the manner used by the CAT in the judgment, as "*the money required to acquire certain inputs*", i.e. the "*Factors of Production needed to make the Focal Product*".

(ii) It then purported to quote the specific definition of "*Capital"* in the Decision as "*the money required to acquire an efficient level of buffer stock to provide against supply interruptions, adjusting for Flynn's debtors and creditors*." That was not, however, a *definition* of Capital used in the Decision. It was a *description* by the CMA (Decision paragraph [5.233]) of the capital in fact employed by Flynn, based on Flynn's own evidence as to the elements of capital employed by it and the other analysis set out at Decision paragraphs [5.226] – [5.232].

(iii) The CAT referred to this as a correct definition of Capital, but incorrectly applied, because it was "*not a Reasonable Rate of Return on the Product Unit Cost of the Focal Product. The Decision comprehensively asks the wrong question and the answer is unsurprisingly similarly incorrect.*" That was because (Judgment paragraph [154]):

> "The money required to acquire an efficient level of buffer stock may well be a cost of running an Enterprise, but (unless "unitised" to constitute part of the Product Unit Cost) it has nothing to do with the Product Unit Cost of the Capsules"

(iv) Having quoted a passage from the evidence of Mr Walters, a director of Flynn, explaining the buffer stock built up by Flynn, the CAT said, Judgment paragraph [155]:

> "155. This is nothing to do with the question posed by the Excessive Limb when assessed by reference to the Focal Product Spreadsheets. That is a consequence of the static way in which Product Unit Costs have been assessed by the CMA, divorced from the manner in which an Enterprise would in fact operate.
>
> (1) An Enterprise would, as we have described, operate dynamically, and it may be that the Annex 3 data could have been compiled in this way. But it was not. A dynamic model would consider Flynn's Capital requirements by reference to its cash flow needs calculated by reference to costs incurred on some dates, and revenues received on other (typically later) dates. In other words, because of revenue coming in from the sale of Product, Flynn's Capital costs would be correspondingly less, and dependent upon the time gap between payment and receipt.
>
> (2) These are factors that operate at the Enterprise level, but they were not taken into account by the CMA when assessing Flynn's Profit Margin. However, because Profit Margin is the difference between Product Unit Cost and Product Unit Price (which are assumed to be received at the same time) the Capital costs of acquisition of Product either need to be included at 100% because the revenue received on (instantaneous) sale is then immediately set off or that revenue needs to be discounted to account for the accelerated receipt.
>
> (3) The latter exercise was not undertaken by the CMA. Nor was any meaningful discount (to take account of setting off the sale receipts) applied by the CMA to the Product Unit Cost. As a result, the CMA has adopted a cost of Capital that is unrelated to the Annex 3 data, risking misstatement of the infringer's Profit Margin.
>
> (4) This case represents a particularly extreme example, because of the very high (Capital) Product Unit Cost of the Capsules. However, this very high cost was passed on by Flynn in its Product Unit Prices, which are set off when calculating Profit Margin against Product Unit Costs with no temporal delay."

(v) Upon this basis the CAT held that the CMA erred in failing to justify having used a cost of Capital "*detached from the data in the Focal Product Spreadsheets*". The figure of £3.5 million was "*a gross understatement of the capital needed by Flynn in the distribution of the Capsules. The Focal Product Spreadsheets put this cost as £74,156,575*".

- *The CMA had no evidence for a 10% WACC used in calculating return on capital*

187. As observed, the CAT had no issue, at least in the abstract, with a ROCE-WACC approach to assessing the RRoR (Judgment paragraph [90]). It stressed the need to separate the two ways in which capital is relevant. It might in any given case be relevant at the stage of identifying actual costs, where the enterprise had borrowed to fund a particular aspect of the business (although that was not the case here: it was not suggested that Flynn incurred any interest costs that fell within the "Cost" element of Cost Plus). That had to be differentiated from the other way in which capital is relevant – "*as a means of assessing the Reasonable Rate of Return*" (Judgment paragraph [90(2)]).

188. As Professor Bailey KC for the CMA said in argument, it was important not to be confused by the fact that the *return* that an investor could reasonably expect to make from funding a business could at the same time be seen as a *cost* to the business. One was the flip-side of the other.

189. The CAT's objection to the CMA's analysis was twofold.

190. First, the CMA's WACC of 10% lacked a "*solid factual foundation*", because "*the basis for the CMA's starting point of 9% is barely articulated in the Decision*". It was a "*conclusory finding*" which it was impossible to unpick further: Judgment paragraphs [164] – [165].

191. Secondly, the CMA failed to calibrate WACC to the appropriate return for distributing capsules, as opposed to the appropriate return for the enterprise, i.e. Flynn:

> "166. Just like the CMA's assessment of Flynn's employed capital, the CMA's WACC looks not to the Focal Product and the Product Unit Cost, but to the Enterprise … The Decision does not ask two key questions: "(i) what is the Reasonable Rate of Return to the entrepreneur for selling the Focal Product; and (ii) does the WACC constitute a good proxy or means of assessing the Reasonable Rate of Return?"

The CMA's grounds of appeal

192. As developed during the hearing the CMA appeals on four grounds:

(i) The CAT erred in concluding that the CMA wrongly placed reliance on the fact that the input prices (charged by Pfizer to Flynn) were excessive.

(ii) The CAT's approach to identifying the capital employed was irrational.

(iii) The CAT misread the Decision when holding that the CMA's identification of WACC was merely conclusory and focused wrongly on the enterprise.

(iv) The CAT was wrong to impose a requirement to consider the "*reasons*" for the extent of the actual margin above Cost Plus.

193. We take each in turn.

Reliance on the fact that input prices were excessive

194. The CAT suggested that the CMA had not used Pfizer's prices to Flynn as an input into the calculation of Flynn's Cost Plus. This is incorrect. This can be seen, for example, from Decision paragraphs [5.206]-[5.209]. The CMA used the full input price in each stage of its cost-plus analysis.

The reasonable rate of return: Capital employed and the ROCE

195. It is convenient to take points (ii) and (iii) together.

- *What did the CMA find?*

196. As to the Cost element, the CMA included Flynn's direct costs and its indirect costs. The former comprised the price actually paid to Pfizer and the fees it incurred in relation to storage, distribution and order services: Decision paragraph [5.207]. The latter was a proportionate share of costs common across a number of its products, comprising varying types of administrative expenditure, including employee costs, professional fees and office expense, apportioned on the basis of sales volume: Decision paragraphs [5.211] – [5.213].

197. As to the Plus element, at Decision paragraph [4.21] the CMA noted that there were various ways to determine a RRoR. It was not a matter of precise mathematics, but a question of judgement and appreciation on which experts might take different views. The CMA considered two methodologies: ROCE and ROS.

198. The ROCE approach seeks to identify the rate of return which investors would reasonably expect from the use of the capital employed by Flynn in connection with the distribution of the capsules. The CMA explained (Decision paragraph [5.34]) that two inputs are required: (1) the amount of capital employed in supplying the capsules; and (2), the cost of capital, being the average percentage return that investors (debt and/or equity) expect in return for providing funds to enable the entity to carry on the business. At Decision paragraphs [5.36] – [5.39] it explained that for entities like Pfizer and Flynn that were funded by a combination of debt and equity it was appropriate, in estimating the cost of capital employed, to use a WACC calculated by reference to observable, real-world, market data, e.g. by reference to corporate bond yields or the returns generated in the capital markets where similar investment opportunities with similar risk profiles compete for financing. While "*grounded in fundamental economic logic*" it provides a "*relevant real-world benchmark*".

199. The ROS approach measured profit margins, measuring returns relative to revenues after deduction of direct and indirect costs. It compared the return for Flynn with the return achieved on sales in relation to suitable comparators.

200. In the first CMA Decision, the CMA adopted a ROS approach to the RRoR for Flynn. In the Decision, however, it adopted a ROCE approach. Flynn appealed to the CAT what it saw as the indefensible shifting away from ROS without a rational basis. The CAT dismissed that ground of Flynn's appeal. It shared the CMA's scepticism as to the usefulness of ROS (Judgment paragraph [92]). Flynn has resurrected this argument by way of its Respondent's Notice. We address this, along with other points raised by Flynn's Respondent's Notice below.

201. As explained at Decision paragraphs [5.218] – [5.220], in addition to adopting the ROCE approach, the CMA carried out analyses to test the suitability of the ROS comparators put forward by Flynn (both during the original investigation and the remittal), including how the ROS figures translated to returns on capital for capsules, and also conducted a cross-check by reference to absolute measures of profitability.

202. As to the ROCE analysis, the CMA observed (Decision paragraph [5.233]) that given that Flynn's role was limited to ordering and holding stock, marketing and promotional activities and ensuring regulatory compliance, it employed very little fixed capital in its business. It had not invested or innovated in relation to the capsules, nor had it incurred any sales or promotion costs during the relevant period. Flynn itself had identified only two elements when describing the capital employed in its supply of capsules: (1) the need to cover the cost of working capital and (2) the need to strengthen the supply chain by identifying a second supplier. In the event, Flynn did not incur any actual expenditure in relation to the second of these elements. So far as working capital was concerned, the CMA estimated that Flynn employed capital of £3.5 million each year during the relevant period. That was arrived at by calculating an amount required to maintain a buffer of stock (£2.8 million) and net debtors (£700,000), taking account of the amounts of debtors and creditors and the credit period for both.

203. Flynn had objected in its submissions to the CMA that this failed to take account of the human capital employed by it. The CMA rejected this, in part because the costs to a business of its human capital are generally reflected in salaries and other employment costs, and these were already factored into the Cost element of Cost Plus (see Decision paragraph [5.250]).

204. Flynn maintains, via its Respondent's Notice, the argument that the inability of a ROCE approach to account for the cost of human capital is a reason to prefer ROS over ROCE. We do not understand it to dispute, however, the figure of £3.5 million for capital employed *if* it is wrong about the choice of ROS over ROCE.

205. The CMA arrived at a figure of 10% for Flynn's WACC. It did so (see Decision paragraphs [5.170], [5.260] – [5.267]) by reference to the following facts and matters:

    (i) Pfizer's evidence that its own WACC was around 9%.

    (ii) The WACC in respect of Pfizer's facility in Freiburg, where it manufactured the Capsules, was materially similar.

    (iii) The average cost of capital of pharmaceutical companies, based on a report by KPMG, was between 7.7% and 8.2% between 2010 and 2014.

    (iv) The fact that this was higher than Flynn's own expert had estimated for its cost of capital on the appeal to the CAT in 2018.

    (v) A valuation analysis of Flynn carried out by an investment firm, Jefferies, in 2012, which discounted future cashflows using a WACC of 10%.

206. Flynn objected (Decision paragraphs [5.262] – [5.263]) that: (i) equity investors expected a higher return from a small company and a single product, than a large diversified pharmaceutical company; (ii) WACC was the *minimum* return investors

would require and could not be used therefore to assess whether returns are or might be excessive; (iii) most industries were not characterised by perfect competition and ROCE was therefore likely to exceed WACC; (iv) WACC was an *ex ante* return which failed to take into account that successful products will earn higher returns *ex post*.

207. The CMA addressed these concerns but rejected them (Decision paragraphs [5.264] – [5.280]). An important factor the CMA relied upon was the limited nature of the commercial activities carried out by Flynn and the relatively low risks it incurred in supplying the capsules: Decision paragraph [5.274]. It observed, in particular that: continuity of supply ensured a substantially guaranteed customer base; Flynn was committed to minimum order volumes much lower than actual product demand; there was no immediate threat from competitors; and, Flynn had a significant measure of commercial protection by reason of indemnities from Pfizer. It noted the finding of the CAT in the First CAT judgment: "*Flynn's involvement in these arrangements was not to provide risk-taking or significant commercial activity*".

208. Flynn appealed to the CAT on the following grounds:

(1) The CMA used an inappropriate measure (ROCE), and was irrational in switching from ROS (the measure used in the First Decision).
(2) The RRoR was so wrong as to be indefensible.
(3) The CMA failed to pay due regard to the fact that Flynn's returns were in line with normal returns in the pharmaceutical industry.
(4) The CMA failed to pay proper heed to Flynn's input pricing (as a result of its "*repeated refrain*" that Flynn and Pfizer set their prices in concert).
(5) Flynn's actual prices are in line with the comparators adduced by it – in particular the phenytoin tablets.
(6) Flynn's alleged excessive prices were not sufficiently high to support a finding of excessiveness.

Analysis and conclusion on the first input in the ROCE analysis: Capital employed

209. In our judgment, the CAT's conclusion that the CMA made a fundamental error in calculating the capital employed by Flynn cannot stand. Far from revealing an error in the CMA's reasoning, it is itself the product of a mistaken view as to the meaning of "*capital employed*" for the purpose of a ROCE analysis.

210. Mr Pascoe, who presented the argument on behalf of Flynn on this point, accepted that the CAT was wrong to include the costs incurred by Flynn in acquiring and distributing the capsules as "*capital employed*" within the ROCE analysis. He was right to do so. The capital which Flynn needed to operate the straightforward business of acquiring capsules from Pfizer and selling them in the market is manifestly not measured as the amount that Flynn expended in acquiring and distributing the capsules. That is an operating cost which was more than met by the operating revenue it received on the sale of the capsules. The relevant question is what capital was required to *enable* Flynn to carry out that business, which the CMA found broadly equated to the cost of carrying stock and of meeting its cash flow.

211. The reason that is the relevant question is because it can be taken to represent the amount of capital which another entrepreneur, assuming workable competition, would need in order to compete.

212. Part of the CAT's objection was that the CMA failed to accommodate for the fact that cash flow needed to be calculated by reference to the dates on which it received, or paid, money. That, however, was precisely what the CMA did when factoring into the working capital requirements, including for credit given/received in respect of debtors/creditors.

213. Mr Pascoe sought to defend the CAT's Decision on this aspect by submitting that, although it wrongly characterised what it was doing as identifying the capital employed for the purposes of a ROCE analysis, its analysis was better understood as having rejected altogether a ROCE approach (as well as rejecting the ROS approach) and having adopted instead a third method for arriving at a RRoR, namely a "*cost-mark-up*" approach. As Mr Pascoe explained, that is similar to a ROS approach, but instead of calculating return as the percentage of profits over revenue, it does so as the percentage of profits over cost. It is what would commonly be called profit margin.

214. He contended that the CAT's conclusion was rational because it reflected the case advanced by Flynn's experts at trial. They had pointed out that Flynn employed very little capital, and that wherever a business was operated without employing much capital, it inevitably followed that the ROCE approach would produce a low rate of return.

215. Mr Pascoe referred to Judgment paragraph [148(4)], as a slightly more involved reason for rejecting the CMA's approach. Here, the CAT discussed the fallacy of distinguishing between different types of capital, saying "*it is – or ought to be – trite that any judgment of excessiveness should not depend on the method of production shown by the entrepreneur*". It contrasted, by way of example, a business that is labour intensive and one which is light on labour but heavily invested in machinery. Mr Pascoe said that the point made here was a universal one, viz., that the ROCE measure used by the CMA discriminated against businesses that "*produce revenue other than capital costs*".

216. We cannot accept Mr Pascoe's submission that the CAT was in fact adopting a cost-mark-up approach.

217. Nowhere in the CAT's judgment is that approach identified as the proper method for calculating the RRoR in this case. That is unsurprising since no party submitted to the CAT that a cost-mark-up approach was appropriate. At Judgment paragraph [90] the CAT saw no reason why a ROCE-WACC approach could not be deployed with a view to assessing a RRoR, provided that the "*Cost*" was not confused with the "*Plus*". It expressly rejected Flynn's contention that the CMA was wrong to switch (as between the First CMA Decision and the Decision) from ROS to ROCE in calculating Flynn's RRoR, implicitly approving the CMA's choice of ROCE as the appropriate methodology. That is reinforced by its comment (Judgment paragraph [116]) that the CMA's approach in the Decision accorded with the CAT's own preference for ROCE.

218. Mr Pascoe's submission that the CAT was following the approach of Flynn's experts does not stand up to scrutiny. In the passages cited to us:

    (1) Mr De Conick (Flynn's expert) made the point that Flynn's actual return on capital employed on phenytoin was large because the denominator (capital employed) was tiny, not because the numerator (profit) was large.

(2) A passage from Mr De Conick's cross examination in which he made the same point: "*the reason the CMA considers that the price of Flynn is excessive is because it reduces the whole analysis to return on capital employed and there is limited capital employed by Flynn in this business*".

(3) A passage from the report of Flynn's industry expert, Mr Williams, which made the point that "*asset light businesses*" are by definition not capital intensive "*and therefore the use of a ROCE measure is not appropriate*".

219. This evidence was unconnected to a cost-mark-up analysis. It was adduced (as Mr Pascoe acknowledged) to support Flynn's case that a ROS approach should be used, because a ROCE approach would always result in a low reasonable rate of return in the case of a capital-light business. That was the point expressly rejected by the CAT.

220. As to the reliance placed on Judgment paragraph [148(4)], the point made there is different. It is that if ROCE is used as a means of measuring a RRoR, then it should not discriminate on the basis of the type of capital employed (labour as opposed to machinery). That is not the same as the alleged discrimination between cases where ROCE is used for (i) a business that does not employ much capital and (ii) one that does.

221. We conclude that the CAT did adopt a ROCE approach but that in doing so it wrongly regarded the total costs incurred by Flynn in acquiring and distributing capsules as "*capital employed*". As Mr Pascoe acknowledged, that was simply wrong. It was not defensible as a possible approach in calculating ROCE but was irrational. Accordingly, the CAT's conclusion that the CMA erred in relation to the capital employed input into its ROCE calculation cannot stand.

Analysis and conclusions on the second input into ROCE: The cost of capital

222. The CAT's next reason for rejecting the CMA's reliance on WACC of 10% was that it lacked a "*solid factual foundation*" and was a mere "*conclusory finding*".

223. Professor Bailey KC for the CMA submitted that this was a misreading of the Decision. The CMA arrived at a WACC of 10% in the Decision on the basis of five pieces of evidence summarised above at paragraph [205]. That was bolstered, in the evidence adduced by the CMA before the CAT, by a bottom-up calculation of the weighted cost of capital adopting the capital asset pricing model specifically for capsules in the report of the CMA's expert, Mr Harman. This produced a range of between 6.2% and 10%.

224. As to the CAT's second, and more fundamental, reason for rejecting the CMA's approach (that it looked not to the Focal Product but to the enterprise), Professor Bailey KC submitted that this, too, was a misreading of the Decision. Aside from considering factors that focussed on the WACC across Flynn's business, the CMA addressed Flynn's argument that the capsules were a successful product which would earn higher returns "*ex-post*". This focussed upon whether any upward adjustment should be made specifically in relation to that part of its business consisting of the distribution of capsules. At Decision paragraph [5.274], the CMA identified six factors, which together demonstrated that Flynn took on very little commercial risk in the distribution of capsules, which pointed strongly against such an adjustment. This, submitted Professor Bailey KC, was the CMA doing precisely what the CAT held it did not do.

In addition, Mr Harman's bottom-up approach was specifically focused on a WACC for the distribution of capsules, but the CAT ignored this evidence.

225. We consider that the CMA's submissions are correct. Moreover, looking at the paragraphs of the CAT's judgment which expanded on the second aspect (Judgment paragraphs [167] – [168]), it appears that the CAT's view that the CMA's WACC looked to the enterprise rather than the Focal Product, was an extension of the error it made in relation to capital employed. At Judgment paragraph [167(1)] the CAT referred back to its definition of Normal Profit as the opportunity cost of entrepreneurial effort, which can be assessed by considering the cost of "*obtaining the funds to finance the Product Unit Cost or (to use the definition of Capital at [60(1)] by assessing the cost of the money required to acquire the Factors of Production necessary to produce one unit of Focal Product*". At Judgment paragraph [167(2)], the CAT then said that "*we know what money is needed to fund the production of the Focal Product because we have the data in the Focal Product Spreadsheets*". At Judgment paragraph [167(3)] it concluded that "*we define the Reasonable Rate of Return for these purposes as follows: it is the sum that the Seller would need to borrow (e.g. from a bank) to fund the Product Unit Cost. It is thus a unit based cost of capital (not a WACC but a Per Unit Cost of Capital or PUCC), and we consider that to be the appropriate measure of the Reasonable Rate of Return*." It was upon this basis that the CAT rejected the CMA's WACC (at Judgment paragraph [168]) for being calculated by reference to the enterprise, not as regards the production and sale of the Focal Product:

> "Thus whilst a cost of capital approach <u>is</u> appropriate, that cost needs to be localised in the Focal Product. We have termed this the PUCC, but recognise that this is not, in any way, a term of art."

226. That, however, built upon the flawed approach that return on capital employed related to the return which an investor would expect on the sum required to fund all the operating costs of the venture, as opposed to the sum required to fund the capital needed to operate the venture.

227. Mr Pascoe's submissions at the hearing on this part of the case focused on the following points: (i) ROCE identifies only a "*break-even*" price or the "*minimum return*" which an investor would expect, but was not a proxy for a reasonable rate of return; (ii) the CMA's error was in equating ROCE with WACC, without articulating why the reasonable rate of return is WACC; and (iii) the CMA's approach failed to have regard to real-world examples of ROCE, whereas Flynn had adduced evidence of real-world comparators, where the return on capital employed by other companies was greatly in excess of 10%. The third point is raised by Flynn's Respondent's Notice.

228. The short answer to the first two points is that they do not answer Professor Bailey KC's criticisms of the CAT's judgment. Specifically, that the CAT had misread the Decision.

229. As to the first point (break-even), Mr Pascoe posited an entity funded wholly by debt, for example where it borrowed from its bank an amount equal to 100% of its capital employed, at a rate of 10% per annum. Its annual cost of maintaining that capital is the interest payable on its bank loan. If the entity generates a profit margin equal to 10% of its bank loans, that would, he submitted, be the minimum amount needed in order to stay in business. By definition, therefore, it would need to generate a profit margin of

more than that just to stay in business. That shows, he said, that ROCE is the *minimum* return that is required to attract investors, not a *reasonable* rate of return.

230. This example appears to us to confuse the concept of return *to the entity* with a return *to its investors*. As we have already observed, it was not suggested that Flynn actually incurred any borrowing costs in connection with the distribution of capsules. It is a purely notional example. Another example would be an entity funded wholly by equity. In that case, profit at the entity level and the return to investors are the same thing. More usually an entity is funded by a combination of debt and equity, where WACC is the appropriate measure because it provides a weighted average between the cost of both.

231. As the CAT recognised in *Le Patourel (ibid)* at paragraphs [566] – [567], while ROCE might be described as the "*minimum sustainable return*" in the sense that it is the amount that makes it worthwhile for investors to commit funds to an enterprise, it is nevertheless an appropriate measure for determining a "*reasonable*" return to investors.

232. The Commission decision in *Aspen* (Case AT.40934), relied upon by the CMA, makes the same point (paragraph [127]), and in the following terms at paragraph [154]:

> "First, the Commission recognises that companies are entitled to make a reasonable rate of return, in order to cover their cost of capital. In fact, the Commission's preliminary assessment of the Product's profitability on the basis of a cost-plus analysis … accounts for a reasonable rate of return, in line with the industry's average performance, by adding a "plus" element to the costs based on the Comparator Profitability. That "plus" element allows recovering the costs of capital. In principle, no further recognition of the remuneration of the capital employed in the products is therefore required."

233. The CAT in this case itself recognised (Judgment paragraphs [63] and [81]) that the return on capital employed can be regarded both as a cost (to the entity) and a return (to the investors), expressly equating in the latter paragraph the reasonable rate of return with "*aka the cost of Entrepreneurship*" (by which the CAT meant "*Normal Profit*" (see Judgment paragraphs [143] – [144]), calculated by reference to what the entrepreneur could have earned if they otherwise invested their money, or what it would cost them to borrow it (Judgment paragraph [167(2)]).

234. As to Mr Pascoe's second point (the CMA erred in equating ROCE with WACC), we do not understand this to have been a criticism made by the CAT at all. Insofar as the CAT criticised the CMA for reaching a "*conclusory finding*", that related to the CMA's finding that a reasonable WACC was 10%. It was not, as we understand it, criticising the CMA for using WACC, as such, as a proxy for the reasonable return on capital employed by Flynn.

235. Mr Pascoe referred to the second sentence of Judgment paragraph [168]: "*The appropriateness of a WACC as a measure for this return is not considered*." That must be read, however, with the rest of the paragraph, and indeed the surrounding paragraphs, from which it appears that the point the CAT was making was that the CMA had been wrong to calculate WACC *by reference to the enterprise*. Thus, in the last two sentences of the paragraph, the CAT found that a cost of capital approach was appropriate (indeed, as we have already observed, the CAT expressly approved the ROCE approach), but it

held that cost needed to be localised in the Focal Product, something which it termed "*PUCC*". This was the point which Professor Bailey KC addressed (above), and which was not answered by Mr Pascoe's submissions.

Flynn's Respondent's Notice relating to the Excessive Limb

236. In its Respondent's Notice, Flynn also identifies various grounds for upholding the CAT's conclusion that the CMA erred in concluding that Flynn's prices were excessive. We address the main points that were developed in oral argument.

237. Flynn contends that the CMA was not justified in using ROCE rather than ROS, and the CAT's reasons for concluding otherwise (and thereby agreeing with the CMA) "*do not stack up*". It does so on three bases. First, that ROCE is inappropriate for an asset-light company, where returns are driven not by capital investments but by intangible assets such as people skills. Second, that there was no new material to justify the CMA's decision to adopt ROCE in the Decision, having adopted ROS in the first decision. Third, that the CAT was wrong to conclude that Flynn's specific criticisms of the CMA's ROCE figure were irrelevant to the anterior question of whether ROCE was a suitable metric.

238. The broad answer is that Flynn's arguments do not get above the threshold for appealing against an evaluative conclusion of the CAT (which upheld the (equally) evaluative judgment of the CMA).

239. As to the first point, the CMA addressed (and rejected) Flynn's arguments on the suitability of ROCE in relation to asset-light companies at some length at Decision paragraphs [5.71] to [5.87]. Flynn contends that the CAT failed to answer (or answer adequately) Flynn's criticisms of the CMA on this point, noting that at Judgment paragraph [148(4)(iii) and (vi)] the CAT said that it would "*come on to*" explain why it was satisfied that ROCE was appropriate for an asset-light company, but does not appear to have come back to this question. In fact, it was in these very paragraphs that the CAT explained that it had reviewed the expert evidence on both sides addressing the suitability of ROCE for an asset-light company, and preferred the evidence on this point of the CMA's expert. The suggestion that they would "*come on to*" explain why it was satisfied that ROCE was appropriate for an asset-light company is confusing, but the fact remains that the CAT did address that point and reach a conclusion on it.

240. Flynn's arguments in its Respondent's Notice do not meet the fact that this was an evaluative conclusion by the CAT, against which an appeal will only lie if there is an error of law, and we can identify no such error.

241. As to the second point, Flynn's essential complaint is that there was no new material which justified the CMA's changed approach. The CMA's conclusion (see Decision paragraph [5.61]) was that in light of the information and submissions provided by Flynn the difficulties which had persuaded the CMA not to use ROCE in its first decision in measuring Flynn's capital base were no longer well-founded. In other words, the change in approach was justified by the materials that Flynn itself provided, and the CMA was now able to identify a reliable estimate of Flynn's cost of capital. The CAT decided that it was not merely open to the CMA to change its methodology, but that it was obliged to consider whether the methodology used first time around remained appropriate (Judgment paragraph [114]). Its conclusion was that this was a

question for the judgment of the CMA, with which the CAT should be slow to interfere, and that it was satisfied that the decision to change to ROCE was adequately explained in the Decision (see Judgment paragraph [116]). This is unimpeachable reasoning, and Flynn's assertion that there was no new material does not reach the hurdle of showing an error of law in the CAT's decision.

242. A similar answer can be made to the third point. The CAT was entitled, in our view, to conclude that the alleged errors in the CMA's application of the ROCE-WACC approach were irrelevant to the anterior question of whether it was appropriate to apply that approach in the first place.

243. Flynn contends that the CAT did not assess Flynn's ROS comparators. This point is put on the basis that if the CAT was wrong as to the appropriateness of ROCE, then it ought to have considered the comparables put forward by Flynn. We need not address it, therefore, given our conclusion on the logically prior point.

244. Next, Flynn contends that the CAT wrongly rejected its criticism of the CMA's WACC figure. This is based on Flynn's contention that the CMA derived its 10% cost of capital figure largely – if not exclusively – from the presentation prepared by Jefferies Bank. As explained, above at paragraph [205], however, that is simply wrong. The Jefferies Bank presentation was referred to as one factor among five.

245. Flynn criticises the cross-check against Flynn's absolute returns, on the basis that since Flynn's percentage margins are known to be distorted by Pfizer's supply price, it was obviously flawed, because there is no justification for relying on absolute profits as an indicator of excessiveness.

246. We do not accept this criticism. As we have explained elsewhere, the CMA was right to take into account the special circumstances of this case, arising from the nature of the agreement between Pfizer and Flynn which enabled the immediate and substantial increase in the price of capsules, and which enabled Flynn to benefit from that substantial increase while assuming only very low risks compared to other drug manufacturers and distributors. The CMA was also justified, in light of those circumstances, in having regard to the profits made by Flynn in absolute terms.

247. Finally, Flynn makes the point that the level of "excess" on the CMA's own calculation was 31-37% for the most popular 100mg capsules and an average of 41-47% across all four strengths. The CMA addressed this at length by reference to all of the evidence adduced by Flynn. Its conclusion that margins of this magnitude were unfair is fully supported by the evidence. It is no answer to the evidence to postulate that percentages of that level are not unfair, when the evidence indicates otherwise.

J. Issue V: Comparables

Introduction

- *What the appeal is about in relation to comparables.*

248. We turn next to comparables. We have summarised the CMA's findings in relation to the evidence of comparables put forward by the undertakings at paragraphs [85] – [104] above. The CMA rejected this evidence as not meaningful save for foreign EU

comparables of phenytoin capsule pricing (see paragraphs [105] – [109] above). The CAT disagreed and identified a long list of errors. The CMA argues that this evidence demonstrates that the CAT's criticisms are unjustified and unfair, and this can readily be seen simply by comparing the Decision with the Judgment.

- *The general relevance of comparables to fairness.*

249. The value of evidence of comparables is affected by the degree of equivalence between the index and comparator products and markets. This is essentially an issue of fact. There will, normally, be three issues to consider. First, the decision maker will consider product characteristics so that apples are compared with apples, and prices for cods' roe or mushrooms are not compared with those for caviar or truffles. That entails comparing the attributes of the index product and the comparable so that if, for instance, the latter has features which are of materially greater value to the consumer than the former index product, then such differences might render prices of the comparator less probative as relevant evidence. Secondly, the analysis involves considering the extent to which prices or returns in the comparator market arise from conditions which, to use the shorthand, are "*workably competitive*". If the posited comparator market is highly concentrated, surrounded by entry barriers, with incumbents holding market power and thereby able to obtain supra-competitive prices and profits, prices charged there might amount to evidence of little if any value. Thirdly, if the decision maker's conclusion is that the posited comparator price *is* affected by market power (i.e. it is inflated and supra-competitive) then it will need to consider any evidence before it which enables it to adjust or regress the price to remove the element of inflation in order that a proper basis for comparison can be identified. Overall, this exercise is heavily fact and context sensitive, and the decision maker must have a generous margin of appreciation or judgement (as the CAT recognised – Judgment paragraphs [206], [269] and [270]).

250. The judgment of the CAT in *Le Patourel* demonstrates how this might work. There, the CAT identified, on the evidence, various benefits flowing from the service for which consumers were prepared to pay a premium above Cost Plus. It also found, again on the evidence, that prices in a workably competitive comparable market were significantly higher than Cost Plus. The CAT held that given the identified benefits and the evidence of prices in the comparable market, there was a reasonable relation between price and value and therefore the ASP was fair and non-abusive. The CAT did not however break down and divide the defendant's ASP into discrete increments. It did not say that the identified benefits justified (say) 60% of the ASP and the evidence of comparables was sufficient to account for the remaining 40%. Instead, for reasons which this Court held to be proper, the CAT applied a relatively broad axe to the exercise. It combined the evidence and concluded, swinging the axe, that collectively it justified the price actually charged.

251. The dispute on this issue boils down to whether the CAT's criticisms of the analysis of comparables in the Decision are properly borne out by the actual reasoning in the Decision.

The CAT criticisms.

252. We turn to the particular criticisms made by the CAT. It addresses comparables in Judgment paragraphs [172] – [184] and substantially agreed with the grounds of appeal

of Pfizer and Flynn. A summary of the CAT's criticisms is as follows. The CMA wrongly:

(i) Applied the false test that any price above Cost Plus was *per se* abusive and, it inevitably followed, *any* comparator relied upon to justify an above Cost Plus price was treated as irrelevant and to be rejected.

(ii) Acted unfairly to Pfizer and Flynn in requiring them to produce evidence of comparables.

(iii) Used a new benchmark of the "*sufficiently competitive market*" instead of the "*Real World*".

(iv) Failed to appreciate the relevance of continuity of supply.

(v) Accorded weight to evidence of prices of phenytoin capsules in other EU states ignoring the fact that regulation elsewhere constrained those prices so that they could never be indicative of prices in workably competitive markets.

(vi) Entirely disregarded the DT prices for phenytoin tablets (paid to Teva) which was "*informative*" of the fact that prices for tablets were substantially above Cost Plus.

(vii) Ignored evidence of prices paid for other non-phenytoin AEDs.

(viii) Was guilty of confirmation bias and thereby systemically focused only upon inculpatory evidence of comparables ignoring exculpatory evidence.

The points at (i), (v) and (viii) above are raised by the CAT in the context of comparables but also in other contexts and we have addressed them separately. We therefore focus below on the other issues.

Putting the criticisms into context

253. We start by putting the CAT's criticisms of the CMA into the context of findings the CAT, *itself*, made about comparables, first in relation to the Decision and then in the retaken decision. In relation to the Decision, whilst levelling serious criticism against the CMA for not attributing sufficient weight to these comparables, the CAT simultaneously held that very limited value should be accorded to them. In relation to the retaken decision the CAT held that comparables were immaterial when determining abuse.

254. In relation to the Decision the CAT held:

(i) Where the index product is governed by dominance, comparables are "… *not going to be very comparable*"; they will be difficult to find: Judgment paragraph [259].

(ii) Competition authorities cannot be expected to conduct full investigations of other markets, and this affects the weight that such authorities can attribute to comparables: Judgment paragraph [260].

(iii) Other phenytoin products (e.g. NRIM capsules and tablets) may be pharmacologically identical but because of MHRA guidance on continuity of supply, authorities should treat "*prices of those products with a high degree of care*" and "*because of continuity of supply they are not good comparators at all*": Judgment paragraph [264].

(iv) Other AEDs are "*nothing like as close substitutes as tablets*". They serve different therapeutic purposes to phenytoin capsules which are a third line treatment. The CAT had no knowledge of their product costs and/or what a reasonable rate of return would be and no knowledge of the "*extent*" of any surplus. Competition authorities were "*well within*" their rights to accord other AEDs "*limited weight*": Judgment paragraphs [269] – [270].

(v) Evidence adduced by the appellants suggested that no one priced at Cost Plus, but the CAT was unable to conclude whether prices charged for other drugs amounted to inculpatory or exculpatory evidence: Judgment paragraphs [267], [268] and footnote [417].

255. In relation to the retaken decision:

(i) As regards Flynn the CAT refers to comparables only in respect of the ROS (i.e. as part of the Plus component of Cost Plus) where reference is made to the ROS of other products supplied by Flynn (Judgment paragraph [306(5)]. However, the analysis there is devoted to explaining how unreliable such evidence is. It suffered from "*fragility*". The CAT knew very little about these other products; their production costs or their unit prices; and very little could be inferred from pricing data (c.f. paragraphs [306 (4) – (5)]). There is no other reference to comparables.

(ii) As regards Pfizer in paragraph [315] the CAT refers to comparables only in relation to whether Pfizer's prices were excessive. It repeats its criticisms of the CMA in relation to tablets and the DT but then says that there are "*other reasons*" for giving that evidence "*limited weight*". The DT was not a comparator "*at all*" and said "*nothing*" about an appropriate price. As for tablets had there been evidence that their pricing was subject to "*Real World*" competition then such prices "*might*" have been informative. However, on the CAT's analysis, suppliers of tables enjoyed dominant market power which made drawing inferences "*difficult*" and, even though the CAT had taken that evidence "*into account*", it did not affect the robustness of the CAT's conclusion, which was that Pfizer was egregiously abusing its dominant position. We interpret the Judgment as saying that even though the CAT formally took tablet pricing evidence into account, on the facts that evidence had no impact upon the final analysis i.e. it was immaterial. This is confirmed in footnote [436]: "*As we have described, the Drug Tariff is not a price but a reimbursement rate to pharmacies which acts as a price ceiling under which competition takes place. The Drug Tariff thus says nothing about price…*". There are no other references to comparables.

(iii) In the round our reading of the Judgment is that the CAT did not accord comparables relied upon by Pfizer and Flynn *any* material weight in its assessment of abuse.

256. Standing back the CAT's criticisms of the CMA are therefore hard to reconcile with the CAT's own conclusion that comparables had little, if any, value in the evidence weighing exercise. Moreover, the fact that the CAT, having heard the evidence, was itself unable to exclude the possibility that the evidence of tablets was inculpatory, and hence not exculpatory, is also hard to square with its criticism of the CMA for concluding that it was not exculpatory. With this in mind we turn to the individual criticisms made by the CAT of the CMA that we have not previously considered.

It was not fair of the CMA to require Pfizer and Flynn to produce evidence of comparables because they are by their nature of limited value

257. In paragraph [176(2)] the CAT held that it was not "*fair*" for the CMA to "*require the production of comparables that closely compare to a product that is dominant because of its unique characteristics*":

> "… we consider that rejecting the evidence on the basis that the comparators were not sufficiently comparable to be unfair to Flynn. As the CMA has found – necessarily, in order to establish a Chapter II jurisdiction – Flynn was dominant in the market, by reason of the characteristics of the Capsules (to which we will be coming). In such circumstances, to require the production of comparables that closely compare to a product that is dominant because of its unique characteristics is unfair. Such evidence will be hard, if not impossible, to obtain. The better approach is to accept that the comparables are likely to be somewhat incomparable, but not to reject them out of hand for this reason. The extent to which comparables are truly comparable should go to weight. To this extent the CMA's binary rejection of Flynn's evidence leaves a great deal to be desired."

258. The gist seems to be that the CMA's conclusion that the comparables were insufficiently comparable was infected by three errors. First, it was wrong and unfair for the CMA to *require* Pfizer and Flynn to adduce evidence of comparables. Secondly, in a dominance case, evidence of comparables will by its very nature be hard if not impossible to obtain and any posited comparables will be *"somewhat incomparable*". Thirdly, even assuming this to be true, such evidence cannot be dismissed in a binary fashion "*out of hand*", as the CAT says the CMA did.

259. We reject this analysis which neither reflects the reasoning in the Decision nor accords with logic.

260. First, the CMA did not *require* Pfizer or Flynn to produce comparables. This Court in *Phenytoin I* was clear that it was open to defendant undertakings, if they wished, to adduce evidence they considered appropriate, which might include evidence of comparables. It was the duty of the CMA to consider that evidence fairly and impartially. Pfizer and Flynn chose, as was their right, to tender evidence of comparables but this was their choice exercised as part of their rights of defence. The CMA was then required in law to assess that evidence fairly and impartially.

261. Secondly, the CAT suggests that whenever an index product is subject to dominance, comparables will be hard if not impossible to obtain. This prejudges the issue. Just

because there is dominance over an index product does not mean that every other comparable market will also be characterised by dominance. The analysis of the CAT is *Le Patourel* is a good illustration. There the CAT identified two very similar and closely related markets (both for the provision by BT of telephony services to consumers) but where only one was subject to dominance. The CAT was able to compare the prices in the index (dominant) market with those in the comparable (workably competitive) market and evidence of pricing in the latter was of material value supporting the defendant's case that its pricing in the index market was not abusive. The CAT was therefore incorrect to say in the Judgment that there was unfairness because comparables would be hard if not impossible to obtain. Where however a purported comparable market *does* bear characteristics of market power then it is obviously relevant for the decision maker to evaluate whether prices in that market are affected by that market power and so cannot be said to reflect prices that would be charged in competitive markets. In the present case that was precisely the exercise conducted by the CMA in relation to the prices paid by the state to Teva for tablets: see paragraphs [89] – [96] above, a conclusion the CAT later agreed with: Judgment paragraph [315].

262. Thirdly, the CAT's premise that if a proposed comparable is insufficiently comparable it should *still* be taken into account is illogical. The CAT accepted that in this case the comparables were of little or no value. That being so, it is difficult to understand how it could be said to be wrong for the CMA to reject them.

The wrongful use by the CMA of the "new" test of a "sufficiently competitive market"

263. The next criticism turned upon the CAT's conclusion that the test or benchmark used by the CMA to measure comparables ("*sufficiently effective competition*") was new and did not reflect the real test which was that of "*Real World Competition".* As we read the Judgment there are two strands to this point. First, that the CMA had not stated "*in terms*" that the reason it rejected tablets as a comparable was because those prices did not derive from sufficiently effective conditions of competition. Secondly, that the CMA failed to appreciate that the evidence was relevant because of continuity of supply, which the CAT says the CMA did not address at all. We take each in turn.

- *Failure to express a conclusion on impaired competition*

264. In paragraphs [266] – [268] the CAT rejected the conclusion in the Decision that tablets prices did not reflect the outcome of sufficiently effective competition. It held:

> "266. … we consider the reasons the CMA gave for taking no account of the Tablet prices. This was because the Tablets market did not demonstrate characteristics of Real World Competition, but rather (so it must be inferred) operated under conditions of Impaired Competition. The CMA parsed the period of competition between Tablets into four periods, analysing each of them closely, ultimately concluding:
>
> > …the Tablets market did not exhibit sufficiently effective competition during the period January 2005 to December 2021. Although there was a short period of more intense competition in Period 3, it was limited by several factors (as

> set out in the conclusion for Period 3). Therefore, at no stage do Tablets ASPs provide a meaningful comparator to establish whether the Parties' supply prices for Capsules were fair."

The CAT (paragraph [267]) rejected this approach. That data could not be "*so easily*" dismissed. The CAT was "*concerned"* at the introduction by the CMA of a new test of "*sufficiently effective competition*". The CAT said: "… *if the CMA is saying that the comparators derive from a market with Impaired Competition so impaired as to be valueless, then the CMA should say so in terms.*"

- *Analysis*

265. First, we reject the criticism that the CMA did not actually say "*in terms*" that it was rejecting evidence *because* it derived from markets characterised by impaired competition. This is exactly what the CMA did say in the Decision: see paragraphs [89] – [96] above which summarise the granular analysis addressing why the Teva price bore the hallmark of being supra-competitive and hence not meaningful as a comparator. We note that in the Decision the CMA referred to contemporaneous disclosure from Pfizer dating from 2012 which, on the face of it, suggests that Pfizer also considered that Teva was earning "*supernormal profits*" from sales to the DHSC: see paragraph [58] above. A valiant effort has been made to explain away this internal statement; yet it was contemporaneous and unguarded and does provide evidence of the unvarnished views held within Pfizer at the time. We also observe that in Judgment paragraph [315] the CAT recognised that tablet pricing was not a comparator *because* suppliers were dominant and it was thereby impossible to say that the prices charged were reflective of workably competitive market conditions.

266. Secondly, as to the criticism that the CMA used a benchmark test of the sufficiently competitive market as the counterfactual benchmark against which to measure fairness, which was "*novel*", instead of a test of the "*Real World*", the point is not understood. In Judgment paragraph [140] the CAT accepted that the two phrases were synonymous and that the sufficiently effective competition test, far from being novel, was part of the language used by the CJEU in *United Brands*. The CAT said: "*Real World Competition [is] synonymous with the phrase "normal and sufficiently effective competition" coined in United Brands*."

Failure by the CMA to appreciate the relevance of continuity of supply

267. The next reason given for rejecting the analysis of the CMA (Judgment paragraph [267(2)]) is that the comparators relied upon by the parties were "…*informative, precisely because of the Continuity of Supply issue (which affected all of the products), which the CMA does not consider at all*". We do not follow the point. The CMA did consider continuity of supply. Continuity of supply flows from the MHRA guidance and effectively hinders switching with tablets. It served to confer dominant market power upon Pfizer and Flynn. As the CAT itself held (Judgment paragraphs [333(7)(iii) and 333(8)]) it is a cause of dominance and facilitates the abuse and is not something that provides value or benefit to users. Continuity of supply is accordingly a reason militating against tablets and capsules being good comparators, not a reason explaining why tablets pricing provided informative evidence.

Wrongful rejection by the CMA of the pricing of tablets (the £30 DT price / Teva)

- *The CMA position in the Decision*

268. The issue concerns the probative value as a comparator of the £30 DT price paid by the DHSC to Teva. The CMA held that the DT was not a relevant comparator. It was affected by market power and did not reflect prices that would arise in a workably competitive market. The CMA considered Teva's pricing as charged when it was a monopolist, a duopolist and when it was competing with two other suppliers (in an oligopoly). It considered how the price had changed over time and linked this to the exercise of market power.

- *Pfizer's argument before the CAT*

269. Pfizer argued before the CAT that it benchmarked its price to Flynn by reference to the DT price for tablets and that this was reasonable. Pfizer did not address the detailed evidence and reasoning in the Decision to the effect that the £30 DT price was not set in conditions of workable competition. It argued that the price was a valid comparator for different reasons. The supply price from Pfizer to Flynn was set at a 50% discount off the DT tablet price, which was bioequivalent to the capsule. It had been set by the DHSC in 2007 and had remained stable for almost a decade. It reflected a price agreed between the DHSC and Teva after the former threatened to use its statutory powers to force a reduction in the tablet price to achieve value for the NHS. It was a price paid by a powerful willing buyer which reflected its medical value.

- *The conclusion of the CAT: The evidence was "informative"*

270. The CAT held that the CMA erred in failing to treat the DT as relevant information. The CAT addressed the DT in Judgment paragraphs [123] and [249] – [255].

271. In paragraph [254], the CAT held whilst the DT was not a like for like comparator that did not render a comparison between the £30 DT price paid to Teva and the upstream supply prices of Flynn inconsistent and lacking in meaning. The DT could be seen as a form of price ceiling and, more significantly "*as an indication of the economic value to be attributed to the service of a pharmacy dispensing capsules*". That economic value (£30) was greater than merely the provision of the drug to the pharmacy; it provided an indication of the value to be attributed to the cost of the drug forming a component part of that service (Judgment paragraph [254(1)(i) – (iii)]).

272. Paragraph [254(2)] is important because it is the part of the Judgment where one might reasonably expect the CAT to grapple with the evidence and reasoning set out in the Decision. Indeed, the CAT purports to address directly the finding of the CMA that the DT "*was not set in conditions of effective competition*".

273. However, the reasons given by the CAT, as we explain below, neither grapple with the reasoning and evidence in the Decision nor, with respect, really address the issue of market power at all.

274. The first point made by the CAT was as follows: "*The CMA appears to have concluded that the Drug Tariff was itself the outcome of a competition law infringement by Teva*". We do not agree. No such allegations were ever made or could reasonably be implied.

To the contrary all that the CMA was doing in the Decision was conducting the very analysis that the CAT first time around criticised it for not carrying out sufficiently i.e. working out whether the DT price was reflective of market power and was therefore not a good comparator. The CAT cited from Decision paragraph [6.192.2] to support its conclusion, but that paragraph said nothing at all about a possible infringement by Teva and nor did it relate to market power.

275. The CAT next explained why it rejected the CMA's conclusions on the evidence. Its reasons are set out in Judgment paragraph [254(2)(i)-(iv)]. But these have nothing to do with the CMA's analysis of market power in relation to tablets and they do not address the extensive evidence set out in the Decision. The CAT first makes a general point about the structure of the DT which is not in dispute (sub-paragraph (i)). Next it states that the CMA's conclusion that the DT is too high is a reflection of its assumption that any price above Cost Plus is illegal (sub-paragraph (ii)). This is a reference to the CAT's conclusion that the CMA assumed that any price above Cost Plus was *per se* illegal. But nowhere does the CAT actually address the evidence relied upon in the Decision.

276. Then, finally, the CAT said that it was not satisfied that the DHSC was induced to agree a DT inconsistent with its public law responsibilities but, nonetheless, it is not relevant to make findings as to what actually occurred between Teva and the DHSC or as to how the DT came to be agreed (sub-paragraphs (iii) and (iv)). This point, assuming it to be validly made by the CAT, does not undermine the CMA's analysis or provide an explanation as to why the DT price should remain "*informative*", notwithstanding the conclusion of the CMA that it was tainted by market power.

277. From all of this the CAT concluded that because it was a fact that the DT was agreed at the £30 rate, third parties were "*entitled*" to rely upon that as "*pricing information*" (Judgment paragraph [254(2)(iv)]). On this basis the CAT concluded that the CMA had no grounds for holding that the economic value of capsules stood at Cost Plus and no higher: Judgment paragraph [255]. With respect, this conclusion is not an answer or response to the actual evidence set out in the Decision.

278. A further indication of the CAT's thinking is found in paragraph [260] where it criticises the CMA for rejecting evidence because it did not emanate from conditions of workable competition. The CAT describes the notion of "*Impaired Competition*" as a "*chimera*". This is difficult to understand. It might be related to its point that comparables should not be excluded altogether where the supplier holds dominant market power, but if that is what the CAT was saying it is a factor which goes to weight. The distinction is more theoretical than real. The purpose of trying to identify comparators is to test whether a price is fair by comparison with prices of similar products supplied in conditions of effective competition. If a particular comparator is tainted because the supplier has market dominance then it may well be that it has no probative value and thus should be given no weight. That is essentially what the CMA concluded here. Moreover, the CAT's comment is inconsistent with its own conclusion in the retaken decision that tablets were not informative for the very reason that suppliers held dominant market power.

279. Notwithstanding all of the above the CAT, in the final analysis, was itself unable to conclude that the evidence was "*informative*" in an exculpatory manner and, indeed, it

accepted that it might in fact prove to be incriminating. Having referred to pricing data (Judgment paragraph [267(2)(iv) Figure 12]) in paragraph [268] it held:

> "We consider that the CMA erred in disregarding this data. We cannot say at this stage whether it is supportive of a finding of unfairness or a contra-indicator. What we can say is that it is material that ought to have been taken into account, and it was a material error on the part of the CMA to disregard it."

280. We therefore reject the CAT's conclusion. We have set out observations on the CAT's reasoning above and we limit ourselves now to pulling threads together.

281. First, the lack of explanation and the adoption of conflicting stances which we have summarised at paragraphs [253] – [255] above, substantially weaken the criticisms made by the CAT of the CMA.

282. Secondly, the fact that the CAT itself was forced to accept that it did not know whether the evidence had any probative worth at all, and indeed accepted that it might be incriminating not exculpatory, is telling. If the CAT was unable, after a full trial of the evidence, to say that tablet pricing was informative in the sense of being exculpatory, then we fail to see how it can conclude that the CMA was in material error when it concluded that the evidence was not exculpatory.

283. Thirdly, we are also struck by the fact that in the Decision, addressing the concerns expressed by the CAT in the First Judgment, the CMA engaged in a very detailed analysis of tablets spanning in excess of 300 paragraphs. The CMA grappled with the very issue the CAT and this Court had indicated needed to be examined, namely whether tablet prices were affected by market power. The CMA held that they were. It was of course open to the CAT to examine that evidence and come to a different conclusion, but it did not do so. It did not engage with a very substantial body of evidence and analysis in the Decision.

284. Moreover, the analysis of the CMA in this case was similar to the analysis of the CAT, endorsed by this Court, in *Cinven* (*ibid*) in relation to the pricing of the generic drug liothyronine. In that case the CAT rejected appeals from the generic pharmaceutical suppliers upon the basis that the price prevailing in the market once monopoly had been lost (post new entry) was a price reflecting decisions of genuinely workable competition and could not be unfair, even though it was many multiples higher that Cost Plus or the prices charged to the NHS prior to the introduction of the dominant undertaking's price optimisation strategy. The CAT held that the price remained tainted by the prior abuse of dominance and was not evidence of what a fair price was. We do not see anything unusual or unorthodox in the approach taken by the CMA to the evidence in the present case.

285. Finally, the appellants have adopted an "*all or nothing*" approach to this evidence. They did not seek, by some form of regression analysis, to track back from the £30 DT price to arrive at a price which stripped out any element of market power. The CMA however adduced expert evidence before the CAT that in a generics market of this sort prices could be expected to move towards Cost Plus. The CAT construed this as proof that the CMA advanced a *per se* approach to pricing above Cost Plus. This incorrectly describes the evidence, which was not a statement of principle, but a conclusion about expected

price movements in a generics market for drugs with the characteristics of phenytoin capsules.

- *The DHSC push back point*

286. We need to add a comment about DHSC "*push back*". In law if a purchaser is prepared to pay a price well above Cost Plus this might indicate that it sees value or benefit in the product or service for which a premium is warranted: see *Phenytoin I* paragraph [172]. Where the buyer is large, sophisticated and, it might be said, well able to look after its own interests, this might form part of the evidence supporting a conclusion that the price paid can be treated as reflective of workably competitive market conditions. Pfizer therefore argued that the fact that the state was prepared to pay the £30 DT price was a compelling indication that the price fairly reflected value. As was made clear in *Phenytoin I*, and has more recently been addressed in *Le Patourel* (*ibid*) at paragraphs [71] – [76], the fact that a buyer pays for something is not an indication that the price paid is fair; it could simply reflect the exercise of compulsive market power by the seller. This was the concern of the CMA. Is it any different if the buyer is the state? In *Cinven* the CAT held that it was not, a conclusion upheld on appeal (*ibid* paragraphs [186] – [195]).

287. In Judgment paragraphs [254(2)(iii) – (iv)] the CAT held that it was irrelevant to consider what occurred between Teva and DHSC or how the DT came to be agreed. It held that the CMA erred in taking this into account. We accept that the position of the DHSC, which is not a competition authority, might tell one little about unfairness: See the analysis in *Cinven* paragraphs [186] – [195]. Be that as it may the CAT's description of the Decision is inaccurate and inconsistent with the CAT's own finding in relation to the retaken decision. First, the CAT nowhere grapples with the evidence set out in the Decision which led to the conclusion that neither the DHSC nor the CCGs ever accepted that the £30 DT price represented the value of capsules: see Decision paragraphs [6.215] – [6.266]. Secondly, in relation to phenytoin capsules (not tablets) in paragraph [254(3)]) the CAT said "*we entirely accept*" that "*push-back*" against Pfizer and Flynn's prices was "*likely to be a factor relevant to the unfair limb"* and, further, that it "*should be taken into account as a factor indicating that the product unit price was unfairly too high*…". The "*push-back*" was that from DHSC. There is no challenge to the proposition that in relation to capsules the DHSC did object, vigorously, and of course made a complaint to the OFT/CMA. Ultimately, we consider this to be an issue of little relevance on the facts of the case.

Wrongful rejection by the CMA of AEDs as relevant comparables

- *The CAT criticisms*

288. We turn next to other non-phenytoin AEDs as comparators. The CAT (Judgment paragraph [272]) correctly described the position of the CMA (Decision paragraph [6.482]) as follows: "*The CMA's view is that the differences between Capsules and the Comparator AEDs described above means that, from a product perspective, these AEDs are not sufficiently similar to Capsules to allow for a meaningful comparison*."

289. What then did the CAT find?

290. In paragraph [270], the CAT accepted that other AEDs were "*nothing like as close comparators*" as tablets. It accepted that phenytoin sodium was used in very specific circumstances as a third line treatment. It acknowledged that (unlike the CMA) it had not considered how comparator AEDs served medical purposes. It accepted that it had no understanding of either the production costs of these AEDs or what a RRoR would be, and therefore it had no understanding of what the extent of the surplus ASP over Cost Plus would be. It said that the value of such comparators was "*impressionistic*". And it held that a competition authority would be well within its rights to treat this material with caution and accord it limited weight.

291. Yet, in paragraph [273], the CAT says that it disagreed with the conclusion of the CMA that the differences between capsules and comparator products rendered the comparators not meaningful and held that it was irrational for the CMA to ignore this evidence:

> "273. We disagree with this conclusion. The question is what the CMA understands by a "meaningful comparison". We consider the comparison to be material in providing insight into what might be a Reasonable Rate of Return for pharmaceutical products and/or in showing what Producer Surplus is prevalent in these markets. Unless Real World Competition is nowhere present this is obviously material to both of the United Brands limbs. The exclusion of this evidence is irrational and not defensible. If the question was "precisely what level should the Reasonable Rate of Return be set at?" or "what level of Producer Surplus is legitimate?", then the CMA might have a point. But that is not the value or importance of this data. The importance of the data is that it suggests that the entire market for AEDs and for the distribution of pharmaceutical products does not operate as the CMA thinks, namely on a Product Unit Cost Plus WACC or ROS return. That fact is fundamental to this inquiry, and the evidence cannot be left out of account."

- *Analysis*

292. We have set out above at paragraphs [97] – [104] a summary of the reasoning of the CMA. The analysis is detailed and granular. In our judgment the reasoning is convincing. It is not submitted by the appellants that any of the evidential matters the CMA examined were irrelevant or that it ignored other relevant matters. Nor is it said that the medical or scientific inferences drawn from the evidence, which highlighted the substantial difference between third line phenytoin sodium and first-line AEDs, is incorrect. The CAT does not gainsay the CMA's findings of fact. There are no challenges to the inferences the CMA drew about relative medical pros and cons and pricing of third line, as against first line, AEDs. In Decision paragraph [6.99] the CMA found that prices of generic AEDs recommended by NICE as first line treatments for focal seizures, prescribed to new patients due to their clinical benefits, were supplied at prices "… *far below the prices charged by Pfizer and Flynn during the Relevant Period*". From this the CMA moved on and considered whether there were other reasons which explained the high prices charged by Pfizer and Flynn. It held (Decision paragraph [6.95]) that as a result of clinical limitations (in particular the NTI and non-linear pharmacokinetics):

> "Capsules are subject to regulatory guidance recommending Continuity of Supply for patients stabilised on the drug. This is the ultimate reason that Pfizer and Flynn were able to impose significant price increases on customers, rather than anything related to the therapeutic benefits associated with the drug."

293. In short, the CMA's approach was: (i) to compare and contrast the characteristics of the index and comparator drugs; (ii) to determine how comparable they were in medical terms; (iii) to consider whether, because of the identified differences, pricing of the comparator drug provided information relevant to pricing of the index drug; and (iv) if it did not, to identify whether there were other reasons which accounted for the pricing of the index drug (i.e. Pfizer's phenytoin capsules).

- *Analysis*

294. We reject the CAT's conclusions. There seem to be four components to its reasoning. First, that in its view the CMA never explained why it came to the conclusion that the comparison with AEDs was not meaningful. Secondly, that AED prices were informative because they were subject to a DT regime. Thirdly, that capsule prices were not out of line with AED prices which had legitimately high RRoR and/or involved legitimate levels of producer surplus and this suggested that capsule prices might be justified. Fourthly, that the CMA rejected this evidence because AED markets did not operate as the CMA thought they should, namely upon the basis of Cost Plus. We do not accept any of these points.

295. First, the CAT is wrong to say that the CMA did not explain its reasons. It did so by reference to comprehensive and detailed evidence explaining why AEDs were not meaningful as comparators. The evidence set out in the Decision establishes substantial therapeutic, clinical, safety, medical, and price related differences between capsules and other AEDs. The CAT does not question the accuracy of these conclusions, and they are not in issue in this case. The CAT accepted that it did not have evidence as to the production costs or unit prices of these AEDs or as to a reasonable RRoR. The CAT did not analyse, or indeed have any evidence, about how the DT for other AEDs was compiled. The CAT held that caution was required. The comparators were of limited value. At best their value was "*impressionistic*". The CAT did not consider that it needed to take account of this evidence <u>at all</u> when it retook the decision.

296. Secondly, insofar as the CAT is saying that the information is relevant <u>because</u> it is in a DT then, absent a challenge by the CAT to the CMA's factual findings, we fail to understand how the fact of the DT can be said to be relevant. When it retook the decision, the CAT accepted that the DT was not a comparator at all in relation to tablets and it accepted that AEDs were less reliable comparators than tablets.

297. Thirdly, in a similar vein, if the CAT is saying that *because* it could infer that AED suppliers were earning a high RoR and/or achieving a substantial surplus of ASP over Cost Plus this, *without more*, meant that those margins were appropriate and legitimate and thereby relevant to phenytoin capsule pricing, this is a *non-sequitur*. It begs the question that the analysis of comparables in the Decision sets out to answer. <u>Unless</u> it is established that AEDs are proper comparators, which the CAT accepted it was unable to establish, pricing of AEDs is not materially informative.

298. Finally, insofar as the CAT is saying that the CMA rejected AEDs because of some unarticulated, private, conviction that any price above Cost Plus was *per se* unlawful then we have already rejected that conclusion on the part of the CAT.

K. Issue VI: Wrongful reliance upon EU comparators

The CAT criticism

299. In Judgment paragraph [215] the CAT states that the CMA erred in taking into account that the nature of the price increases was selective by reference to EU comparables (citing Decision paragraphs [6.6] – [6.26]). In Judgment paragraphs [228(2)(i) – (iii)] the CAT rejected this evidence:

(i) This was not a point that could apply to Flynn "*at all*". The CMA erred in failing to consider unfairness separately as between Pfizer and Flynn.

(ii) The CMA considered wrongly that because prices in highly regulated EU pharmaceutical markets were much lower that Pfizer was obliged to price similarly in all such markets. The CMA had adduced no material to support this conclusion.

(iii) There was not even a *prima facie* infringement of competition law for a dominant enterprise to charge differentially from one jurisdiction to another.

(iv) The CAT construed the Decision as saying that capsule production unit costs for Pfizer were the same across Europe, but prices were different and higher in the UK so that it followed the UK prices were not following cost. The CAT said that this conclusion appeared "*sound*" but was "*again a CMA Cost Plus point*". The CAT was suggesting that the CMA analysis was false because it assumed that any price above Cost Plus was *per se* illegal.

Analysis

300. These criticisms do not represent an accurate account of the reasoning in the Decision. The CMA did not rely upon this evidence to bolster some false notion that any price above Cost Plus was unlawful. The analysis in the Decision is summarised at paragraphs [105] – [109] above. The CMA considered this evidence for the purpose of refuting the argument of Pfizer that it needed to increase prices to ensure commercial viability. The CMA cited the fact that costs were common across the EU and the UK. It cited evidence, for example in relation to Sweden, where Pfizer had successfully applied to the regulator for an increase in prices to ensure commercial viability and had been allowed to raise prices to £7.40 (see paragraph [109] above), which is a long way below the prices Pfizer and Flynn charged in this jurisdiction. It carried out a detailed analysis of the extent to which Pfizer might need to raise prices to cover costs and ensure viability, and it then compared that price with the prices actually charged. There has been no appeal against any of these findings.

301. The CMA did point out that the approach of Pfizer was selective, which it was. If the prices of a dominant undertaking are materially out of kilter in one market compared to another that might indicate that the higher prices require justification. The mere fact of selectivity might not be dispositive but is a red flag to be placed into the mix. At base

however, the issue concerned the commercial viability of phenytoin capsules as to which the evidence in the Decision is cogent and relevant and indicated that the price increases went far beyond anything needed to support viability. The suggestion by the CAT that the CMA's analysis assumed some form of unlawful price discrimination is not understood. The CMA made no such finding nor does its reasoning rest upon such a finding.

L. Issue VII: The CMA wrongly took into account the evolution of prices over time

The CAT criticism

302. In Judgment paragraph [215(1)] the CAT cited the CMA as relying upon price increases over time: "*The price increases imposed over time by both Flynn and Pfizer were significant, resulting in very high prices relative to costs, which 'went well beyond the level that might have been required to ensure the drug was commercially viable or sustainable*'".

303. In Judgment paragraph [228] the CAT says that this was wrong because it:

> "… is explicitly a CMA Cost Plus factor, with its emphasis on very high prices relative to costs. In other words, the factor identifies that Producer Surplus exists and presumes it to be unjustifiable and so unfair."

In paragraph [312(3)] the CAT held that the evidence was irrelevant because to take it into account was to "…*prejudge matters without considering the facts objectively* ".

> "We are conscious that the CMA placed considerable weight on the fact that Pfizer's prices for the Capsules were significantly lower prior to the arrangements between Pfizer and Flynn in 2012, and that those prices significantly increased after those arrangements came into effect. In Phenytoin 1 (CoA), the Court of Appeal commented on these increases, and they are clearly of interest as relevant background. But we do not consider that the mere fact that prices have increased – even dramatically – can assist very much in determining whether the increased prices are "demonstrably immoderate" or otherwise meeting the Excessive Limb. The fact is that Pfizer contended that its prices before its arrangements with Flynn were put in place were loss-making. Given the judgmental difficulties in ascertaining Product Unit Cost and Product Unit Price, competition authorities need to be confident that the evidence justifies the rejection of such a contention, and in this case, we are not. Similarly, whilst an ability to increase prices dramatically is certainly evidence of dominance, to regard it as evidence of abuse is to prejudge matters without considering the facts objectively."

Analysis

304. In our judgment the CAT erred. The criticism is linked to the Pfizer argument that it needed to raise prices to ensure commercial viability and to this extent there is some

overlap with the issue relating to EU phenytoin capsule pricing as a relevant comparable – see above. At all events we do not accept the CAT's analysis.

305. First, the position of the CAT is inconsistent because both in the First CAT Judgment, and the Judgment, the CAT accepts that this evidence is relevant but then goes on to criticise the CMA for taking it into account. In the First CAT Judgment, the CAT held (paragraphs [429], [432], [435] and [439]) that the evolution of prices over time, on a before and after basis, could be relevant (though not decisive) subject to recognition of potential limitations:

> "439. We agree that a large price rise, sustained over a considerable period, may be indicative of an abuse of a dominant position that needs to be examined, and we understand the weight that the CMA placed on this matter. However, whilst this may be a valid reason for a competition authority to investigate a case, it should not be confused with the test for unfair pricing itself."

In the Judgment paragraph [281(2)] the CAT held that the "… *fact that price increases – of a dramatic nature – occurred practically overnight is a factor impossible to disregard, and one that should not be disregarded*". The CAT cited the Court of Appeal in *Phenytoin I* which held that there was a "*stark reality*" which it was "*important keep in mind*" that, literally overnight, Pfizer and Flynn increased their prices for phenytoin sodium capsules by factors of between 7 and 27, when they were in a dominant position in each of their markets (see paragraph [12] above).

306. Yet, in relation to the CMA's handling of the evidence the CAT says only that it is "*clearly of interest as relevant background. But we do not consider that the mere fact that prices have increased – even dramatically – can assist very much…*".

307. Secondly, on a fair reading of the Decision, the CMA did not rely, as decisive proof of abuse, upon the "*mere fact*" of the sheer scale of the price increase on a before and after basis. Its conclusion was that the increase was unrelated to any commercial justification based upon the viability or sustainability of supply since the prices charged: *"…went well beyond the level that might have been required to ensure the drug was commercially viable or sustainable*", a conclusion which seems unequivocally correct. As to the argument made by Pfizer that prior to the price increases its sales were loss making this is not proven on the facts and the CAT should not have treated it as correct absent proper inquiry. As a proposition it was in fact fully addressed and rejected in the Decision. But, even assuming it were true, it might at best have enabled prices to be increased by some modest increment to render them no longer loss making but that is far removed from providing an explanation for the scale of the increases which actually took place and which the CAT itself said were "*grotesque"* and *"extreme"*.

308. Finally, we fail to understand the reference to this being no more than a Cost Plus point. It is not about Cost Plus. It is about the justification for a sudden, dramatic and unexplained hike in the difference between Cost Plus and ASP. If the CAT was using the expression "*a Cost Plus point*" as shorthand for its conclusion that the CMA treated any price above Cost Plus as *per se* illegal, then we have already rejected that reasoning elsewhere.

M. Issue VIII: The CMA wrongly took into account that Pfizer and Flynn had exploited their market power

The CAT criticism

309. The CAT held that the CMA wrongly took into account an immaterial consideration when it treated as relevant that Pfizer and Flynn had knowingly exploited their market power: Judgment paragraphs [215(3)] and [228(3)].

Analysis

310. The CMA's reasoning on market power, insofar as it founds the basis of market definition and dominance, is set out in the First CMA Decision. It is predicated upon the basis that the MHRA guidance on continuity of supply meant that switching between possible substitutes was clinically unsafe and served to confer market power upon each supplier. None of this is in dispute.

311. The reasoning in the Decision in paragraphs [6.6.3] and [6.38] – [6.72] is not mentioned or referred to in the Judgment. The CMA considered: the absence of competitive constraints on pricing; the existence of high barriers to entry; the awareness on the part of Pfizer and Flynn of their market power and their ability to exercise it without threats to high pricing from competition. Those conclusions are borne out by the analysis of the history of the coming into being of the Pfizer/Flynn agreement in the light of the internal contemporaneous documents as summarised at paragraphs [51] – [65] above.

312. As we understand the argument now, it is not as to the fact that Pfizer and Flynn held market power enabling them to raise prices. It is more limited and is whether Pfizer and Flynn *intended t*o exploit that market power and as to the relevance in law of a finding that they did have such an intention. We disagree with the conclusion of the CAT that this evidence is irrelevant and that the CMA erred in taking it into account.

313. First, we observe that the CAT agreed with the CMA on this point in Judgment paragraphs [333(5) – (7)], in the section on the intentional nature of the infringement. There the CAT explained that the prices were abusive because Pfizer and Flynn "*took advantage*" of their market power which arose because of continuity of supply. This "*… was not something they delivered to the market, but rather something that they took advantage of*". The CAT labelled the conduct of Pfizer and Flynn as "*gouging the market in a manner that can only be characterised as unjustifiable or opportunistic or – in a word – unfair.*" This is a clear statement to intention as a factor relevant to abuse. The CAT's position is hence inconsistent.

314. Secondly, it is well established in case law that whilst a dominant undertaking's subjective intention does not make otherwise acceptable conduct abusive, evidence of intention and object can still be admissible as part of the matrix of inculpatory factual evidence which goes to abuse. The point was considered in *Cinven* (*ibid)* at paragraphs [123] – [124] where the case law is referred to at length. Before this Court, the CMA referred also to Case C-549/10P *Tomra et ors v Commission* (19th April 2012) which makes the same point. The CJEU observed:

> "19. It must be observed in that regard that where the Commission undertakes an assessment of the conduct of an

> undertaking in a dominant position, that assessment being an essential prerequisite of a finding that there is an abuse of such a position, the Commission is necessarily required to assess the business strategy pursued by that undertaking. For that purpose, it is clearly legitimate for the Commission to refer to subjective factors, namely the motives underlying the business strategy in question.
>
> 20. Accordingly, the existence of any anti-competitive intent constitutes only one of a number of facts which may be taken into account in order to determine that a dominant position has been abused.
>
> 21. However, the Commission is under no obligation to establish the existence of such intent on the part of the dominant undertaking in order to render Article 82 EC applicable."

315. We conclude that the CAT erred in holding that the CMA wrongly took into account the undertakings' business strategy or purpose as part of its analysis of abuse.

N. The appeal of Pfizer and Flynn in relation to the re-taken decision of the CAT / Procedural unfairness

Submissions of the parties

316. We turn, finally, to the appeals of Pfizer and Flynn based upon procedural fairness. We have already indicated that we accept the submissions of Pfizer and Flynn on this and that there was no material opposition from the CMA to a conclusion that the CAT's remade decision was adopted through an unfair process. Nonetheless, as was set out in written submissions, the issue is important and raises significant policy considerations. We therefore address the submissions of the parties.

317. Pfizer raised points of both a procedural and substantive nature. It argued that the retaken decision should be set aside on the following grounds which it summarised in its written submission as follows:

> "• First, the CAT wrongly arrogated to itself a jurisdiction which it did not possess under Schedule 8, paragraph 3 CA 1998. The CAT re-made the infringement decision on a factual basis that was fundamentally different from the basis advanced in CMA Decision II and was not (therefore) the subject of Pfizer's Notice of Appeal. The CAT disregarded its own judgment in Imperial Tobacco Group v OFT which outlined the limits of the CAT's power to re-make an infringement decision.
>
> • Second, even if it did have jurisdiction, the CAT acted procedurally unfairly because the re-made infringement decision is based on a novel theory of economic value and certain factual findings to which Pfizer was not given a fair chance to respond. The CAT's process is contrary to the principles of fairness

> enunciated in Imperial Tobacco on the exercise of the statutory power to re-make an infringement decision.
>
> • Third, even leaving aside the vires and procedural unfairness issues, the CAT's reasoning in the re-made infringement decision is in any case flawed and the decision is wrong as a matter of law. First, there is no logical basis why, even on the CAT's own fictional patient test, the fictional patient would not pay the Pfizer/Flynn price. Second, the fictional patient test is the wrong test. It leads to an under estimation of the distinctive value of phenytoin. Further, the Tribunal's focus on distinctive value alone, as defined in its Case 2 framework, is unduly narrow and inconsistent with the existing authorities in relation to excessive pricing. Third, the decision ignores probative evidence of comparator prices which supports the fairness of Pfizer's price."

318. Flynn also argued that the CAT acted in a way which was procedurally unfair and/or outside the scope of its statutory powers by making findings of its own based on analysis and mathematics that had not been canvassed in the Decision under appeal and therefore had not been addressed by Flynn's evidence.

319. In written submissions the CMA did not say that the retaken decision was procedurally unfair. Its main argument was that the CAT should have upheld the Decision and it would not then have needed to retake it. In oral submissions Mr Holmes KC for the CMA acknowledged the force of the appellants' argument that if (contrary to its arguments on the main appeal) the CAT had been right to set aside the Decision, the procedure adopted by the CAT to retake the decision was procedurally unfair.

The jurisdiction of the CAT

320. As to jurisdiction, Pfizer argues that the CAT wrongly arrogated to itself a jurisdiction which it did not possess under Schedule 8(3) CA 1998. Its argument can be summarised as follows. Section 46 CA 1998 provides that an undertaking may appeal "*against, or with respect to the decision*", which is defined as a decision as to whether the prohibitions in sections 2 and 18 CA 1998 have been infringed. Schedule 8 CA 1998 provides further details as to how an appeal must be made. Paragraph 2(1) provides that an appeal must be made by a notice of appeal which must set out the grounds of appeal. The grounds must be in sufficient detail to indicate to what extent the decision against which the appeal is brought was based on an error of fact or law. Paragraph 3(1) provides that the CAT "*must determine the appeal on the merits by reference to the grounds of appeal set out in the notice of appeal*." Paragraph 3(2) provides that the CAT may confirm or set aside the decision which is the subject of the appeal, or any part of it and may (a) remit the matter to the CMA and (e) "*make any decision which the CMA could itself have made.*"

321. Pfizer relies upon *Imperial Tobacco* [2011] CAT 41. The OFT adopted a decision finding that Imperial Tobacco ("*IT*") had concluded unlawful agreements with retailers to ensure parity of pricing with competing cigarettes brands. An appeal followed. In judgment (paragraph [28]) the CAT summarised the restraints alleged during the appeal to be the mechanism of the unlawful agreements: (1) if the retail price of a Gallaher

brand increased the retailer would increase the price of the Imperial brand; (2) if the retail price of an Imperial brand increased the retailer would increase the price of the Gallaher brand; (3) if the retail price of an Imperial brand decreased the retailer would decrease the price of the Gallaher brand; and (4) if the retail price of a Gallaher brand decreased the retailer would decrease the price of the Imperial brand, i.e., a lockstep price movement allegation. In the course of the appeal, which included oral evidence, IT objected that the OFT was not putting its case as set out in the Decision to witnesses, who were parties to agreements with IT and who denied the agreements operated in the manner described in the decision. The OFT acknowledged that the mechanism described in its decision had been "*cast too narrowly*" and that the case it advanced to defend the decision was, in fact, broader. The CAT ordered the OFT to articulate its new, refined, case in writing and held a hearing to determine whether the OFT should be permitted to advance the new case as part of the appeal. The OFT submitted that the CAT could exercise its powers under Schedule 8(3)(2)(d), (e) to find the existence of an infringement based on the evidence as it had emerged during the appeal by reference to the OFT's new case. The CAT disagreed. As a question of statutory construction, it was obliged to determine the appeal by reference to the grounds of appeal and the infringement set out in the decision, and not in some new and unheralded case articulated for the first time during the appeal. The CAT set aside the decision. Pfizer relies upon paragraph [14] of the judgment:

> "The OFT's submission in favour of the Tribunal's continued jurisdiction depend, in our judgment, on a construction of our powers which is not supported either by the wording of the statutory provisions or by earlier jurisprudence. According to paragraph 3 of Schedule 8 to the 1998 Act our primary duty is to determine the appeals on the merits by reference to the grounds of appeal set out in the notice of appeal. Rule 8 of the Tribunal Rules specifies the content of the notice of appeal, requiring it to spell out the ways in which it is alleged that the decision challenged is wrong. The evidence that must be served with the appeal is directed at supporting the appellant's attack on the decision. The defence served by the competition authority responds to those allegations and that evidence. The parties' decisions about what factual and expert evidence is needed and the Tribunal's case management decisions in preparation for the final hearing are informed by and directed towards the case pleaded in the notice of appeal."

322. In this light Pfizer argued that the CAT had no jurisdiction to make a new finding of infringement outside the scope of the appeal before it. The statutory limitation was "*fundamental*". It recognised that evidence that an appellant was required to file at the outset of its appeal was directed at the methodology and findings in the Decision. Pfizer argued therefore:

> "Appellants cannot be expected to appeal against an evolving infringement, still less one that emerges for the first time in the CAT's judgment following trial (as occurred here). It also reflects the limitation that the CAT should not transform itself from an appellate forum to a forum of first instance as that would

> alter the structure of competition law enforcement in the UK whereby the CMA conducts a lengthy investigation leading to an administrative decision which becomes the subject of a judicial appeal. The model is not a prosecutorial one where the CAT starts afresh and makes, or re-makes, the decision."

323. In our judgment, formally, the CAT had jurisdiction. This flows from the express language of Schedule 8 CA 1998. The judgment in *Imperial Tobacco* is distinguishable. It was not a case where, at the point in time when the CAT came to consider the exercise of jurisdiction under Schedule 8(3), it had already set aside the impugned decision. Schedule 8(3), in its up to date form, provides:

> "Decision of the tribunal
>
> 3(A1) This paragraph applies to any appeal under section 46 or 47 other than—
>
> (a) an appeal under section 46 against, or with respect to, a decision of the kind specified in subsection (3)(g), (h), (ha) or (hb) of that section, and
>
> (b) an appeal under section 47(1)(b), (c), (d) or (e).
>
> (1) The Tribunal must determine the appeal on the merits by reference to the grounds of appeal set out in the notice of appeal.
>
> (2) The Tribunal may confirm or set aside the decision which is the subject of the appeal, or any part of it, and may—
>
> (a) remit the matter to the CMA,
>
> (b) impose or revoke, or vary the amount of, a penalty,
>
> (c) grant or cancel an individual exemption or vary any conditions or obligations imposed in relation to the exemption by the CMA,
>
> (d) give such directions, or take such other steps, as the CMA could itself have given or taken, or
>
> (e) make any other decision which the CMA could itself have made.
>
> (3) Any decision of the Tribunal on an appeal has the same effect, and may be enforced in the same manner, as a decision of the CMA.
>
> (4) If the Tribunal confirms the decision which is the subject of the appeal it may nevertheless set aside any finding of fact on which the decision was based."

324. The Schedule 8(3)(2) powers can be exercised where the CAT sets aside a decision. Where a decision has been set aside, under sub-paragraph (e), the CAT can take any "*other decision*" that the CMA could have taken. It follows from the statutory language that the CAT has the power to embark upon entirely new infringement proceedings in such circumstances. In this case because the CMA decision had been set aside when the CAT came to exercise its powers, it was, necessarily, considering the initiation of new infringement proceedings against Pfizer and Flynn. It was not concerned with the scenario arising in *Imperial Tobacco*, where the exercise of power was in relation to a regulatory decision which remained live and which the regulator wished to defend as part of the extant appeal but with a new theory of the case not articulated in the disputed measure.

The exercise of the power to take a new decision; the procedural unfairness of the re-taken decision.

325. Schedule 8(3)(2)(e) confers a broad power upon the CAT once an appeal is finished and the impugned decision set aside. At that point the CAT must consider the exercise of its discretion over future courses of action. Such a discretion must be exercised in accordance with principles of procedural fairness. The way in which that principle operates will be fact and the context dependent, taking into account the nature and extent of the errors the CAT has found, as well as the extent of requisite, consequential, remedial action. In every case the CAT must ask itself what fairness requires.

326. At one extreme, if the CAT finds a narrow, self-contained error in the decision (perhaps an error in the maths), which it can readily cure upon the basis of existing submissions of law and evidence, then there might be no procedural unfairness in the CAT moving seamlessly from its decision to set aside the CMA decision, or a part of it, to the exercise of a power under Schedule 8(3). However, for the reasons that follow, we consider that the present case was at the other extreme, such that the CAT should have handed down a judgment limited to the appeals of Pfizer and Flynn in terms sufficient to enable the parties to know the reasons why the Decision was being set aside so as to enable them to consider and make submissions as to the consequences.

327. First, the decision to set aside was based upon both the alleged unfairness of the procedure adopted by the CMA, including its conclusion that the CMA was guilty of bias, and errors which the CAT classified as numerous, fundamental and material. Such defects were incapable of cure by minor remedial action. It followed from the CAT's reasoning that any new decision would have to be taken by reference to a new, root and branch, procedure addressing new evidence and points of law.

328. Secondly, and given the history of the case, before exercising Schedule 8(3) powers, fairness dictated that Pfizer and Flynn should have been given the opportunity to submit that the Decision should remain quashed and no further action be taken. By parity of reasoning the CMA should have been informed that it had failed in its defence of the Decision and given the chance to submit that either the case be remitted to it or that, if the CAT was minded to retake the decision it should do so upon a new legal and evidential basis advanced by the CMA (and responded to by Pfizer and Flynn) which took account of the CAT's criticisms.

329. Thirdly, fairness also required that if and to the extent that the CAT had formed a provisional view that its proposed remade decision would be adverse to Pfizer and

Flynn, that should have been communicated to the parties. When the CMA proposes to take an adverse decision, it is required in law to issue a Statement of Objections giving the parties warning of its views and intentions which are necessarily provisional. It does this to ensure a fair hearing of undertakings whose conduct it proposes to proscribe and penalise and who are entitled to know the case they must meet. This point is reinforced by the fact that a finding of breach of competition law including the imposition of substantial penalties is treated in law as penal and quasi-criminal: see *Phenytoin I* (*ibid*) paragraph [115] and case law cited thereat.

330. Fourthly, it is evident from the Judgment that the CAT intended in the retaken decision, to apply new principles of law which all parties, including the CMA, were entitled to address. Given the complexity, novelty and importance to the public interest of principles governing the pricing of generic drugs, affording to the parties fair warning of the provisional views of the CAT in these respects was essential. This is illustrated by the adoption by the CAT of the "*ultimate consumer test*", as the benchmark for assessing value and hence fairness. The details are summarised at paragraphs [115] – [118] above. Both Pfizer and the CMA argued that the CAT erred in adopting this test. Many aspects of the CAT's approach were controversial:

(i) We see that when assessing value, the decision maker must be able to assess value by reference to the person for whom a drug is intended, who is the patient /consumer. But, in the world of medicine purchasing, the state exercises purchase control and acts as a proxy for the medical best interests of the patient. It takes into account a range of considerations some of which might be irrelevant to an particular patient. The CAT created the hypothetical ultimate consumer as a test in law even though it accepted (Judgment paragraph [294]) that the scenario bore no relation to reality. There it acknowledges that in the case of medicines the person benefitting from the drug is the patient who does not pay for the drug but pays a means-tested prescription charge bearing no relationship to the cost or price of the medicine itself. The party who pays, via the pharmacy and the Drug Tariff, is the state (usually in the form of the CCG). The CAT accepted that: "*Neither the patient nor the CCG has any particular agency in what product is prescribed: that is a matter for the clinical judgment of the doctor treating the patient*." The fictitious consumer's personal knowledge of medicine, or their condition, or of their willingness to comply with a medicine regime, or as to the depth of their purse, are unrelated to the practicalities of drug purchasing by the state.

(ii) The choice of the ultimate consumer's characteristics are unclear. Why should the consumer have knowledge "*…commensurate with that of a doctor, by which we mean a GP and not a specialist…"*? Why should the consumer have an income that is "*significantly above the average in the UK*", and what does this mean in monetary terms or purchasing power? (see paragraph [116)] above). Is the CAT suggesting that there is no public interest problem if a patient of average or less than average means is declined access to the drug? Why should the analysis assume that the prescription charge regime be "*abandoned*"?

(iii) We have difficulty in understanding *how*, if fairness is to be tested from the perspective of the fictitious individual consumer, wider public interest considerations, which might properly influence the state in deciding whether to fund a drug and if so at what price, can be fed into the analysis. An example is

portfolio pricing whereby the state agrees to pay an increment for drug *x* in order to assist in the cross subsidisation of risky research work in relation to other drugs: See the discussion in *Cinven* (*ibid*) paragraphs [176] – [184]. But the characteristics of the fictitious consumer with only average means and a focus upon personal health and wellbeing would preclude broader public interests' approach to pricing. Inconsistently, the CAT appears to have held that portfolio pricing is a valid consideration that, in every case, feeds into value. The CAT has not explained how this is consistent with the benchmark of the fictitious consumer nor how or why the need to cross-subsidise risky research elsewhere played any part in the reasons behind the increases in prices on the actual facts of this case which, as clearly articulated in the disclosed material and recorded in the Decision, had nothing to do with the need to research and develop products elsewhere. If the CAT was saying that in every case dominant undertakings could use high pricing in a dominant market to cross-subside product development in other markets, howsoever disconnected from real life facts, then that it is a big statement of principle which is not self-evidently correct, which is inconsistent with existing case law, and which cried out for mature consideration following full argument.

(iv) There is also the statement that because the capsules have medical benefits this, seemingly automatically, means that consumers would pay a premium (above Cost Plus) for those drugs. This statement does not explain why, if it be true, the RRoR does not already take sufficient account of the value of the drug (i.e. within the concept of a reasonable return which then goes to the make-up of Cost Plus) so that to attribute a further value beyond Cost Plus would not be double counting. If the RRoR is considered to be an inadequate mechanism for capturing the value of this benefit, then there was at least some obligation on the CAT to explain why and how that incremental value might be evaluated and measured. As drafted the Judgment suggests that in any pharmaceutical case, even in relation to third-line drugs, long off patent and subject to no investment or material improvement over the course of many years, a price above Cost Plus can still be charged. Once again this is a bold proposition which is inconsistent with the CAT's own position in *Cinven.* If it were to be adopted as the new position of the CAT it demanded full exposition and submissions from the parties before proper and reasoned adjudication by the CAT in a judgment.

(v) Finally, there is the analysis of continuity of supply. We have difficulty in understanding the CAT's reasoning which, on the one hand, says that continuity of supply is no more than a structural factor flowing out of government policy which enables Pfizer and Flynn to exploit, in an abusive manner, their market power, and which has no value for consumers (see Judgment paragraphs [333(7)(iii)] and [333(8)]) but, on the other hand, is an important benefit to consumers (see Judgment paragraph [320(3)]). It cannot be both a benefit to consumers justifying a price increase over Cost Plus but, simultaneously, a structural market weakness enabling "*egregious"* and "*extreme*" pricing abuse having no value to consumers.

331. Fifthly, it is also evident from the Judgment, that at the point when the CAT intended to take the new decision it did not have before it adequate evidence or submissions from the parties on issues that, it expressly acknowledged, were important to its proposed

analysis. To overcome these gaps, the CAT adopted a slanted evaluative framework which gave the benefit of the doubt to the undertakings, an approach it justified upon the basis that if it proceeded upon a basis that was favourable to Pfizer and/or Flynn, no harm would be done. But both Pfizer and Flynn dispute this and argue that instead of making assumptions about what was favourable to them, the CAT should have given them a chance to address the issues in question with evidence and submissions. There is force in this. In any event the duty of the CAT is to endeavour to come to the right result which means taking decisions upon a best evidence basis in the public interest seeking to be fair to all parties, including the CMA.

332. Finally, we also know from the Judgment that there are issues which the CAT considered irrelevant to its new decision, such as the position of tablets and AEDs as informative comparables, but in respect of which it had earlier criticised the CMA for not taking into account. Had the parties been given notice of this altered stance then no doubt submissions would have been made which the CAT would then have had to address.

Conclusion

333. In conclusion the retaken decision was vitiated by procedural unfairness and should be set aside.

Conclusion /Disposition

334. For the reasons set out above we: (i) grant permission to appeal to the CMA to challenge the Judgment insofar as it set aside the Decision; (ii) allow the appeal of the CMA; (iii) allow the appeals of Pfizer and Flynn against the retaken decision of the CAT and set aside the retaken decision; and (iv), in consequence of (i) – (iii) set aside the Judgment in its entirety.

335. We indicated during the hearing that, in so far as it became relevant, we would deal with the question whether, if the Judgment was set aside, the Decision should be reinstated, and with any consequential issues as to penalties, separately. In the circumstances we will receive submissions from the parties upon these issues and address them in a separate ruling.

336. As ever we are very grateful to all counsel for their clear and helpful written submissions and oral advocacy.