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Article

Rethinking the legal test for excessive pricing: insights from the landmark UK *CMA v Pfizer/Flynn* Case and its legal implications

Miroslava Marinova[1,*]

[1]Senior Fellow at the George Washington Competition and Innovation Lab, George Washington University, Washington, DC, USA

*Corresponding author. E-mail: M.Marinova@uel.ac.uk.

ABSTRACT

The legal treatment of excessive pricing in the pharmaceutical sector has been a topic of intense debate. This article examines the UK Competition and Market Authority (CMA) approach in the Pfizer/Flynn case and the subsequent appeal. It explores the implications of the Courts' findings on the CMA's latest investigations. The article criticizes the UK Courts for imposing unnecessarily high burden on the CMA, which will likely impose additional burdens on future investigators. The analysis also suggests that the cost-plus test conducted by the CMA is a very advanced methodology that can provide different benchmarks not only for assessing the excessiveness but also for assessing the unfairness under the 2-fold *United Brands* test.

KEYWORDS: Competition law, Abuse of dominance, Excessive pricing, Unfairness
JEL CLASSIFICATIONS: K21

1. INTRODUCTION

The legal treatment of excessive pricing has been a topic of intense debate for decades due to the differing viewpoints on whether authorities should intervene.[1] Recent enforcement actions by National Competition Authorities (NCAs) tackling excessive pricing in the pharmaceutical sector have reignited the debate on the appropriate legal framework.[2] In an

[1] OECD, Excessive Pricing in Pharmaceutical Markets, DAF/COMP/WD (2018); see also Pedro Caro de Sousa, 'Excessive Pricing in Pharmaceutical Markets—as the First Wave Ebbs' (2020) 41E.C.L.R. 434.

[2] Aspen Italian NCA (Case A480, Autorità Garante della Concorrenza e del Mercato) decision of 29 September 2016; CD Pharma Danish NCA (Konkurrence- og Forbrugerstyrelsen) decision of 31 January 2018; the CMA opens six new investigations into anticompetitive drug pricing <https://pharmaceutical-journal.com/article/news/cma-opens-six-new-investigations-into-anticompetitive-drug-pricing> accessed 19 February 2023.

infringement decision, the UK Competition and Market Authority (CMA) found that Pfizer and Flynn Pharma abused their dominant position by imposing excessive prices for phenytoin sodium capsules in the UK.[3] The CMA based its assessment on the leading European Union (EU) excessive pricing case, *United Brands*, and concluded that the prices were excessive and unfair in themselves without considering whether they were also unfair compared to competing products.[4] On appeal, the Competition Appeal Tribunal (CAT) set aside the CMA decision on the ground that the CMA misapplied the legal test for finding that prices were unfair and, as such, did not prove the finding of abuse. The CAT's findings prompted the European Commission to participate in the CMA's appeal before the Court of Appeal by submitting an *Amicus Curiae* brief.[5] The Court of Appeal held that the CMA can establish excessive pricing by showing that the price is excessive and also unfair in itself. It does not have to be considered whether it is also unfair when compared with competing products disagreeing with CAT's position on this point.[6] However, the Court of Appeal also held that the CMA could not ignore the evidence and arguments put forward by the defendants, providing valid comparators as evidence as to why the prices they charge are, in fact, fair and sent the case back to the CMA to consider the comparators raised by the defendants.

The findings of the Court of Appeal renewed the debate on the appropriate legal standard to tackle excessive pricing and raised the question as to whether the CMA has to consider both alternatives under the unfairness test, that is, whether the 'in itself' test and the 'competing products' test are cumulative conditions or true alternatives.

According to some commentators, the Court of Appeal upheld the CAT's judgment, quashing the CMA's decision on the basis that the CMA misapplied the legal test and failed to evaluate all the evidence.[7] Another interpretation of the judgment is that the Court of Appeal took a restrictive interpretation of the conditions under the second limb of the *United Brands* test, considering them as cumulative rather than as alternative conditions as the wording of *United Brands* suggests, which can be regarded as a departure of the EU jurisprudence.[8] Others argue that the Court of Appeal's interpretation of the second limb of the *United Brands* test, that is what 'qualifies a price as being unfair in itself' is unclear and problematic, and remains unanswered.[9]

The aim of this article is to explore the approach adopted by the CMA in the *Pfizer/Flynn* decision, and the following judgments delivered by the CAT and the Court of Appeal (Section 2), in order to understand the impact of these judgments on the CMA's approach to tackle excessive pricing (ie the remittal decision delivered in 2022 and the CMA's recent decisions with respect to liothyronine tablets and hydrocortisone tablets).[10] It aims also to contrast the approach of the UK Courts with similar cases in the pharma industry conducted by other European NCAs and with the recent European Commission decision in Aspen

[3] CMA Decision: Case CE/9742-13, Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK (7 December 2016) (hereinafter: Pfizer/Flynn).

[4] Case 27/76 *United Brands v Commission* [1978] ECR I -207, para 252.

[5] Commission's skeleton argument of 14 June 2019, for hearing on 26–28 November 2019.

[6] Phenytoin CoA [2020] EWCA Civ 339.

[7] James Killick and Assimakis Komninos, 'Excessive Pricing in the Pharmaceutical Market–How the CAT Shot Down the CMA's Pfizer/Flynn Case' (2018) 9 JECL & Practice 530.

[8] See Marco Botta, 'Sanctioning Unfair Pricing Under Art. 102(a) TFEU: Yes, We Can!' (2021) 17 ECJ 156, 169 and Frederick Abbott, 'The UK Competition Appeal Tribunal's Misguided Reprieve for Pfizer's Excessive Pricing Abuse' 49 (7) (2018) IIC 49, 845 criticizing the CAT judgment on the same ground.

[9] Grant Stirling, 'The Elusive Test for Unfair Excessive Pricing under EU Law: Revisiting United Brands in the light of Competition and Markets Authority v Flynn Pharma Ltd' (2020) 16 ECJ 368, 369.

[10] CMA Decision: Case 50395, Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK (29 July 2021) (hereinafter: Liothyronine decision); CMA Decision: Case 50277, Hydrocortisone tablets, Excessive and unfair pricing and Anti-competitive agreements (15 July 2021) (hereinafter: Hydrocortisone decision).

(Section 3).[11] Finally, the article concludes with the argument that the UK Courts imposed an unnecessarily high burden on the CMA, which is likely to impose additional evidentiary burdens on future investigators by the competition authorities.

2. EXCESSIVE PRICING ENFORCEMENT IN THE PHARMACEUTICAL INDUSTRY

The UK pharma cases

The pharmaceutical industry is characterized by its research-intensive nature, heavy regulation, intellectual property protection, and very narrow markets. Due to the high entry barriers caused by these factors, a small number of dominant companies are in a highly concentrated market. Moreover, the high price of drugs in this industry may be necessary to incentivize innovation, research, and development. In addition, the demand side is influenced by multiple stakeholders with different interests, that is, patients, physicians, reimbursement bodies, and insurers. This creates a complex market dynamic where cost–effectiveness and sustainability are crucial for reimbursement bodies and insurers. In contrast, patients and physicians prioritize medical effectiveness. These market dynamics have the potential to lead to exceptionally high prices, especially when demand is extremely inelastic and the bodies liable for the payment of medicines have no control of the demand.[12] Moreover, these specific characteristics of the industry, suggest that competition law interventions may not always be appropriate as the competition authorities should strike a balance between the need to promote dynamic efficiency and innovation and the harm that high prices might cause to consumers and society.[13] Some authors suggest that instead of intervention, a combination of policy tools, such as price regulation, public procurement, and government-funded R&D, may be more appropriate to address excessive pricing in the pharma industry.[14] In some jurisdictions, for example, this issue was solved by the adoption of pharmaceutical cost transparency bills with the aim of compelling pharmaceutical companies to disclose detailed information regarding their expenditures which ultimately would likely unveil the discrepancies underlying the justifications for the drug price increases.[15] Others, while acknowledging the fact that excessive pricing may be self-correcting in some cases, argue that competition intervention might have an important role, especially in markets with significant barriers to entry and where consumers may lack information or the ability to switch to alternative products.[16]

Pharmaceutical markets for off-patent drugs which are subject to less stringent regulation are likely to be subject to inter-brand competition from generics. However, the recent enforcement activities by several competition authorities discussed in the following section of

[11] For a full-blown analysis of the evolution of EU case law on excessive pricing and the impact of the Aspen decision, see Miroslava Marinova, 'Unmasking Excessive Pricing: Evolution of EU Law on Excessive Pricing from United Brands to Aspen' (2023) ECJ <https://www.tandfonline.com/doi/full/10.1080/17441056.2023.2280329> accessed 23 March 2024.

[12] OECD, *Competition Issues in the Distribution of Pharmaceuticals*, DAF/COMP/GF (2014) 5.

[13] Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009–2017) <https://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf> accessed 21 March 2023.

[14] Claudio Calcagno, Antoine Chapsal and Joshua White, 'Economics of Excessive Pricing: An Application to the Pharmaceutical Industry' (2019) 10 JECL & Practice 166, 171. See also, Robert O'Donoghue, 'The Political Economy of Excessive Pricing in The Pharmaceutical Sector in The EU: A Question of Democracy?' (2018) CPI <https://www.competitionpolicyinternational.com/wp-content/uploads/2018/07/CPI-ODonoghue.pdf> accessed 24 February 2024, suggesting that if the excessive pricing is as a result of lack of regulation, then the solution should be changing the regulatory regime and not using art 102 TFEU as a form of ad hoc plug for a perceived regulatory gap.

[15] In the USA, S.1523—Drug Price Transparency Act of 2021, 117th Congress; more extensive analysis, see in general Jennifer L Graber, 'Excessive Pricing of Off-patent Pharmaceuticals: Hatch it or Ratchet' (2017) 92 NYUL Rev 1146.

[16] Ariel Ezrachi and David Gilo, 'Excessive Pricing, Entry, Assessment, and Investment: Lessons from the Mittal Litigation' (2009) 76 ALJ 873, 878.

this article show that a number of off-patent drugs that have small/declining market and very inelastic demand, can make the entry of generics unlikely under specific circumstances.[17] These conditions may lead to substantial market power and ability to foster exploitative practices, drawing scrutiny from competition authorities, which will be discussed below.

The CMA v Pfizer/Flynn case

The CMA's 2016 decision

In December 2016, the CMA fined pharmaceutical suppliers Pfizer and Flynn Pharma for a breach of UK and European competition law by selling an epilepsy drug, phenytoin sodium, at excessive prices. The case concerns the manufacture and supply of phenytoin after the patent expiry for the original brand in 2000, when Pfizer acquired the brand (sold under the name Epanuim). In 2012, Pfizer decided to debrand the medicine (in order to circumvent the UK's price control system) and transferred its Marketing Authorizations (MAs) for Epanutin to Flynn, without the associated trademark. By doing this, Flynn got over the price caps placed on Pfizer's branded medication, which allowed for a considerable price increase, as it was no longer subject to any form of price regulation. As a result of this, although having been stable for years, the prices of phenytoin sodium capsules increased significantly overnight.[18]

The CMA considered that both parties held dominant positions due to their very high market shares, the inability of their competitors to impose enough competitive constraints, high barriers to entry, and the fact that they both were unavoidable trading partners for the National Health Services (NHS), who did not hold sufficient countervailing buyer power to effectively constrain either Pfizer's or Flynn's conduct.[19] The CMA also observed that because of the principle of Continuity of Supplythe patients were locked, which means that they cannot change the product, together with the small and declining patient base, no potential entrant will have the incentive to enter the market (in fact, entrants did come into the market, but it did not matter since these specific patients could not change).

The CMA based its assessment on the leading excessive pricing case, *United Brands* in which the Court of Justice (CJEU) held that excessive pricing can amount to an abuse of dominant position if (i) the difference between the costs incurred and the price charged is excessive (excessiveness limb) and (ii) the price is unfair either (a) in itself or (b) when compared to the price of competing products (unfairness limb).[20] For the excessiveness limb, the CMA conducted a comparison between costs actually incurred plus a reasonable rate of return and the price, the so-called 'cost plus' test. The CMA examined three possible measures for each of Pfizer's and Flynn's rate of return, namely the return of capital employed (ROCE); return of sales (ROS); and gross margins, and considered that a 6 per cent ROS would be a reasonable benchmark (which represented the standard ROS under the Pharmaceutical Price Regulation Scheme). Based on that, the CMA concluded that the prices exceeded the level of cost by 29 per cent for 25 mg capsules, 100 per cent for 50 mg capsules, 705 per cent for 100 mg capsules, and 690 per cent for 300 mg capsules for Pfizer.[21] The CMA concluded that each of the excesses was 'material' and 'sufficiently large to be deemed excessive' in the context of the excessive limb of the *United Brands* test.[22]

[17] da Sousa (n 1) 436.
[18] The British Parliament passed legislation to close the gap that allowed Pfizer to use its debranding initiative to circumvent the pricing regulations.
[19] *Pfizer/Flynn*, para 4.190.
[20] Case 27/76 *United Brands v Commission* [1978] ECR I -207, para 252.
[21] *Pfizer/Flynn*, para 5.125.
[22] ibid para 5.127.

Similarly, the CMA found that Flynn's prices exceeded the cost plus by 133 per cent for 25 mg capsules, 70 per cent for 50 mg capsules, 31 per cent for 100 mg capsules, and 36 per cent for 300 mg capsules,[23] and concluded that each of the excesses was 'material' and 'sufficiently large to be deemed excessive' in the context of the excessive limb of the *United Brands* test.[24] Further, the CMA conducted price comparisons over time (which is a test that has been endorsed by the courts as a separate benchmark, ie it did more than a cost-plus test) and found considerable price increases.[25]

The next step of the assessment included an evaluation of whether the prices were also unfair.[26] The CMA considered the unfairness test of the *United Brands* test which asks whether the price is unfair 'in itself' or 'when compared to competing products'. These were said to be alternative rather than cumulative tests and, as such, it was sufficient to demonstrate that one of these tests was satisfied in order to establish an infringement.[27] The CMA assessed whether the prices were unfair in themselves by assessing their economic value and found that there were no non-cost-related factors, such as consumer preferences, which would increase the economic value of the products beyond their cost of production plus a reasonable rate of return.[28]

Having reached the conclusion that prices were unfair in themselves, the CMA held that it was not necessary to conclude as to whether those prices are also unfair when compared to competing products because the tests are alternative.[29] However, for completeness, the CMA considered whether such a comparison could be conducted considering possible products that can be used as comparators such as parallel import, Nortriptyline (NRIM's) product, and tablets and concluded that these comparators cannot provide a basis for a meaningful comparison to assess whether the prices under consideration were unfair.[30]

The CMA also considered additional factors to establish that the price was unfair, such as the substantial disparity between the prices and the economic value of the products, the competitive conditions of the market, and the fact that the prices have an adverse effect on the end consumers. Thus, the CMA looked at a variety of factors to establish that the price was unfair in addition to the non-cost factors justifying the price increase.[31] In addition, the characteristics of phenytoin sodium capsules and the fact that it was an old drug that has been off-patent, superseded by other anti-epilepsy drugs, and been sold for many years at a much lower price means that the substantial increase was not as a result of any changes in the cost investment or any risk that had been considered.[32] The CMA observed, for instance, that Pfizer continued to profitably sell the same medication at significantly lower costs in other EU Member States.[33] Finally, the CMA found that the Parties had failed to provide an objective justification and reached the conclusion that the price was excessive and as such abusive. The CMA imposed a penalty of £84.2 million on Pfizer and £5.2 million on Flynn and directed both companies to reduce their prices.

[23] ibid para 5.218.
[24] ibid para 5.222.
[25] In the NAPP, CD Farma and Aspen cases (both the Italian Aspen cases and the Commission Decision of 10 February 2021 relating to a proceeding under art 102 of the Treaty on the Functioning of the European Union (TFEU) and art 54 of the EEA Agreement (Case AT.40394 (Aspen)), this comparator was used in combination with other tests. AG Wahl also recognized that the evolution of pricing over time is an appropriate approach to measure excessive pricing, see Case C-177/16 *AKKA/LAA*, Opinion of AG Wahl, 6 April 2017, EU:C:2017:286, para 19.
[26] ibid para 5.243 (the CMA referred to the *United Brands* judgment, para 252).
[27] ibid para 5.244.
[28] ibid para 5.247.
[29] ibid para 5.476.
[30] ibid para 5.491.
[31] ibid para 5.351.
[32] ibid para 5.356.
[33] ibid para 5.450.

The CAT's decision

On appeal by Pfizer and Flynn, the CAT set aside the CMA decision on the ground that the CMA misapplied the legal test for finding that prices were unfair.[34] The CAT stated that the CMA did not appropriately consider what was the right economic value for the product at issue and did not take sufficient account of the situation of comparing to the price of other comparable products (in particular of the phenytoin sodium tablet). In its reasoning, the CAT considered that the two-limb test from *United Brands* has not actually always been applied in practice, particularly in cases in which the ascertainment of costs of production is impracticable (ie performing rights cases) and, as such, unfair prices could be established by other means than the two-limb approach.[35] Referring to Advocate General Wahl's opinion in AKKA/LAA (rather than to the CJEU judgment), the CAT considered that the 'cost plus' approach adopted by the CMA was an insufficient basis for establishing excessive pricing if other methods were available.[36] Further, following AG opinion, the CAT considered that for the excessiveness limb, the CMA should establish a benchmark price (or range) that would prevail if there had been normal and sufficiently effective competition, and compare that price with the price that has been charged in practice in order to determine whether that price was excessive.[37] Furthermore, the CMA should consider the market conditions, the evolution of pricing over time, and the stability of the differential pricing when assessing excessiveness.

For the unfairness limb, the CAT suggested that the CMA should assess whether the price is unfair by using either of the alternative tests but give due consideration to any arguments that the price is fair under either alternative if the results could be conflicting. In particular, the CAT held that the CMA did not give full and adequate consideration of the competitive conditions surrounding the most obvious comparator product, phenytoin sodium tablets, which were considered by Pfizer as clinically identical, and to examine if this comparator product could be deemed a meaningful comparator.[38] The CMA argued that the unfairness limb of the *United Brands* test does not require the CMA to consider both alternatives. Therefore, if the price was unfair in itself, the CMA had no obligation in law to evaluate whether the prices were unfair by reference to competing products.

Further, the CAT held that if the price is considered unfair, an assessment of whether it bears a reasonable relation to the economic value should follow as a standalone assessment.[39] On this point, the CAT criticized the CMA for not taking into account the fact that at least some economic value should be derived from the therapeutic benefit to patients of phenytoin sodium capsules,[40] given that all relevant circumstances have to be considered when determining the economic value of the product.[41] The CAT was clear that the term 'economic value' is a legal rather than an economic concept, which is highly fact-specific and, as such, a matter of judgement.[42] Further, the court made it clear that while a substantial and prolonged price increase might prompt an investigation into potential abuse of a dominant position, this factor should not be conflated with the actual test for unfair pricing.[43] However, the CAT agreed that a large price increase, sustained over a considerable

[34] Judgment of the CAT of 7 June 2018, in Joined Cases 1275–1276/1/12/17, *Pfizer Inc and Pfizer Limited v Competition and Markets Authority and Flynn Pharma v Competition and Markets Authority* [2018] CAT 11 (CAT judgment).
[35] ibid para 289.
[36] ibid para 356 referring to Case C-177/16 (n 25).
[37] ibid para 443.
[38] ibid para 391.
[39] ibid para 443.
[40] ibid para 419.
[41] ibid para 425.
[42] ibid para 407.
[43] ibid para 439.

period, may warrant scrutiny as it could indicate potential abuse of a dominant position, having in mind that Pfizer did not increase prices in the same way in other Member States and UK prices were significantly higher. The CAT made it clear that cases of pure unfair pricing are rare in competition law and difficult to bring in, and the CMA should be wary of casting themselves in the role of price regulators. The CAT decided not to deliver a judgment on substance because the CMA did not evaluate relevant facts, and provisionally concluded that the case should be remitted back to the CMA for further consideration in light of the existing case law and the judgment.[44] The CAT's judgment was appealed by the CMA, Pfizer, and Flynn.

The judgment of the UK Court of Appeal

In a judgment delivered on 10 March 2020, the UK Court of Appeal overturned some parts of the CAT's ruling but nonetheless referred the case back to the CMA for further assessment of the arguments put forward by the defendants regarding whether the prices were excessive and unfair.[45] In particular, the Court of Appeal held that the CAT was wrong to suggest that the CMA was required to establish a hypothetical benchmark price, beyond a cost-plus calculation, in order to determine whether the price was excessive.[46] However, the Court agreed that 'a' benchmark or standard against which to measure the excessiveness is required. In this respect, numerous counterfactuals can be used including the costs of the dominant undertaking or an assessment of what an appropriate ROS or ROCE would be for that undertaking. The Court of Appeal clarified that the first step in the analysis for the excessive limb in most cases is likely to be for the competition authority to consider whether the costs of production or the costs actually incurred in relation to the product in question, including a reasonable rate of return, can be ascertained.[47] However, much of the debate before the Court of Appeal concerned the assessment of second step—the unfairness. On this point, the Court of Appeal considered that it was not necessary to adhere rigidly to *United Brand's* assessment of unfairness (either 'in itself' or by comparison) because it was neither purely disjunctive (ie 'one or the other') nor a combinatorial test. The Court of Appeal agreed with the CMA that it can establish excessive pricing abuses by showing that the price is excessive and as such unfair in itself, and it does not have to consider whether it is also unfair when compared with a competing product, disagreeing with CAT's position on this point.[48] Nonetheless, the Court of Appeal held that the CMA cannot ignore evidence and arguments put forward by the defendants providing valid comparators as evidence as to why the prices they charge are in fact fair, clarifying that:

> (i) *'the CMA has no duty in every case proactively to investigate all comparators put forward by an undertaking that prima facie demonstrate that the prices charged were fair, and that (ii) the CMA does, however, have a duty fairly to evaluate any such comparators.'*[49]

This statement is in line with the CAT's position that the two limbs of the unfairness test are not strict alternatives. In addition, the Court of Appeal considered that the question of patient benefit will need to be revisited when the matter is reconsidered by the CMA,[50] but

[44] ibid para 443.
[45] The Competition and Markets Authority v (i) Flynn Pharma Limited; (ii) Flynn Pharma (Holdings) Limited; (iii) Pfizer Inc., and (iv) Pfizer Limited [2020] EWCA Civ 339.
[46] ibid paras 248 and 254.
[47] ibid para 252.
[48] ibid para 259.
[49] ibid para 273. On this point, Green LJ clarified that: 'if an undertaking adduces evidence of a type unlike that which the competition authority relies upon to establish an abuse then the authority is under a duty to consider that evidence.'
[50] ibid para 281.

disagreed with the CAT that a free-standing assessment of economic value in addition to the assessments of excessiveness and unfairness was required.[51] The Court of Appeal clarified that there are several ways to consider whether the price charged bears no relation to the economic value of the product value and, as such, that there is 'no single method' or 'way' of measuring it. Therefore, the Court of Appeal made it clear that the CMA has a 'margin of manoeuvre' in deciding which approach to use and which evidence to rely upon when assessing excessive pricing. The Court of Appeal disagreed with the CAT that the enforcement authority should consider the unfairness under both alternatives and sent the case back to the CMA to consider the issues in line with the principles clarified by the Court of Appeal.

The CMA's investigation on remittal: the decision of 2022

Following the Court of Appeal's judgment, the CMA decided to re-investigate the case and, on 21 July 2022, issued an infringement decision finding that the parties have infringed competition law by charging unfairly high prices for phenytoin sodium capsules.[52] The CMA's approach was similar to the first decision, based on the *United Brands'* judgment following the two-limb test, but with a few differences.

First, the assessment under the first limb of *United Brands*, that is price/cost comparison was considered to be sufficient to satisfy the excessive limb of the test and, as such, no other methods were considered.[53] As regards the reasonable rate of return for Pfizer, the CMA considered it appropriate to apply the ROCE methodology in order to cross-check the results from the ROS analysis.[54] In addition, the CMA carried out various analyses to test the suitability of ROS comparators put forward by the parties during the previous investigation and remittal.[55] The CMA found that the ROS allocated to Pfizer's product increased from 6 per cent in the first decision to 10 per cent on remittal to account for the full infringement period to 7 December 2016.[56] This estimation was based on a comparison with ROS earned by the business units within Pfizer and the Global Established Pharma (GEP) division after 2014.[57] For the products under investigation, the CMA found that the prices exceeded the costs actually incurred plus a reasonable rate of return (collectively referred to as 'Cost Plus') by 24 per cent for 25 mg capsules, 91 per cent for 50 mg capsules, 667 per cent for 100 mg capsules, and 653 per cent for 300 mg capsules.[58] The CMA concluded that each excess was 'material' and 'sufficiently large to be deemed excessive' in the context of the excessive limb of the *United Brands* test.[59] As regards the reasonable rate of return for Flynn, the CMA considered it appropriate to apply the ROCE methodology using 10 per cent in its base case calculation.

The CMA then considered the second limb of the *United Brands* test. It reiterated its position that the two parts of the unfairness limb—prices can be either unfair in themselves or when compared to competing products—are alternative and not cumulative, that is if prices during the relevant period were unfair in themselves, then the CMA is not required to

[51] ibid para 282.
[52] CMA Decision: Case 50908, Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK (21 July 2022). The non-confidential version of the CMA's decision was published 7 months later, on 21 February 2023 (hereinafter the Remittal).
[53] ibid para 4.11.
[54] ibid para 5.120.
[55] ibid para 5.121.
[56] ibid para 5.142.
[57] ibid para 5.143.1. For Flynn, following the ROCE approach, the reasonable rate of return was reduced to 2 per cent at para 5.284.
[58] The CMA assessment of whether Flynn's prices were excessive is set out at paras 5.356–5.366 of the Remittal; The assessment of Pfizer's prices is set up at paras 5.124–5.55 of the Remittal.
[59] ibid para 5.188.

demonstrate that the prices were also unfair when compared to competing products.[60] However, following the Court of Appeal position, CMA now evaluated the relevant evidence put forward by the parties and included an additional assessment relevant to the two comparators advanced by the parties: tablets and other Antiepileptic drugs (AEDs) (similar products that treat the same condition with similar levels of efficacy and a comparable lack of serious side effects).[61] The CMA concluded that the £30 Drug Tariff price of Tablets and the comparator AEDs are not meaningful comparators for assessing the fairness of the parties' prices for capsules because of the different product characteristics, clinical differences, differences in the preferred usage, and the relevant prescribing guidelines.[62] Next, the CMA reassessed the factors relevant to the economic value of the parties' products on both the supply and demand side, following the Court of Appeal's clarification that 'economic value needs to be factored in and fairly evaluated into one of the tests', that is either in the excessiveness or in the unfairness test, as there is no obligation to assess it 'as a discrete advantage or justification for a high price'.[63] Thus, the CMA conducted an assessment of the economic value as part of the application of the assessment of excessiveness and unfairness under the *United Brands* test. The CMA concluded that the demand-side factors in this case, including patient benefit, do not add economic value above or in addition to the economic value already reflected in the parties' cost-plus figures. Further, the CMA considered whether there were any factors, specific to the drug which enhance the value of capsules from the customer's perspective and concluded that although the drug is still essential for some patients, their use as a treatment for epilepsy has significantly diminished over time. In addition, no product improvement, innovation, investment or commercial risk-taking, or any other identifiable enhancement to the product or its supply that could have justified the significant price increases was found.[64] Finally, the CMA considered that the parties have failed to provide any objective justification for imposing price increases for an off-patent drug that has a much lower price that was profitable for years, and which had been superseded as a first-line AED by superior treatments without any relevant change in costs, improvement, or innovation.[65] On 12 October 2022, the parties filed fresh appeals against the CMA's infringement decision, which re-imposed the fines from 2016 and put into scrutiny the CMA's assessment again by arguing that the CMA has wrongly ignored real-world indicators of the economic value of phenytoin sodium and rejected (again) possible comparators.[66]

Lessons learned: the CMA's decisions in the pharma industry issued after the Court of Appeal judgment in Pfizer/Flynn

It seems that the Court of Appeal's judgment has had an immediate effect on the CMA's approach in its recent *Hydrocortisone* and *Liothyronine* decisions. In the *Hydrocortisone* decision, the CMA found that Auden (formally known as Actavis UK) abused its dominant position by charging excessive and unfair prices for 10 mg and 20 mg hydrocortisone tablets in the UK. As in the *Pfizer/Flynn* case, Actavis obtained the medicine from the MA holder Merck and debranded the product in order to circumvent price controls, followed by a significant

[60] ibid para 4.26.
[61] The 2022 decision, para 6.142.
[62] ibid paras 6.466 and 6.530.
[63] ibid para 7.2 ref to para 172 from the Court of Appeal judgment.
[64] ibid para 7.12.
[65] ibid para 8.4.
[66] Flynn's eight grounds of appeal can be found at <https://www.catribunal.org.uk/sites/default/files/2022-10/20221026%20Summary%20of%20Appeal%20in%20case%201525%20per%20Rule%2014.pdf>; Pfizer's five grounds of appeal can be found at <https://www.catribunal.org.uk/sites/default/files/2022-10/20221026%20Summary%20of%20Appeal%20in%20case%201524%20per%20Rule%2014.pdf> accessed 17 December 2022. The appeals have been heard and the judgment is pending as at February 2024.

price increase. The CMA conducted a cost-plus test and considered that a return of 5–15 per cent was reasonable (using the ROCE methodology as a well-established metric in the pharmaceutical industry that measures the ROCE).[67] It found that prices were in excess of up to: 3100 per cent for 10 mg hydrocortisone tablets and by 2400 per cent for 20 mg hydrocortisone tablets and, as such, the differences were sufficiently large to be deemed excessive. Next, the CMA applied **both alternatives** from the unfairness limb of the *United Brands* test and concluded that they were unfair, both in themselves and when compared to competing products. By referring to the *Pfizer/Flynn* decision from 2016, the CMA considered the following factors to be relevant in the assessment of unfairness: '*the increase in price; the selective change of prices in the UK but not elsewhere; the impact on the buyer; the lack of any independent or objective justification; the commercial purpose of the arrangements and the approach of the parties to them*'.[68]

However, the CMA made it clear that these tests are alternatives rather than cumulative tests, and either of them would be sufficient to find unfairness in law.[69] The CMA also clarified that: '*If the relevant undertaking does not adduce other methods or evidence, competition authorities may proceed to a conclusion upon the basis of that method and evidence alone,*' and that the competition authority has a margin of manoeuvre or discretion when assessing whether an excessive price is also unfair.[70] Further, by referring to the Court of Appeal *Pfizer/Flynn* decision, the CMA explained that '*irrespective of which alternative is chosen, … the competition authority will always need, at least as part of its duty of good administration, to give some consideration to prima facie valid comparators advanced evidentially by the undertakings.*'[71]

Lastly, the CMA found that the economic value of the hydrocortisone tablets was no greater than the cost-plus calculation because there were no non-cost-related factors associated with hydrocortisone tablets that could increase their economic value, and, as such, the prices bore no reasonable relation to the economic value of the tablets. The CMA's decision was appealed before the CAT.[72] The CAT's judgment was handed down in September 2023, which confirmed the CMA's approach and rejected the grounds of appeal, which argued that (i) the CMA overlooked the prices of comparable products, (ii) the economic value of the focal products was not adequately assessed by the CMA, and (iii) the CMA neglected to acknowledge that the prices were no longer abusive.[73]

The CMA utilized a similar approach in its liothyronine decision, delivered 2 weeks after the hydrocortisone decision. As in the previous decisions, the conduct involved debranding a generic medicine, followed by a significant price increase. The CMA used the same cost-plus methodology and considered that a return of 10 per cent was reasonable. It found that the prices charged by Advanz for liothyronine tablets were excessive within the meaning of the excessive limb of the *United Brands* test, as the difference between the prices and the costs plus a reasonable rate of return was significantly increased during the infringement period from around 900 per cent in 2009 to 2450 per cent by 2017 and 2500 per cent in 2015.[74] Regarding the unfairness limb, the CMA considered that the prices were unfair by themselves, and there was no justification for considering whether Advanz's prices were

[67] Hydrocortisone decision, para 5.150.
[68] ibid para 5.53 referring to para 369 of the 2016 infringement decision.
[69] ibid para 5.43.
[70] ibid para 5.44.
[71] ibid para 5.45. This statement is also in line with the CJEU decision in *Intel* holding that authorities have an administrative duty to consider defences submitted by parties.
[72] Case 1413/1/12/21 *Auden Mckenzie (Pharma) Limited & Another v CMA*, CAT (UK) and Case 1407/1/12/21 *Allergan plc v Competition and Markets Authority*, CAT (UK).
[73] Judgment of the CAT of 18 September 2023 in Joint cases 1407/1/12/21, 1411/1/12/21 1412/1/12/21, 1413/1/12/21, 1414/1/12/21 *Allergan PLC and others v the Competition and Markets Authority*.
[2023] CAT 56.
[74] The Liothyronine decision, para 5.103.

unfair when compared to competing products. In coming to this conclusion, the CMA nevertheless evaluated extensively the comparators advanced by the parties.[75] The CMA noted that the parties had not provided evidence to suggest the presence of any prima facie valid comparator or argument.[76] In concluding that the pricing was unfair by itself, the CMA considered additional factors, such as the prices had a substantial disparity from their economic value, lack of alternative suppliers, high demand inelasticity, high barriers to entry, and absence of regulatory constraints which allowed Advanz to sustain their prices that did not relate to economic value. The pricing strategy aimed to exploit the lack of competitive pressure from the abovementioned competitive conditions. The CMA further found that the price increases were significant without significant increases in production costs or innovation.

The CMA concluded that there were no demand-side factors that would add to the economic value of Advanz's liothyronine tablets.[77] In reaching this conclusion, the CMA considered that first, the price of unbranded generic medicine is determined by competition among suppliers and is unrelated to its therapeutic value. Secondly, the therapeutic value of the liothyronine and levothyroxine tablets [which was considered as the most appropriate comparator, given that they treat the same primary condition as liothyronine tablets and they are in the same (tablet) format] is likely to be similar. In contrast, the latter prices were priced significantly below the Cost Plus of liothyronine tablets.[78] Thirdly, the Department of Health and Social Care/NHS refused to pay extra for the liothyronine tablets because it disagreed with Advanz's high prices but did so anyway because of the lack of alternatives available to the Department of Health and Social Care (DHSC).[79] Further, the CMA evaluated the comparators put forward by the parties as being potentially relevant to assessing the economic value of the liothyronine tablets, specifically: post-entry prices; forecast prices; prices derived from Cournot modelling; entry plan prices; and multi-firm prices, and concluded that these do not provide evidence of additional economic value beyond that already reflected in cost plus.[80] Lastly, Advanz's pricing strategy has negatively impacted the NHS and patients, and there was no independent or objective justification for Advanz's conduct.[81] The parties have appealed the CMA's decision before the CAT.[82] The CAT's judgment was handed down in August 2023 which dismissed the appeals brought by Advanz Pharma, Hg Capital, and Cinven and confirmed the CMA's approach.[83]

Other NCA/EC cases in the pharma industry

The Aspen case in Italy

In September 2016, the Italian Competition Authority (ICA) fined Aspen Pharma for imposing excessive prices and threatening to reduce or terminate the supply of drugs sold under the name 'Cosmos' and used for the treatment of cancer in the Italian market.[84] The ICA found that, although these drugs were off-patent and has been present on the market

[75] ibid para 5. 204: comparators include post-entry prices, entry plan prices, forecast prices, and prices derived from Cournot modelling.
[76] ibid para 5.207.
[77] ibid para 5.208.
[78] ibid.
[79] ibid.
[80] ibid para 5.209.
[81] ibid para 5.251.
[82] Case 1411/1/12/21 *Advanz Pharma Corp v CMA*, Competition Appeals Tribunal (CAT) (UK).
[83] Judgment of the CAT in joint cases 1419/1/12/21, 1421/1/12/21, 1422/1/12/21, *Advanz Pharma Corp and others v CMA* [2023] 52.
[84] Aspen Italian NCA (Case A480, Autorità Garante della Concorrenza e del Mercato) decision of 29 September 2016; AGCM, Press Release, 'A480—Price increases for cancer drugs up to 1500%: the ICA imposes a 5 million Euro fine on the multinational Aspen' (14 October 2016) <http://en.agcm.it/en/media/press-releases/2016/10/alias-2339> accessed 7 January 2019.

for several decades, Aspen had increased prices by 300 to 1500 per cent as compared with the prices previously charged by GSK, from whom Aspen bought the trademark and marketing rights in 2009.[85]

The ICA followed the approach from the *United Brands* judgment and started its assessment with an estimation of the excessiveness based on the percentage gross margin by comparing the current prices with the cost of production before and after the price increase. It found that the profit return on sales before the increase was well above the costs.[86] The new price generated excess ranging from 100 per cent to almost 400 per cent.[87] Then, the ICA applied methodology based on profitability analysis measured by the ROS and considered a 13 per cent reasonable profit margin based on a comparison to competitors' companies in the generics sector.[88] It found an extremely significant excess of prices on cost plus—from 150 to 400 per cent.[89] The approach of the ICA regarding the excessive limb is consistent with the approach taken by the CMA. Finally, the ICA considered the second limb of the *United Brand* test, namely, whether the price was either unfair in itself or when compared to the price of competing products. It concluded that there were no competing products to be used as a benchmark and that the different regulatory regimes in the other Member States made it impossible to compare with the prices charged in the other countries.[90] Thus, the approach of the ICA regarding the unfairness limb is consistent with the approach taken by the CMA's decision not to investigate further whether the price was unfair compared to the price of competing products. However, after the Court of Appeal judgment in the Pfizer/Flynn case, along with subsequent actions by the CMA as explained above, the CMA now has to take one step further. Despite the alternative nature of the two limbs of the unfairness test, the authority felt compelled to examine both as part of good administration and procedural fairness, which practically made the test cumulative in practice.

An important observation was the finding that Aspen did not engage in any investment in R&D in order to improve the product or to promote sales; and that no actual competitors or potential competitive pressure due to the barriers to entry or countervailing bargaining power were found.[91] For that reason, the ICA concluded that the significant difference between prices and cost cannot be justified and, as such, it was considered unfair. In addition, the ICA found that Aspen was engaged in pricing negotiations with abusive intent by repeatedly requesting the Italian Medicines Agency (AIFA) to include Cosmos drugs in a Class of drugs whose prices are not reimbursed by the NHS and can be freely determined by pharmaceutical companies if the requested price increase was not accepted. If such reclassification did not occur, Aspen threatened to withdraw the drugs from the Italian market while using a 'stock allocation mechanism' to limit parallel imports and create transitory shortages in the Italian markets.[92] The decision was upheld on appeal.[93]

[85] David Hull and Michael Clancy, 'The Application of EU Competition Law in the Pharmaceutical Sector' (2017) 8 JECL & P 205, 211.

[86] Gianluca Faella and Luiss G Carli presentation of the Aspen case <https://www.coleurope.eu/sites/default/files/uploads/event/gianluca_faella.pdf> accessed 30 October 2018.

[87] OECD, DAF/COMP/WD(2018)106, Excessive Pricing in Pharmaceutical Markets—Note by Italy <https://one.oec d.org/document/DAF/COMP/WD(2018)106/en/pdf> accessed 30 December 2021.

[88] Elisabetta M Lanza and Paola R Sfasciotti, 'Excessive Price Abuses: The Italian Aspen Case' (2018) 9 JECL & P 382, 386.

[89] ibid.

[90] Emilio De Georgi, 'Excessive Pricing in the Pharmaceutical Industry: the Aspen Case' <https://www.linkedin.com/pulse/excessive-prices-pharmaceutical-industry-aspen-case-emilio-de-giorgi> accessed 7 January 2019.

[91] Lanza and Sfasciotti (n 88) 387.

[92] Gianluca Faella, 'Excessive Prices: the Aspen Case', *Presentation at the 95th GCLC Lunch Talk*, 11 November 2017.

[93] Judgment of the Lazio Regional Administrative Tribunal n. 8948/2017 Aspen of 26 July 2017. The Council of State (Consiglio di Stato) upheld that Decision in its Judgment of 20 February 2020 in Case No 8447/2017. For a discussion, see Michaela Angeli, 'The TAR Lazio's Judgement in The Italian Aspen Case on the Imposition of Unfair Prices Under Art. 102 (a) TFEU', (2017) 2 Italian Antitrust Review 220. See also Ingrid Vandenborre and Stanislas De Villoutreys, 'The Aspen Italy Decision: A "Quick Look" Assessment Leaves Open Questions', Global Compet Rev (2018).

The CD Pharma case in Denmark

In January 2018, the Danish Competition Authority found that CD Pharma (a pharmaceutical distributor) was dominant in the Danish market for the sale of oxytocin based on its exclusive distribution agreement with the product's producer.[94] The drug Syntocinon has existed since the 1950s and has been out of patent long ago with a stable price during 2007–2014. In this period, Syntocinon was the only oxytocin product with a Danish MA. The only competitor of CD Pharma was Orifarm, a parallel importer of the drug. Orifarm had delivery difficulties and could not deliver the full amount of the drug to Amgros (a wholesale buyer for hospitals), which meant that Amgros had to buy Syntocinon from CD Pharma.[95] The Authority found that CD Pharma was charging Amgros unfair prices for the drug Syntocinon, approximately EUR 780,000 more than the price in the original contract with the parallel importer, for a period of 6 months.

The Authority found that the price was unfair after comparing the historic prices of former exclusive distributors with the prices charged by CD Pharma in other countries. In addition, CD Pharma submitted no evidence showing that the price increase could be justified. Based on that, the Authority found that CD Pharma's price for the drug was excessive and consequently abused its dominant position in Denmark. The Authority did not consider the *United Brands* cost-plus test and consider other comparators endorsed by the EU Courts, such as comparing prices over time and comparing prices in other countries.[96] The Maritime and Commercial High Court of Denmark upheld the decision of the Danish Competition and Consumer Authority ruling that the pharmaceutical wholesaler CD Pharma abused its dominant position in 2014 by increasing the price of a labour pain-stimulating pharmaceutical called Syntocinon by 2000 per cent.[97]

The recent European Commission's Aspen commitment decision

The European Commission opened an investigation against Aspen Pharma in 2017, following significant price increases on six off-patent cancer medicines imposed by Aspen.[98] Aspen acquired the medicines from GlaxoSmithKline and outsourced the manufacturing, commercialization, and distribution to third parties. The drugs are prescription based, have no substitutes, and the patent expired 50 years ago, which means that any R&D investment has already been fully recouped. Finally, Aspen implemented a strategy to achieve the price increase, including a threat to de-list or withdraw the products from the market. The Commission assesses the excessiveness of Aspen's profit by comparing Aspen's profit before and after the price increase and by comparing its profitability with a sample of other undertakings that sell similar products and have a profile similar to Aspen.[99] Similarly to the approach adopted by the CMA, the Commission applied the cost-plus test, using the return of 23 per cent as reasonable, and concluded that Aspen was

[94] CD Pharma Danish NCA (Konkurrence- og Forbrugerstyrelsen) decision of 31 January 2018; Danish Competition Authority press release—CD Pharma has abused its dominant position by increasing their price by 2000 per cent <https://www.en.kfst.dk/nyheder/kfst/english/decisions/2018-cd-pharma-has-abused-its-dominant-position-by-increasing-their-price-by-2-000-percent/> accessed 10 March 2021.

[95] Price increases in the pharma sector may be considered abuse of a dominant position <https://www.antitrust-alliance.org/price-increases-in-the-pharma-sector-may-be-considered-abuse-of-a-dominant-position/> accessed 11 March 2021.

[96] Case 26/75 *General Motors v Commission* [1975] ECR 1367, Case 226/84 *British Leyland plc v Commission* [1986] ECR 3263, Case 226/84 *British Leyland plc v Commission* [1986] ECR 3263 and Case C-177/16 *Biedrība 'Autortiesību un komunicēšanās konsultāciju aģentūra—Latvijas Autoru apvienība' v Konkurences padome* (hereinafter 'AKKA/LAA') ECLI:EU:C:2017:689.

[97] Judgment of the Danish Maritime and Commercial Court, confirming the Danish Competition Authority finding excessive pricing for medicine Syntocinon in March 2020, see https://www.en.kfst.dk/nyheder/kfst/english/decisions/2018-cd-pharma-has-abused-its-dominant-position-by-increasing-their-price-by-2-000-percent/ accessed 13 March 2023.

[98] And investigations by NCAs in Italy and Spain.

[99] Aspen Commissions decision, para 104.

able to generate a return, which ranged from 40–50 per cent excess to 400–420 per cent above cost plus.[100] The Commission found that the Aspen pricing was unfair in itself due to the fact that Aspen did not offer any material improvement of the products or any justifications to reflect commercial risk-taking activity, innovation, or investment. Instead, the Commission found a strategy to exploit health systems and patients. The Commission rejected Aspen's proposed comparisons with competing products and stated that there was no need to consider the second alternative for the unfairness limb of the test.[101] Aspen did not submit any other justifications for its pricing conduct.[102] In April 2021, the Commission accepted commitments offered by Aspen to address its concerns which reduced drug prices by an average of around 73 per cent across the European Economic Area.[103] It should be noted that the Aspen decision which was adopted after the Court of Appeal Pfizer/Flynn judgment, despite the fact that it cannot change or replace judicial decisions, provides very important clarification of the legal test for excessive pricing. It shows that if there is sufficient information for the cost-plus test to be conducted, it can be used to provide different benchmarks, such as benchmarks against the profitability of similar companies in the same industry and for the assessment of profitability before and after the price increase and that these comparators may be relevant to both limbs of the *United Brands* test.[104] It further demonstrates that by employing different benchmarks, the Commission can refute Aspen's economic evidence regarding proposed comparisons with competing products without in-depth analysis, which is in striking contrast with the outcome of the Court of Appeal ruling in the Pfizer/Flynn case.

3. ANALYSIS OF THE RECENT DEVELOPMENT OF THE LEGAL STANDARD FOR EXCESSIVE PRICING IN THE PHARMA INDUSTRY AND DISCUSSION

The analysis of the excessive pricing cases within the pharmaceutical industry above aimed to examine the CMA's strategy in the Pfizer/Flynn ruling and subsequent decisions by the CAT and Court of Appeal; to assess how these rulings have influenced the CMA's strategy in addressing excessive pricing; and to compare the UK Courts' approach with similar cases handled by other European NCAs in the pharmaceutical sector and the recent EU Commission decision in the Aspen case. The analysis reveals that the factual patterns underlying the cases that prompted investigations by competition authorities are very similar. In most of the cases, the finding of excessive pricing was associated with the willingness of pharmaceutical companies to breach, circumvent, or ignore regulatory constraints leading to significant price increases of medicine without substitutes/locked-in patients, which is off patent, with no material improvement of the products or any justifications to reflect commercial risk-taking activity, innovation, or investment.[105] In all cases (except CD Pharma), the competition authorities consistently applied the *United Brands* test. The following section will analyse the application of the two parts of the test.

[100] ibid para 140.
[101] ibid para 196.
[102] ibid para 206.
[103] ibid para 210. The Commission also accepted supply commitments, para 212.
[104] See Marinova (n 11).
[105] A recent study even suggested the utility of per se rules in addressing excessive pricing, particularly in the pharmaceutical industry when the products that are off-patent, no longer protected by regulatory market exclusivity, the cost of the products does not reflect R&D, risk factors, or sales promotions. According to Abbott, if the margin between cost plus and price is unusually high, and there is no justification of the unusually high margin, then a finding of excessive pricing should be established. See Frederick Abbott, 'Prosecuting Excessive Pricing of Pharmaceuticals under Competition Law: Evolutionary Development' (2023) 24 CSTLR 173, 245.

The assessment of the excessiveness of the price

The excessive limb from the *United Brands* pertains to the evaluation of unit prices *vis-à-vis* unit costs.[106] However, the precise methodology for conducting this test and the incorporation of a reasonable profit margin to the costs were not expounded upon by the CJEU. The analysis of the excessive pricing cases within the pharmaceutical industry above shows that, in the context of the excessive limb of the *United Brands* test, competition authorities have predominantly employed the cost-plus approach, which is a comparison of the actual costs incurred plus a reasonable rate of return against the price.[107] As a matter of fact, throughout the years, a robust methodology for evaluating a company's profitability within competition cases has been proposed, which has been used in a number of excessive pricing cases by competition authorities.[108] In this sense, the price–cost test suggested by the CJEU in the *United Brand* judgment was developed to reflect the costs incurred in the production and provision of goods or services alongside a reasonable rate of return/profit margin. The economic logic underlying using a cost-plus test for assessing excessive pricing can be elucidated further. By incorporating a margin, the cost-plus test recognizes the need to provide firms with a reward for entrepreneurial activity, risk-taking, and the incentive to invest, innovate, and sustain their operations in the market. The profit margin should generate a satisfactory return on companies' investments. Thus, the inclusion of a margin within the cost-plus test reflects companies' profitability and aligns with the broader economic principles of incentivizing innovation and maintaining a competitive marketplace.

The profitability analysis is crucial to understand the levels of profitability **and therefore prices**.[109] There are several approaches to the determination of the 'plus' part of the cost-plus calculation, such as ROCE, ROS, gross margin, etc. The CMA predominantly used ROCE for the calculation of a reasonable rate of return. These indicators have broad application in the industry. For example, by comparing the ROCE of a company with similar businesses in the industry, investors and analysts can gauge whether the company's return on capital is above or below average. Comparing a company's ROCE to industry benchmarks and competitors is a common approach to assess its performance relative to others in the same industry.[110] From this perspective, profitability indicators serve as a comparator of the levels of profitability and therefore prices with similar companies in the same industry. Measuring profitability is also possible when using different products within the same company as comparator to test the profitability of a specific product. This approach is known as internal benchmarking or internal comparator. Using different products within the same company can provide insights into the relative profitability and performance of various products or business segments. By comparing the ROCE of different products within the company, the profitability and efficiency of each

[106] The excessiveness test was further developed by the EU Courts, ie whether the price is excessive by reference to some benchmark—be that price cost or comparable prices elsewhere but for the purpose of this analysis the focus will be on the price–cost test. For further analysis of the development of the case law of excessive pricing, see Marinova (n 11).

[107] The European Commission acknowledged in the Scandlines case, para 224, that it is reasonable for a company to aim at recovering its capital costs. Correspondingly, in the Albion Water II case, the CAT recognized that costs usually should encompass a return on capital. Thus, when determining the 'incurred costs', it is typically essential to assign a fair rate of return to account for capital expenses.

[108] Oxera, 'Assessing Profitability in Competition Policy Analysis' Economic Discussion Paper 6, (2003) report for the UK Office of Fair Trading, July <https://www.oxera.com/wp-content/uploads/2018/03/OFT-Assessing-profitability.pdf> accessed 14 July 2023. According to Oxera, this methodology has been further developed over time by competition authorities and competition economists, see Oxera, Excessive Pricing: Excessively Ignored in Competition Law Excessive pricing.indd (oxera.com) accessed 14 June 2023.

[109] CMA, *Land Mobile Radio Network Services Profitability Methodology Approach*, 13 December 2021, para 10 <https://assets.publishing.service.gov.uk/media/61b73279e90e07043c35f589/Profitability_methodology_approach_working_paper–MRN.pdf> accessed 14 June 2023.

[110] Suciu Gheorghe, The Analysis of Profitability Indicators' (2013) 4 AES 132, 137.

product in relation to the capital invested can be assessed.[111] Having mapped the importance of the profitability indicators and the different benchmarks that can be used, the next part of this section analyses how this methodology was used by the CMA.

In the *Pfizer/Flynn* decision, the CMA conducted the cost-plus analysis by first identifying the costs (the decision provides extensive details regarding the cost accounting methodology) and then identifying the appropriate methodology to evaluate the reasonable rate of return/profitability. The CMA examined three possible measures for each of Pfizer's and Flynn's rate of return, namely the ROCE; ROS; and gross margins and considered that a 6 per cent ROS would be a reasonable benchmark (which represented the standard ROS under the Pharmaceutical Price Regulation Scheme).[112] The CMA's analysis included several benchmarks to compare companies profitability to industry benchmarks and competitors in order to assess their performance relative to others in the same industry. This suggests that the cost-plus test provides different benchmarks that measure the excess of the price. Yet, this was not enough for the CAT which found that the cost-plus test is not a sufficient method for the assessment of excessiveness of the price.

The CMA went even further in its analysis in the remittal decision where it considered it appropriate to apply the ROCE methodology in order to cross-check the results from the ROS analysis.[113] In addition, the CMA carried out various analyses to test the suitability of ROS comparators put forward by the parties during the previous investigation and remittal. The CMA increased the ROS allocated to Pfizer's products, from 6 per cent in the first decision to 10 per cent on remittal to account for the full infringement period to 7 December 2016.[114] This estimation was based on comparison with ROS earned by the business units within Pfizer and the GEP division after 2014.[115] The CMA analyses included (i) measuring profitability within company's business units (known as internal benchmarking as explained above) and (ii) comparison with other similar companies in the industry [generic drugs, branded generics, and over-the-counter (OTC) medications].

The same cost-plus methodology was used by the CMA in the recent infringement decisions in the *Hydrocortisone* and *Liothyronine* cases, by the ICA[116] and the European

[111] When using internal comparators, it is important certain factors that can ensure the reliability of the indicator are to be considered such as, eg, similarities in capital investment, similarities in product characteristics, their cost structure or market dynamics.

[112] The price regulation in the UK is complex. It is summarized in paras 24–28 in the Court of Appeal judgment in Pfizer/Flynn: ' … . *Patients do not normally pay for an AED. It is paid for by the NHS which reimburses pharmacies for medicines dispensed by it. The "Drug Tariff" sets the amounts that pharmacies can seek by way of reimbursement. It reflects the voluntary and statutory price controls applying to various pharmaceutical products and takes account of any clawback discounts. Drugs are either branded or generic (non-branded).' This has implications for the regulation of the drug and its Drug Tariff price. There are three categories of products for the purposes of calculating the Drug Tariff price: A, C and M. Category C applies to drugs not readily available in generic form and the price is determined by reference to the list price for the particular product, manufacturer or supplier. Category M applies to generics and the price is calculated upon the basis of a volume-weighted average selling price derived from information submitted to the DOH by suppliers. When the Pfizer-Flynn capsule was genericised it came within Category C. The Teva tablet is in Category M. Drug prices are regulated in three main ways*:

a) *Voluntary schemes agreed between the Government and industry bodies in accordance with* section 261 *National Health Service Act 2006 (the "NHSA").*
b) *Non-voluntary schemes established by the DOH under* sections 263-264 *NHSA. There were no non-voluntary schemes in place for generic medicines after 2007.*
c) *Exercise by the DOH of statutory powers to regulate the prices of NHS medicines or the profits accruing to manufacturers or suppliers pursuant to* sections 261-266 *NHSA.*

[113] Remittal decision, para 5.120.

[114] ibid para 5.142.

[115] ibid para 5.143.1. For Flynn, following the ROCE approach, the reasonable rate of return was reduced to 2 per cent at para 5.284.

[116] In the Italian Aspen case, the profit of the price before the increase was compared with the profit after the price increase, plus a 13 per cent profitability rate. However, according to some commentators, the ICA did not carefully choose the correct comparators to assess the excessiveness and the unfairness. Moreover, due to the specific features of the case, its precedential value is limited. See Patrick Perinetto, 'The Italian Pharmaceutical Antitrust (r) Evolution and its Most Recent Example: the Aspen Case' (2017) 13 Eur Compet J 93.

Commission in the *Aspen* case. In all of the cases, this methodology was accepted as reliable for the assessment of the excessiveness as more than one comparator was used. An important characteristic of these indicators should be considered, namely that profitability indicators are not calculated for themselves but are compared with similar companies in the same industry. From this perspective, it can be suggested that the development of the *United Brands* price–cost test includes comparators that allow comparison of the profitability (and as such prices) of the dominant company against profitability/prices of similar companies within the same industry, which resemble the second element of the unfairness test of the *United Brands* test. Therefore, the cost-plus methodology used by the CMA might be considered to provide additional benchmarks that can identify unfairness as well. Most of the ambiguity in the case law analysed above is related to the unfairness of the price, which will be discussed in the next section.

The assessment of the unfairness

The second element of the 2-fold test from *United Brands* requires a determination of unfairness which consists of two elements, whether the price is 'unfair in itself' or when 'compared with competing products'. It is also generally accepted that the two elements/limbs are alternatives. It means that once the excessiveness of the price is established, the competition authority has to establish that the price is either unfair in itself or when compared to competing products.

The application of the unfairness test has been raised as a main issue before the UK Courts in the *Pfizer/Flynn* case. The CMA assessed whether the prices were unfair in themselves (limb 1) and concluded that it was not necessary to reach a conclusion as to whether those prices are also unfair when compared to competing products (limb 2) because the tests are alternative. On this point, the CAT suggested that the unfairness should be assessed under either alternative if the results could lead to conflicting results and criticized the CMA for not fully considering whether the most obvious comparator product could be considered a meaningful comparator. This can be interpreted as suggesting that the two limbs of the unfairness test are cumulative rather than alternatives, which is clearly a departure from the established case law.[117] On appeal, the Court of Appeal confirmed that the two limbs are alternatives but nonetheless send the case back to the CMA, stating that the CMA cannot ignore evidence and arguments put forward by the defendants providing valid comparators as evidence as to why the prices they charge are in fact fair. The judgment significantly impacted the CMA's approach as shown in the remittal decision as well as its recent *Hydrocortisone* and *Liothyronine* decisions. In the *Pfizer/Flynn* remittal, the CMA evaluated the relevant evidence put forward by the parties and included an additional assessment relevant to the two comparators advanced by the parties. Although the CMA reiterated that it is not a requirement to demonstrate that the prices were unfair when compared to competing products, the CMA carried out this additional assessment on almost **100 pages** of its decision, only to arrive at the same conclusion as in the first decision. This seems unnecessary as indicated in the Commission's *Amicus Curiae*, stating that in principle, 'a *valid prima facie argument can be refuted by prima facie indications to the contrary*'.[118] In that regard, the

[117] John Davies and Jorge Padilla, 'Another Look at the Economics of the UK CMA's Phenytoin Case' in Y Katsoulacos and F Jenny (eds) *Excessive Pricing and Competition Law Enforcement* (Springer 2018) 71. Some economists supported the view that the CMA should consider both alternatives because the only meaningful benchmark for 'economic value' is the price of a similar product in a reasonably competitive market, so the 'comparator' version of this part of the test has a compelling logic in economic theory. Secondly, this is particularly the case if the alternative is for the CMA to fall back on the same price–cost analysis that led it to find the price to be excessive in the first place. They also claim that economics of producing generic medicines can be similar for different products, because production costs are often a small part of the total cost of the supply chain. Consequently, the price of a similar capsule that has an entirely unrelated clinical use might be of interest, if such a product can be found priced under conditions of competition.

[118] Commission *Amicus Curiae*, para 32.

Commission explained that the CMA provided sufficient arguments why comparing prices with tablets was not appropriate to demonstrate fairness, as both tablets and capsules faced similar supply constraints, rendering tablet prices unsuitable for such a comparison.[119] Following the Court of Appeal judgment, the CMA applied **both alternatives** from the unfairness limb of the *United Brands* test in the *Hydrocortisone* decision and concluded that the prices were unfair, both in themselves and when compared to competing products. Similarly, the CMA evaluated extensively the comparators advanced by the parties in the *Liothyronine* decision. This analysis was in line with the Court of Appeal decision according to which, regardless of the fact that the two limbs are alternatives, the authority should evaluate evidence related to the second limb (comparison with competing product) put forward by the dominant party, which ultimately makes them cumulative. This would ultimately impose an unnecessarily high burden on the CMA.[120]

4. CONCLUSION

The analysis in this article shows that the recent investigations into excessive pricing in the pharmaceutical industry consistently reveal certain patterns. These cases typically involve significant price hikes for off-patent medicines that have been available on the market for a considerable period without any corresponding improvements or justifications. Additionally, since these products have been on the market for some time, it is presumed that the original manufacturers have already recouped their research and development costs, which mitigate concerns that price interventions could stifle innovation.[121] A common similarity is that all cases involve a deliberate strategy by the parties to exploit the regulatory system and take advantage by charging an excessive price. Furthermore, these interventions often target medicines with declining total volumes, primarily used by consumers who have limited or no ability to switch to alternative drugs, effectively rendering them 'locked in' to the product. Further, the analysis illustrates that the competition authorities have predominantly employed the cost-plus approach in assessing excessiveness, regardless of the fact that excessiveness can be measured by various benchmarks.[122] This approach has been instrumental in determining excessiveness. Next, by careful examination of the cost-plus test employed by the CMA in the *Pfizer/Flynn* case, it becomes apparent that assessing profitability through metrics like ROCE, ROS, and gross margins enables the authority not only to evaluate a company's financial performance and thereby establish an excess of profit (excessive limb), but also to establish benchmarks for comparing the company's performance with that of similar businesses in the industry (the second part of the unfairness limb). This suggests that the cost-plus test encompasses certain benchmarks that can be utilized for the second aspect of the unfairness component, namely, comparison with competing products. Assuming that 'competing products' that are suitable for this comparison extends beyond products in direct competition in a sense of a market definition analysis that confines products interchangeable for consumers, it seems that comparison with similar companies within the same industry provides suitable comparator within the meaning of the second limb of the unfairness test.[123] However, the CJEU endorsed a similar comparator, that is, a comparison with a product delivered by a similar company in a different geographical area, in the AKKA/LAA case, as a reliable benchmark for the excessive limb of the *United Brands* test.[124] This

[119] ibid, subparas 32.1–32.3.
[120] Similar interpretation was provided by Abbott (n 8).
[121] Hull and Clancy (n 85) 210.
[122] See the case law as in (n 96).
[123] Jacquelyn D Veraldi, 'Excessive Pricing in Pharmaceuticals under Article 102 TFEU' (2023) EJRR 1, 5.
[124] Case C-177/16 (n 96).

indicates that if there is reliable data accessible to perform the cost-plus test in a manner similar to the CMA's approach, the result will offer sufficient evidence for both limbs of the *United Brands* test, and as such, there is no need for separate assessment that involves comparison with competing products. This interpretation tends to blur the distinction between the two components of the *United Brands* test.[125] Therefore, by employing different benchmarks within the cost-plus methodology relevant to both limbs of the test, the authority can refute the economic evidence the investigated dominant company put forward regarding proposed comparisons with competing products without in-depth analysis, as demonstrated in the Commission's Aspen case above. Hence, after the establishment of excessiveness through the cost-plus test methodology, the decisive question shifts to whether the price aligns reasonably with the economic value of the product. Consequently, an excessive price that is not justified is also unfair.

The analysis above also revealed that regardless of the fact that the two limbs of the unfairness test are alternatives, the CMA has found itself under an obligation to conduct both alternatives as a separate assessment as a matter of good administration and procedural fairness, after the Court of Appeal ruling, which has the effect of making the test cumulative in practice.[126] Having in mind that dominant companies will presumably always put forward some evidence that the price under consideration is not unfair, an evaluation of both alternatives will be required in all cases. This would ultimately impose an unnecessarily high burden on the CMA, which will likely impose additional burdens on future investigations. In a similar vein, Abbot aptly observes that the CMA engages in redundant and potentially unnecessary analyses in an effort to anticipate the legal standards that may be applied during the appeals process.[127] This results in the competition authority dedicating significant resources to preparing these decisions, ultimately causing delays in the process.

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[125] On this point, see Marinova (n 11).
[126] The same position was expressed by the Commission in its supportive statement in which the Commission argued that this would essentially oblige competition authorities to fulfil the examination criteria under both alternatives.
[127] Abbott (n 8).

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