Case No. CA-2025-000630

IN THE COURT OF APPEAL (CIVIL DIVISION)

ON APPEAL FROM the Competition Appeal Tribunal
Sir Marcus Smith, Professor Simon Holmes and Professor Robin Mason [2023] CAT 56; [2023] CAT 57; [2024] CAT 29

B E T W E E N:-

(1) AUDEN MCKENZIE (PHARMA DIVISION) LIMITED

(2) ACCORD-UK LIMITED

Appellants

-and-

THE COMPETITION AND MARKETS AUTHORITY ("CMA")

Respondent

AUDEN/ACTAVIS'S APPEAL SKELETON ARGUMENT

References: Core bundle: **[Core/tab/page]**; Core supplementary bundle: **[CSupp/tab/page]**; Reference supplementary bundle: **[RSupp/tab/page]**; Authorities bundle: **[Auth/tab/page]**.

Reading list: It is proposed that the parties should collaborate to produce a common agreed reading list once the bundles are available.

A. INTRODUCTION

1. This is the appeal skeleton argument on behalf of Auden Mckenzie (Pharma Division) Limited ("**Auden**") and Accord-UK Limited ("**Accord-UK**"), formerly known as Actavis UK Limited ("**Actavis**"), collectively referred to as "**Auden/Actavis**".

2. Auden/Actavis appeals with the permission of the Competition Appeal Tribunal (the "**Tribunal**"), granted by Reasoned Order (Permission to Appeal) dated 4 March 2025, against the Tribunal's judgments in Hydrocortisone 1 and 4, and Hydrocortisone 2 so far as it concerns penalty.[1] Those judgments determined Auden/Actavis's appeal under s.46 of the Competition Act 1998 brought against the decision of the Competition and Markets Authority ("**CMA**") in Case 50277 (Hydrocortisone Tablets: Excessive and unfair pricing and anti-competitive agreements) dated 15 July 2021 (the "**Decision**"). **[Core/19/627-629]** **[Auth/67/2246-2247]** **[Core/23/649-1749]**

3. The Decision found Auden/Actavis liable for four infringements of the Competition Act 1998 in relation to the sale of its instant release hydrocortisone tablets:

   (a) Abuse of a dominant position by charging excessive and unfair prices, thereby infringing the Chapter II prohibition (together the "**Unfair Pricing Abuses**"):

      (1) between 1 October 2008 and 31 July 2018 (Periods A1, A2, A3 and A4) concerning the supply of 10mg tablets (the "**10mg Unfair Pricing Abuse**"), and

      (2) between 1 October 2008 and 8 January 2017 (Periods B1, B2 and B3) concerning the supply of 20mg tablets (the "**20mg Unfair Pricing Abuse**"); and

   (b) Entry into anti-competitive agreements (the "**Agreements**"), thereby infringing the Chapter I prohibition:

      (1) with Waymade, between 11 July 2011 to 30 April 2015 (a single period), in relation to the supply of 20mg tablets (the "**20mg Agreement**"), and

      (2) with Waymade, between 23 October 2012 and 30 October 2012, and then AMCo, between 31 October 2012 and 24 June 2016 (Periods C1 and C2), in relation to the supply of 10mg tablets (the "**10mg Agreement**").

[1] "**Hydrocortisone 1**" is [2023] CAT 56 (Abuse of Dominance Infringements); "**Hydrocortisone 2**" is [2023] CAT 57 (Cartel Infringements); "**Hydrocortisone 3**" is [2024] CAT 17 (Due Process); and "**Hydrocortisone 4**" is [2024] CAT 29 (Penalties). **[Core/16/294-521]** **[Core/17/522-616]** **[Auth/56/1615-1709]** **[Core/18/617-626]**

4. This matter has already been considered by the Court of Appeal in its judgment of 6 September 2024 ([2024] EWCA Civ 1023) which concerned appeals and/or applications for permission to appeal from Hydrocortisone 2 and Hydrocortisone 3 in respect of points going to liability under the 10mg Agreement.[2] By its judgment, the Court of Appeal reinstated the CMA's finding of infringement in respect of the 10mg Agreement. **[Auth/57/ 1710-1749]**

5. The present appeal is brought against:

   (a) The Tribunal's judgment in Hydrocortisone 1 in which it upheld the Decision's findings of infringement in respect of the Unfair Pricing Abuses (albeit for very different reasons from those given in the Decision) (**Ground 1**); and

   (b) Each of Hydrocortisone 1, 2 and 4 insofar as they upheld the CMA's imposition of penalties on Auden/Actavis (**Grounds 2, 3 and 4**).

6. Accord-UK and its direct and indirect parent companies, Accord Healthcare and Intas Pharmaceuticals ("**Intas**"), are separately represented for Period A4, and Auden/Actavis also relies on Intas's appeal in relation to Period A4, on both issues.

7. As to Ground 1 concerning the Unfair Pricing Abuses, the Tribunal has purported to formulate its own test for excessive and unfair pricing which wrongly departs from binding authority of this Court in important respects. The Tribunal further erred in failing to give any, or any proper weight to appropriate comparators; and in failing to recognise that any unfair pricing abuse ended by the end of May 2015.

8. As to Grounds 2-4 concerning penalties, the Tribunal erred in upholding the CMA's approach to penalty. The CMA imposed enormous and excessive fines on Actavis which in total stood at **almost four times the statutory cap**. It was wrong and disproportionate for the CMA to fine Actavis four times over in respect of the same course of conduct. The CMA's uplifts at 'Step 4' in the name of specific deterrence were likewise disproportionate. In any event, the Tribunal erred in failing to recognise that its departure from the CMA's market definition required a different approach to fines.

9. The 10mg Agreement penalty remains at large following the Court of Appeal's judgment. However, a central point made in Auden/Actavis's appeal on penalty is that the four

[2] Pursuant to para. 3 of the Court of Appeal's Order of 20 May 2024, applications for permission to appeal in respect of points going to penalty were directed to be made before the Tribunal. **[RSupp/67/ 1979]**

penalties which have been imposed on it should be considered in a joined-up way, because they arose out of a single course of conduct and the proportionality of the position must be considered overall. It therefore advances its appeal on that basis and in the hope that either the 10mg Agreement penalty will have been reconsidered by the Tribunal by the time of the hearing of this appeal and can be addressed with it, or that this Court will be able to determine principles which will apply *a fortiori* to the 10mg Agreement penalty.

B. FACTUAL BACKGROUND

B1. Hydrocortisone tablets

10. Hydrocortisone tablets are "*an essential, lifesaving medicine on which tens of thousands of patients depend for the treatment of adrenal insufficiency*": Decision, para. 1.8. The **[Core/23/659]** active substance hydrocortisone is a pharmaceutical form of cortisol, the main steroid hormone secreted by the adrenal gland. Hydrocortisone is a first-line treatment for patients suffering from adrenal insufficiency. Adrenal insufficiency is a condition where the adrenal glands do not produce enough cortisol, which causes symptoms such as weight loss, muscle weakness, fatigue, and low blood pressure. The number of patients who suffer from adrenal insufficiency is low but it is a very serious condition for those patients and they require life-long treatment to replace their missing cortisol.

11. Hydrocortisone can be delivered to patients:

    (a) Orally (through soluble hydrocortisone in tablet form).

        (1) Instant release hydrocortisone tablets are sold in two strengths, 10mg and 20mg, with 96% of sales by volume being the 10mg strength.

        (2) Modified release hydrocortisone tablets, marketed under the brand name **Plenadren**, were at the material time sold only as 20mg tablets.

    (b) By injection (of a hydrocortisone acetate suspension). **Hydrocortistab** is an example.

12. Instant release hydrocortisone tablets have been available since 1955 and were previously marketed under the brand name Hydrocortone by MSD, the original MA holder.

13. Since they were sold under a brand name, they fell within a complex NHS price-capping regime known as the Pharmaceutical Pricing Regulation Scheme ("**PPRS**"). Under the previous MA holder, the price was typically 70p per pack for 10mg hydrocortisone tablets and £1 per pack for 20mg hydrocortisone tablets. MSD was the only holder of an active

MA at the relevant time. No other company was allowed or able to place on the market hydrocortisone tablets unless and until it obtained its own MA.

14. MSD decided no longer to market its hydrocortisone tablets.[3] It confirmed to the CMA that its plan was to "*delete the product in any event*". It seems to have considered that the continued marketing of the branded product under the PPRS would have been "*generally unattractive*" due to the lower and potentially negative margins associated with such products. Indeed, Auden's costs of goods were greater than the PPRS reimbursement price (Decision, para. 5.98). MSD was therefore preparing to pay "*internal costs of disposal*". The result would have been the removal of the product from the market altogether. **[Core/23/1095]**

15. Instead, in April 2008, Auden bought the necessary licences from MSD. It discontinued the previous brand name, so that hydrocortisone tablets no longer fell under the PPRS. The price recoverable by pharmacies which dispensed hydrocortisone tablets from 21 April 2008 was determined by the NHS's Drug Tariff: Decision, paras. 3.174-183. **[Core/23/738-741]**

16. Auden was subject to the Department of Health's pricing powers set out in s.262 of the NHS Act 2006. Actavis was a voluntary member of 'Scheme M', which gave the Department of Health specific additional powers to intervene on pricing. **[Auth/70/2266]**

B2. Plenadren and 'full label' and 'skinny label' indications

17. In May 2006, the European Medicines Agency granted a so-called 'orphan' designation to Plenadren, a modified release hydrocortisone tablet, now marketed by Shire Pharmaceuticals. Plenadren was specifically developed for a niche use, suitable for so few patients (adult sufferers of adrenal insufficiency) that an 'orphan' designation was appropriate: Decision, paras. 3.160-161. Plenadren obtained an MA in November 2011 and launched in the UK in December 2012. The practical effect of the orphan designation was that, for 10 years from November 2011, only Plenadren and those MAs granted before November 2011 could include the indication "*adrenal insufficiency in adults*". The 10mg and 20mg MAs held by Auden and the 20mg MA held by Waymade therefore benefited from this indication and were "full label". Later MAs could not and were "skinny label". **[Core/23/735]**

18. As the Decision acknowledges at paras. 1.43-44 and 3.226, however, as long as the medicinal products in question are bioequivalent, it does not matter whether a medicinal **[Core/23/667 and 756]**

[3] See Document [00561] in response to Questions 5 and 6 for the references in this paragraph.
[CSupp/11/99-100]
[RSupp/63/1956-1957]

product technically has the relevant indication. It is always open to healthcare professionals – doctors and pharmacists – to prescribe or dispense a licensed medicine for so-called "off-label" use. The overwhelming majority of prescriptions at the time were "open" and did not specify the use of full label or skinny label tablets (Decision, paras. 3.237-238). **[Core/23/760-761]** Pharmacists had an incentive to dispense the cheapest available medicinal product which fell within the scope of a prescription (Decision, para. 3.239). **[Core/23/761]**

B3. The Agreements

19. On 11 July 2011, Auden and Waymade entered into the 20mg Agreement; and on 23 October 2012, they entered into the 10mg Agreement. Waymade transferred to AMCo a matter of days later, from 31 October 2012. The 10mg arrangements were recorded by two written contracts subsequently entered into between AMCo and Auden: see Decision, paras. 3.523 and 3.577. Nowhere in those documents can be found any agreement by either Waymade or AMCo not to enter the market with its own product; the CMA inferred that there was a "*common understanding*" to this effect at Decision, para. 6.553. **[Core/23/1359]**

[Core/23/879 and 896] [RSupp/29/1679-1699] [RSupp/32/1709-1730]

B4. Independent generic entry

20. Generic suppliers of hydrocortisone tablets began to enter the market in 2015 (Decision, paras. 3.308-309). In **July 2015**, Waymade entered with its own 20mg product, manufactured by Aesica and marketed under its pre-existing 'full label' 20mg MA. In **October 2015**, Alissa Healthcare Research Ltd entered with a 10mg product, manufactured by Orion and marketed under a 'skinny label' MA. In **March 2016**, Resolution Chemicals entered with 'skinny label' hydrocortisone tablets manufactured by Eirgen Pharma Limited. In **March-April 2016**, Bristol Laboratories entered with 'skinny label' 10mg and 20mg hydrocortisone tablets which it manufactured.

[Core/23/799-800]

21. The Decision acknowledges that prices began to fall once generic entry occurred (Decision, para. 3.313). Auden/Actavis's prices fell more slowly than others (Decision, para. 3.314). 20mg prices fell more quickly than 10mg prices (Decision, para. 3.319). **[Core/23/805]**

[Core/23/802]

C. THE DECISION AND THE TRIBUNAL'S JUDGMENTS

C1. Market definition

CMA

22. In the Decision, the CMA concluded that the relevant markets comprised only full and

skinny label instant release hydrocortisone tablets (not including Plenadren), and that there initially existed a combined 10mg and 20mg market but separate 10mg and 20mg markets following independent generic entry (Decision, paras. 4.5-7). **[Core/23/944-946]**

Tribunal

23. In Hydrocortisone 1 at [256]-[257], the Tribunal overturned the CMA by finding that the market included (a) both 10mg and 20mg strengths throughout, with no separation following independent generic entry; and (b) Plenadren. **[Core/16/415-417]**

24. Auden/Actavis remained dominant on this market definition, but these findings have important implications for (a) Plenadren as a comparator in the context of the findings of unfair pricing, and (b) penalty, in particular the decision to impose four separate fines.

C2. Unfair Pricing Abuses

CMA

25. At Decision, paras. 5.76-364, the CMA carried out a detailed Cost Plus analysis of the prices charged by Auden/Actavis. It stated its conclusion at the start (para. 5.76): that the prices were excessive, "*because when Auden/Actavis's prices are compared to Cost Plus, the resulting differences are material and hence excessive*". **[Core/23/1089-1171]** **[Core/23/1089]**

26. The CMA considered the issue of possible comparators on a decidedly secondary basis, emphasising at Decision, para. 5.366, that: "*The Unfair Limb is an alternative rather than a cumulative test. Accordingly, it is sufficient to demonstrate that one of the unfairness alternatives ('unfair in itself' or 'unfair when compared to competing products') is satisfied to establish an infringement.*" The CMA failed to direct itself by reference to the Court of Appeal's key insight in ***Flynn/Pfizer*** (see §53 below), namely that, while the Limb 2 unfairness test may formally be an alternative one, the CMA must fairly evaluate all of the evidence and comparators introduced by a respondent undertaking. **[Core/23/1171-1172]**

27. The CMA concluded that only hydrocortisone tablets which directly competed with those sold by Auden/Actavis – i.e., given the CMA's earlier market definition, the hydrocortisone tablets of the independent generic entrants – constituted sufficiently close comparators (Decision, paras. 5.371-372). **[Core/23/1173]**

28. Its actual consideration of the comparators put forward by Auden/Actavis was slender. In respect of Plenadren, considered at Decision, paras. 5.404-420, the CMA said that it was a **[Core/23/1183-1186]**

superficially similar product, but the CMA found that:

(a) There are "*significant qualitative differences between Plenadren and hydrocortisone tablets*" (Decision, para. 5.406). That statement is, of course, nonsensical on its face; Plenadren is itself a hydrocortisone tablet. Plenadren's distinguishing feature is merely that it is modified release as opposed to immediate release. **[Core/23/1183]**

(b) Plenadren was expensively priced. Despite the fact that it was within the same treatment area as Auden/Actavis's hydrocortisone tablets, it was "*barely prescribed*" in the UK, being used by less than 1% of patients with adrenal insufficiency (Decision, paras. 5.413-414). **[Core/23/1184-1185]**

(c) There was "*no evidence that [Plenadren's] price is set in conditions of effective competition*" (Decision, para. 5.417) and no discernible switching despite Auden/Actavis's price increases (Decision, paras. 4.81 and 5.420). **[Core/23/1185]** **[Core/23/973 and 1185-1186]**

29. As Auden/Actavis explained in its Notice of Appeal and submissions to the Tribunal,[4] the reason why Plenadren (a much more expensive medicine) was not prescribed more widely in the UK during the relevant period was its very similarity to Auden/Actavis's hydrocortisone tablets, which meant that CCGs preferred to mandate the prescription of Auden/Actavis's better value product – in other words, they were in direct price competition. The clinical advantages of Plenadren were minimal, given that the biological effect of taking modified release 20mg tablets could be achieved by taking instant release 10mg tablets at prescribed intervals during the day. By way of example, three CCGs approached by the CMA explained that "*the limited potential benefits of Plenadren are not significant enough to justify the considerable extra cost associated with prescribing Plenadren*" (see Decision, para. 3.133(c)). **[Core/23/727]**

30. Thus, the CMA's only real reason for not treating Plenadren as a comparator product was the fact that its price was high. That reasoning is obviously circular: it precludes Auden/Actavis from being able to rely on this highly material comparator in circumstances where, if they were allowed to do so, the CMA would have been forced to accept that it cannot safely conclude that Auden/Actavis's pricing was unfair.

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[4] See the detailed evidence referred to at Auden/Actavis's Notice of Appeal, paras. 91-100; Auden/Actavis will ensure that the evidence referred to there is included in the appeal bundle. **[CSupp/8/29-36]** **[RSupp/7/336-343]** **[CSupp/2-5 and 6]** **[RSupp/30, 33, 38, 40-48, 50, 55, 58-59 and 64]**

31. The CMA declined to address Hydrocortistab as a comparator at all at Decision, para. 5.402, despite its having been properly raised by Auden/Actavis as a material comparator during the investigation. Auden/Actavis had pointed out[5] that there was evidence that Auden in fact used Hydrocortistab as a pricing reference at the time, that other companies identified Hydrocortistab as a comparable product to hydrocortisone tablets too, and that it contained the same molecule as hydrocortisone tablets (the API, hydrocortisone acetate, is a precursor for hydrocortisone in the body, which is the molecule bringing about the therapeutic effect). Because the CMA declined to address Hydrocortistab as a comparator, it failed to take necessary investigative steps including issuing s.26 notices. **[Core/23/1181]**

Tribunal

32. The Tribunal upheld the Decision's finding of excessive pricing, but for substantially different reasons. In particular, the Tribunal "*substantially agree[d]*" that "*the CMA failed sufficiently to take "economic value" into account*" (at [337]). **[Core/16/459]**

33. It quoted Auden/Actavis's submission on economic value at [338]. However, the Tribunal then rejected that submission in short order, without in fact addressing the actual points made, holding in essence that it was not legitimate to take into account patient benefit at all: [339]. **[Core/16/460]** **[Core/16/459-460]**

34. The Tribunal then developed its own novel taxonomy of economic value, which it summarised at [341] as: "*where one has a level of price substantially exceeding Cost or (in this case) the Cost Plus value as calculated by the CMA, then (absent an articulated and pro-competitive explanation) any excess will be abusive*". This taxonomy hinged on identifying three reasons why Price might exceed Cost, identified at [322] as: **[Core/16/449-452]** **[Core/16/461]**

    (a) Case 1 – relative inefficiency amongst Sellers;

    (b) Case 2 – provision of distinctive value by a Seller, including a specific acceptance at [322(2)(iv)] that "*the ability to supply an otherwise undifferentiated product when others cannot is, in our view, the provision of distinctive value*"; and **[Core/16/451-452]**

    (c) Case 3 – generation of producer surplus without added value to Buyers, which arises only where the Seller has market power.

[5] Again, Auden/Actavis will ensure that the underlying documents referred to in its Notice of Appeal at paras. 101-107 are in the appeal bundle. **[CSupp/8/36-38]** **[RSupp/7/343-345]** **[CSupp/3-4, 7 and 12]** **[RSupp/24-28, 37, 39, 41-42, 54, 57, 61-62 and 65]**

35. The Tribunal repeatedly in the judgment places the burden of justification on the appellants to show why they are within Case 2 and not Case 3: see [341] already quoted, and to similar effect [342(1)], requiring a "*competitive reason for the excess producer surplus [to] be articulated*", [342(3)] and fn 402, requiring a "*legitimate explanation*" for the absence of new entry, and [342(4)], requiring the producer surplus to be "*justifiable*" under Case 2; see also [325], [336] and [339(3)]. At [340], the Tribunal said that the need for a procompetitive explanation was the key question when differentiating Case 2 from Case 3. At [342(1)] the Tribunal reached its conclusion on the basis that: **[Core/16/452 and 461-462]** **[Core/16/453 and 459-460]** **[Core/16/460-461]**

"*It is significant that none of the Appellants advanced any explanation for the excess that was consistent with a competitive market or which justified a producer surplus through the maximisation of economic value through product differentiation. We find that telling.*" **[Core/16/461]**

(As noted, the Tribunal had not in fact addressed the points made by Auden/Actavis.)

36. The Tribunal addressed comparators on a desultory basis, under a heading "*Other points that require determination*" which "*do not affect the conclusion we have expressed*" ([346]). It said that "*In a competitive market, one would expect comparable products to act as a competitive constraint on the Focal Product*" ([347]), but "*the prices of medicinal products in the market were not competitive prices, but were distorted for reasons that we have given. Nothing can be learned from them*" ([348]). That is the total of the reasoning dismissing the relevance of Plenadren, notwithstanding the Tribunal's prior conclusion that it was a substitute product in the same market. Hydrocortistab is not mentioned at all. **[Core/16/463]** **[Core/16/463]**

C3. Penalty

CMA

37. The CMA took the approach of treating as separate infringements (Decision, paras. 10.150-154): (a) the 10mg Pricing Abuse; (b) the 10mg Agreement; (c) the 20mg Pricing Abuse; and (d) the 20mg Agreement. This has resulted in Actavis (now Accord-UK) being fined over four times its statutory cap in respect of essentially the same course of conduct.[6] **[Core/23/1668-1669]**

38. The CMA found that each infringement was committed intentionally or negligently,

[6] The statutory cap must be applied under s.36(8) of the Competition Act 1998, and falls to be calculated in accordance with The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (SI 2000/309) (as amended). In this case, it is **£28.4 million**. **[Auth/67/2245]**

[Auth/69/2255-2264]

including the period following 29 May 2015 when Mr Amit Patel had left Auden: Decision, paras. 10.23 and 10.31. **[Core/23/1622 and 1627]**

39. Applying the Penalty Guidance,[7] under Step 1, the CMA adopted the maximum possible starting point of 30% for each of the penalties (Decision, para. 10.171). At Step 2, the CMA applied the duration of the infringements which it had found (Decision, para. 10.186). At Step 3, the CMA found that "*directors and senior management*" were involved, justifying a 15% uplift (Decision, paras. 10.195-203). **[Core/23/1675]** **[Core/23/1682]** **[Core/23/1685-1689]**

40. At Step 4, the CMA imposed an uplift on the penalty on the basis of a stated intention to ensure that its fine exceeded the financial benefits it had calculated. The CMA set out its table of financial benefit calculations at Decision, paras. 10.260 and 10.300. Taking this approach means that the CMA at the end of Step 4 applied a truly extraordinary uplift to the fine exacted on Actavis (Decision, paras. 10.260 and 10.285-290 (10mg), and 10.300 and 10.302-303 (20mg)), as follows: **[Core/23/1707 and 1719]** **[Core/23/1707, 1714-1716 and 1719-1720]**

    (a) For Periods A1 and A3, from £40.6 million to £87.65 million (a 116% increase).

    (b) For Period A2, from £6.8 million to £37.9 million (a 457% increase). There is then a further uplift to £74.3 million (a c. 1,000% increase overall) imposed on Allergan, for which Actavis is not jointly and severally liable.

    (c) For Period A4, from £8.9 million to £12.5 million (a 40% increase). There is then a further very significant uplift to £44.4 million (a c. 400% increase overall) for which Actavis is jointly and severally liable with Intas.

    (d) For Period B2, from £1.0 million to £2.0 million (a 100% increase).

    (The CMA applies no uplift for Periods B1 and B3, because the amount reached by the end of Step 3 already exceeded the financial benefit it had calculated.)

41. Next, at Decision, paras. 10.265-268, the CMA mentions a series of factors supporting the uplift which mirror those already addressed for the purpose of general deterrence under Step 1 (see Decision, para. 10.172). **[Core/23/1675-1678]** **[Core/23/1709-1710]**

42. When adopting the necessary "*step back*" at the end of its penalty calculation exercise, the CMA finds that it has done the following (see the table at Decision, para. 10.413): **[Core/23/1746]**

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[7] Guidance as to the appropriate amount of a Penalty (CMA73), April 2018: Decision, fn 3490. **[Auth/82/2462-2489]** **[Core/23/1617]**

(a) It has fined Actavis a total of **£67.7 million** for Periods A1-3, B1-3, C1-2 and the period of the 20mg Agreement, even though its statutory cap is only **£28.4 million**. That includes fining it in respect of the 10mg strength at the statutory cap **twice over** and then imposing a further £10,880,644 in penalties in respect of the 20mg strength.

(b) It has fined Actavis and its current parents a yet further **£44.4 million** in respect of Period A4 (in respect of which Actavis is jointly and severally liable), taking Actavis's total fine liability to **almost four times the statutory cap**.

Tribunal

43. In Hydrocortisone 1, the Tribunal assessed the CMA's penalties imposed in respect of the Unfair Pricing Abuses across two paragraphs, at [375]-[376], in an avowedly "*broad-brush*" manner ([374(1)]). In particular, the Tribunal did not: **[Core/16/471-472]**

(a) Consider the issue of intention/negligence in light of Auden/Actavis's submissions, and in particular whether the position changed after 29 May 2015.

(b) Address Auden/Actavis's point that it had been fined well in excess of its statutory cap, nor the significance of its changed market definition.

(c) Address or even mention the problem of the uplift imposed by the CMA.

44. In Hydrocortisone 2, [in the context of considering the 10mg Agreement infringement,] the Tribunal made an important factual finding at [137]: "*… because it is relevant to penalty, it is important that we state that we do not consider that any of the later entities acquiring the holder of the Merck, Sharpe & Dohme MA did know (intention) or should have known (negligence) of the illegal aspects of the 10mg Agreement[.]*"[8] **[Core/17/604-605]**

45. It appears from this that it intended to find that no penalty ought to be imposed on Auden/Actavis for the period from 29 May 2015. However, at [159] it declined to consider the question of penalty (because it did not uphold the finding of infringement). **[Core/17/615]**

46. In Hydrocortisone 4, the Tribunal upheld the 20mg Agreement penalty. **[Core/18/617-626]**

[8] This factual finding was not disturbed by the Court of Appeal in its earlier judgment in these proceedings, which upheld the finding of infringement at [111] on the basis that "*Evidence of the subjective state of mind of parties to an anti-competitive agreement is not required.*" **[Auth/57/1745]**

D. EXCESSIVE PRICING – GROUND 1

D1. Legal background

The test for showing an excessive pricing abuse

47. The leading case in the UK on excessive pricing is now ***CMA v Flynn Pharma and Pfizer*** [2020] EWCA Civ 339; [2020] 4 All ER 934 ("**Flynn/Pfizer**"). ***Flynn/Pfizer*** identified the CJEU case of ***United Brands v Commission***, Case C-27/76, EU:C:1978:22 as 'seminal' (e.g. [9]). At [252], the CJEU required a two-limbed analysis as follows: **[Auth/48/1233]**

"*The question therefore to be determined is whether the difference between the costs actually incurred and the price actually charged is excessive and, if the answer to this question is in the affirmative, to consider whether a price has been imposed which is either unfair in itself or when compared to competing products.*" **[Auth/1/81-82]**

48. The CJEU had already identified at [250]: "*In this case charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied is such an abuse.*" **[Auth/1/81]**

49. After a careful review of the previous case-law in ***Flynn/Pfizer***, Green LJ summarised the test for the existence of an excessive pricing abuse at [97], noting that the "*basic test*" is "*whether the price is "unfair"*". Green LJ developed his observations in respect of the "*economic value*" criterion at [153] ff. He explained that it pertains to "*what consumers are prepared to pay for the good or service in an effectively competitive market*" ([155]). The "*economic value*" question is "*part of the overall descriptor of the abuse; it is not the test*"; however, "*In so far as an issue of fact arises which can be categorised as an aspect of "economic value" **it needs to be measured** and it can be evaluated in various parts of that test*" ([172], emphasis added). **[Auth/48/1256]** **[Auth/48/1274-1280]** **[Auth/48/1275]** **[Auth/48/1279]**

50. Because the question of unfairness is separate from the question of excessiveness (and indeed is the overarching issue, as articulated by Green LJ in ***Flynn/Pfizer***), there is no presumption of unfairness under Limb 2 of ***United Brands*** merely because excessiveness has been established under Limb 1. As the Tribunal explained in ***Le Patourel v BT*** [2024] CAT 76 (in the context of a judgment which found that BT's prices were excessive but not unfair), at [56] (emphasis added):

"*… it would, in our view, be wrong to approach the Limb 2 exercise as if there were a presumption of unfairness established already by the mere fact that the price was excessive* **[Auth/59/1774]**

*under Limb 1, **subject only to any justification which the defendant can establish**. We do not see the decision in United Brands as directing such an approach, nor do we see why it is necessary. Nor do we see the reference by Green LJ in Phenytoin at paragraph 97 (v) to "other factors which might otherwise serve to justify the price charged as fair" (quoted at paragraph 49 above) to mean that there was some presumption of unfairness. All it meant was evidence or arguments pointing towards fairness rather than unfairness. Indeed that is demonstrated by paragraph 97 (vi).*" **[Auth/59/1774]**

51. The Tribunal in ***Le Patourel*** referred in this regard to the judgment of Laddie J in ***BHB v Chandler*** [2005] EWHC 1074 (Ch) at [51]. Laddie J emphasised, in particular, in relation to the CJEU's judgment in ***United Brands***, that "*What it did not do was suggest that high prices or high margins are the same as unfair prices.*" **[Auth/10/436]**

Burden of proof and the duty to consider comparators

52. The CMA bears the burden of proof:

    (a) In ***United Brands*** itself, the CJEU held that "*it is for the Commission to prove that the applicant charged unfair prices*" ([264]). It went on to find that the Commission had "*not effectively refuted*" an assertion made by the applicant (supported only by apparently unreliable data) that its prices in Ireland were not an appropriate benchmark because they were loss-making ([261]-[267]). It followed that the Commission "*[had] not adduced adequate legal proof of the facts and evaluations which formed the foundation of its finding*" ([267]). **[Auth/1/83]** **[Auth/1/82-83]** **[Auth/1/83]**

    (b) In ***Ineos Vinyls Ltd v Huntsman Petrochemicals (UK) Ltd*** [2006] EWHC 1241 (Ch), Blackburne J held that the burden of proving an unfair price fell squarely on the complaining party ([210]), and there must be "*strong and compelling evidence of infringement*" ([211]). The burden was not discharged in that case ([219]). **[Auth/14/490-491]** **[Auth/14/491]** **[Auth/14/492]**

53. In ***Flynn/Pfizer***, the Court of Appeal emphasised the CMA's duties in respect of the proper evaluation of the evidence, in particular evidence of material comparators:

    (a) As is apparent from Green LJ's summary, the test of whether there exists an unfair pricing abuse is an essentially unitary one. In particular, Green LJ had rejected the CMA's contention that the 'unfair' limb of the test was a binary alternative, and that it was sufficient for the CMA to establish either that the price was unfair "in itself", or that it was unfair by reference to comparator data, such that if it establishes abuse

using one method or alternative then it can ignore evidence of another type adduced by a defendant undertaking (see [68]). Accordingly, in that case, "*there was an obligation upon the CMA properly and fairly to evaluate the comparator evidence because it was adduced by the undertakings as part of their defences*" ([127]), even though the CMA thought it had sufficiently demonstrated that the price was unfair in itself without reference to comparators.

[Auth/48/1246-1247] [Auth/48/1267]

(b) If the CMA adopts a cost-plus test, then "*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*" ([97(v)]). [Auth/48/1256]

(c) Where a defendant undertaking adduces alternative methods of evaluation or evidence in its defence, the CMA "*must fairly evaluate i*t" ([97(viii)]). [Auth/48/1257]

(d) A competition authority "*has a duty to conduct a fair evaluation of all the evidence before it*" ([113]). This duty is particularly cogent in relation to the need to consider comparators. By definition, the undertaking in question will not necessarily have access to all essential details about apparently appropriate comparators. It is the CMA which has the ability to obtain such information by issuing section 26 notices, and it is under a duty to do so where necessary ([116]). [Auth/48/1262-1263] [Auth/48/1264]

54. The importance of taking into account as wide a range of benchmarks as possible follows from the fact that there is a high risk of errors occurring in this context.[9] It would be counterproductive if dominant companies were prevented from charging the high prices which ought to act as signals to third parties to enter the market and compete. In order to avoid such errors, it is necessary to consider as much data and evidence as possible, including comparators where available.

The role of economic value

55. According to standard economic theory, the economic value of a product or service is determined jointly by supply and demand. That therefore necessarily entails looking at both supply-side and demand-side factors. The significance of demand-side factors (and not only costs of production) has been repeatedly emphasised in the case-law.

[9] Opinion of AG Wahl in ***Latvian Copyright***, Case C-177/16, EU:C:2017:286, [42]-[43]. AG Wahl's Opinion was endorsed by the CJEU at [37] of its judgment (EU:C:2017:689). [Auth/38/915]

56. In ***Scandlines***[10] the Commission stated at [227] (and see also [226], [228], and [232]-[233] making similar points): **[Auth/71/ 2273-2274]**

"*The demand-side is relevant mainly because customers are notably willing to pay more for something specific attached to the product/service that they consider valuable. This specific feature does not necessarily imply higher production costs for the provider. However it is valuable for the customer and also for the provider, and thereby increases the economic value of the product/service.*"

57. In that case, which concerned the port of Helsingborg, as the Commission explained at [209], important demand-side factors included: **[Auth/71/ 2269-2270]**

(a) The port had very high sunk costs. It would be very expensive to build it again from scratch. These were not, however, reflected in ongoing costs.

(b) The port had considerable intangible value. Its location met ferry operators' needs perfectly.

(c) The land used for the port was also valuable; using it for ferry operations and not something else had a high opportunity cost.

58. In ***Attheraces Ltd v British Horseracing Board Ltd*** [2007] EWCA Civ 38; [2007] Bus LR D77 the Court of Appeal attached decisive importance to flaws in the assessment of "*economic value*" in overturning an excessive pricing finding. At [218], the Court of Appeal said (emphasis added): **[Auth/18/ 606]**

"*For all the above reasons we conclude that, **in holding that the economic value of the pre-race data was the cost of compilation plus a reasonable return, the judge took too narrow a view of economic value** in Article 82. In particular he was wrong to reject BHB's contention on the relevance of **the value of the pre-race data to ATR** in determining the economic value of the pre-race data and whether the charges specified by BHB were excessive and unfair.*"

59. At [195], the Court of Appeal specifically approved an observation of Laddie J in ***BHB v Chandler*** at [48], when he pointed out that it is wrong to assume that the competitive price is Cost Plus: "*some markets are buyers' markets, some are sellers'. I do not see that there* **[Auth/18/ 602]** **[Auth/10/ 435]**

[10] Commission Decision in Case COMP/A.36.568/D3 (23 July 2004).
[Auth/71/2267-2277]

is any necessary correlation between the cost of production and the cost of capital and the price which can be achieved in the market place." **[Auth/10/435]**

60. At first instance in ***Flynn/Pfizer*** ([2018] CAT 11), at [419], in a finding which was not disturbed by the Court of Appeal and indeed is consistent with the Court of Appeal's approach, the Tribunal noted that patient benefit was a particular demand-side factor which ought to have been taken into account further to a qualitative assessment (emphasis added):

"*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.*" **[Auth/39/1073]**

Duration and absence of competitive pressure to bring prices down

61. In ***Napp Pharmaceutical Holdings Limited v DGFT*** [2002] CAT 1 204, also a pharmaceuticals excessive pricing case, the Director of Fair Trading had held ([390]) that no excessive pricing abuse could exist unless "*it is clear that high profits will not stimulate successful new entry within a reasonable period*", such that it was necessary to demonstrate that "*there is no effective competitive pressure to bring them down to competitive levels, nor is there likely to be*". The Tribunal agreed that this approach was "*soundly based*" ([391]) and applied it at [403]. **[Auth/7/362-363]** **[Auth/7/391]** **[Auth/7/366]**

62. The ***Napp*** test was approved by the Court of Appeal in ***Flynn/Pfizer*** at [91]. **[Auth/48/1254]**

D2. Ground 1(a) – The Tribunal's test for excessive and unfair pricing in Hydrocortisone 1 is contrary to binding authority and wrong in law

63. The Tribunal has purported to formulate its own test for unfair pricing which departs from binding authority from the Court of Appeal (***Flynn/Pfizer***, and ***Attheraces***) in two important respects (at least in the manner in which the Tribunal has applied it). The Tribunal has in consequence erred in law in upholding the finding of infringement.

64. First, the Tribunal's novel taxonomy at [322] fails to measure economic value because it fails to ask what users and customers value and will reasonably pay for, which entails consideration of demand-side factors, as set out in the case-law above (at §§55-60). Instead, the Tribunal erred by engaging in an abstract enquiry into what constitutes "*legitimate*" producer surplus, which is not what the case-law requires (see [325], [336], **[Core/16/449-452]** **[Core/16/453 and 459]**

[339(3)]). To the extent that the Tribunal does accept the need to consider the presence of demand-side factors under its Case 2 (for example, it does say that "*the ability to supply an otherwise undifferentiated product when others cannot is, in our view, the provision of distinctive value*" at [322(2)(iv)]), its focus on the identification of "legitimate" producer surplus meant that it wholly failed actually to factor in the requisite demand-side factors when it came to considering the issue of economic value in this case.

[Core/16/460] **[Core/16/451-452]**

65. Second, the Tribunal's conclusory approach under 'Case 3' of its taxonomy misapplies the legal test in two ways:

(a) It places the justificatory burden on the defendant to explain why its prices are legitimate. This is an impermissible reversal of the burden of proof and offends against the presumption of innocence which applies in this quasi-criminal context.

(b) It in substance amounts to an imposition of the Cost-Plus test without (much) more, which is contrary to binding authority which makes clear that it is necessary to consider fairness separately from excessiveness (see §§47-51 above). In particular, at [152(5)], it is apparent that the Tribunal focuses on the key issue as being whether prices are high because a market is not contestable, in which case (it says) that "*the monopoly profits of the market incumbents are improperly maintained*". But that at most tells one whether an incumbent which has a dominant position has maintained profits which are excessive relative to costs in the Limb 1 sense. The presence of such excessive prices is an indicator that there is a market power problem (and ought to be a signal to third parties to enter the market).[11] But it does not follow that it can be automatically concluded that the prices are also unfair and so an abuse of dominance.

[Core/16/361-362]

66. Auden/Actavis's summary submissions at para. 6.1.3 of its Notice of Appeal are quoted at [338]. The Tribunal dismissed those points as a "*red herring*" ([336]). At [339], the Tribunal took Auden/Actavis simply to be saying that economic value ought to be ascribed to Auden/Actavis's hydrocortisone tablets on the basis that they are a life-saving drug, and stated that this circumstance "*does not justify a Seller charging more*". That conclusion in itself ignores demand-side factors and is wrong in law:

[RSupp/7/298] **[Core/16/459-460]**

(a) As the Tribunal held at first instance in ***Flynn/Pfizer***, it is wrong in principle to ascribe a value of nil to patient benefit. An attempt should be made to assess it on the basis of

[11] Cf G Niels *et al*, *Economics for Competition Lawyers* (3rd ed.), para. 5.259. **[Auth/86/2510-2511]**

qualitative factors. At trial, Auden/Actavis emphasised the relevance of comparators in this regard (addressed further below). It also referred to evidence on the level at which NICE considers life-saving medicines to represent good value (where they cost less than £20,000 per quality-adjusted life year).[12]

(b) Applying the factors identified by the Commission in ***Scandlines*** (see §57 above), it is clear that hydrocortisone tablets possessed considerable intrinsic value as a product. It would cost a great deal of money to develop them again from scratch if they did not exist. The mere fact that they are and were an old and off-patent drug makes no difference at all to that intrinsic value. There is no rule that a pharmaceutical company must immediately drop the price of a drug once its initial R&D investment has been recouped. Indeed, any such rule would be highly damaging as it would disincentivise the making of such investments in the first place (as well as disincentivising generic entry). The Tribunal's approach encourages a dangerous bias towards short-term efficiency at the cost of long-term dynamic competition.[13]

67. But the Tribunal also wholly ignored other important points made by Auden/Actavis:

(a) The life-saving medicine was present on the market at all only because Auden/Actavis had managed to secure and maintain an MA where others had not. Auden/Actavis acquired the MA and de-branded it, making it viable to continue to produce the medicine, in circumstances where the previous MA holder was simply going to "*delete*" it and pay "*internal costs of disposal*" (see §14 above). That is a critical feature of the case which the Tribunal simply ignored, contrary to its own recognition that "*the ability to supply an otherwise undifferentiated product when others cannot is, in our view, the provision of distinctive value*" under Case 2.

(b) Further, that MA was a full-label one. Auden/Actavis's product was the only full-label product on the market for many years (apart from Waymade's 20mg MA) even after the advent of generic entry. Whether or not it was wholly rational for prescribers, pharmacists and patients to value this, they did, and this factor went to the drug's economic value. Other hydrocortisone tablets available following generic entry did not have this benefit and so were not good comparators.

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[12] Auden/Actavis's Notice of Appeal, para. 84.3. **[CSupp/8/26] [RSupp/7/333]**

[13] R O'Donoghue & J Padilla, *The Law and Economics of Article 102 TFEU* (3rd ed.), 937-938. **[Auth/84/2498-2499]**

(c) The need in the pharmaceutical context to ensure that companies can make proper profits from valuable drugs is also reflected in Auden/Actavis's point that, like most pharmaceutical companies, it approached pricing during the material period on a portfolio basis. That means that excessive profits made in respect of one drug may not be unfair when viewed in context. Whilst Auden/Actavis did not provide detailed figures (because it did not contest the CMA's cost-plus analysis of excessive pricing under Limb 1), it did highlight this point because it made it especially important for the CMA and the Tribunal to consider comparators fairly under Limb 2.

68. Had the Tribunal properly enquired into demand-side factors, it would have concluded that there were reasons why customers would reasonably pay a higher price for Auden/Actavis's product in this case. It failed to carry out that enquiry, and failed to address itself to the portfolio pricing issue. In consequence, it failed properly or at all to assess whether Auden/Actavis's prices were unfair as opposed to merely excessive.

D3. Ground 1(b) – The Tribunal erred in failing to give any, or any proper, weight to comparators

69. It was imperative that the Tribunal, and the CMA, consider appropriate comparators in their evaluation of economic value. The Tribunal erred in law in failing to do so. Had the Tribunal properly taken appropriate comparators into account, including examination of the evidence relied on by Auden/Actavis (see §§29 and 31 above), it would have had to conclude that the CMA had not established that Auden/Actavis's prices were unfair.

Plenadren

70. The Tribunal inappropriately dismissed the relevance of Plenadren. Its only reason for doing so was its assertion that Plenadren's prices were not set in conditions of effective competition. But that is both wrong and conclusory:

(a) It is wrong, because Plenadren was in price-based competition with Auden/Actavis's product (as followed from the Tribunal's own conclusion in the context of market definition that Plenadren was a substitute product). The very reason why Plenadren's prescription numbers were so low was because CCGs universally required Auden/Actavis's product to be prescribed instead because it was cheaper and therefore represented relatively good value for money. To exclude Plenadren as a comparator on the basis that it was priced too high is to disregard the entire pricing dynamic

between Plenadren and Auden/Actavis's product which demonstrates the latter to be better value. It was wrong for the Tribunal to exclude this highly relevant comparator.

(b) It is conclusory, and unfairly so, because the standard imported by the Tribunal is that a product can only be a relevant comparator if its prices were set in conditions of 'effective' competition; but by definition, if one is at the 'is there an abuse?' stage of the analysis, one has concluded that the market is affected by the presence of a company which possesses market power. The Tribunal's approach sets an impossible standard preventing consideration of direct competitors.

Hydrocortistab

71. The Tribunal failed to consider Hydrocortistab at all notwithstanding Auden/Actavis's submissions and evidence, which included pointing out that Hydrocortistab was considered an appropriate pricing benchmark by Auden and other market participants at the time (see §31 above). That circumstance made it especially appropriate that Hydrocortistab be given careful consideration as a comparator, because the CMA's and the Tribunal's dismissal of it is contrary to market expectations.

72. The Tribunal's failure renders its assessment of fairness unjust because of a serious procedural or substantive irregularity, as well as wrong in law, because it did not consider a comparator relied on by the defendant as required by the Court of Appeal in ***Flynn/Pfizer***.

D4. Ground 1(c) – The Tribunal erred by failing to conclude that any unfair pricing abuse ended by the end of May 2015

73. As the Tribunal identified in ***Napp***, there is no unfair pricing abuse where it is likely that there will soon be effective competitive pressure bringing prices down. Finding the existence of an infringement in such circumstances would be very dangerous in economic policy terms, because high prices constitute important signals telling potential competitors when excessive profits are being made such that market entry is incentivised.

74. Here, the Tribunal ought to have concluded that any unfair pricing abuse ended by (approximately) the end of May 2015, because by (i) this point it was apparent that there would soon be effective competitive pressure to bring prices down, as the contemporaneous documents from Actavis's acquisition of Auden show.[14] Such

[14] See Document [00679] at Slides 2 and 4-7, and Decision, paras. 3.113 and 3.627 and fn 151.

competitive pressure merely reflected the gradual diminishment of the distinctive position of Auden/Actavis's product as competitor products arrived.

E. PENALTY

E1. Intention/negligence (Ground 2)

75. As noted, in Hydrocortisone 2, the Tribunal made the important factual finding that there was no intention/negligence on the part of Actavis for the period from 29 May 2015. However, at [159], it failed to quash the CMA's imposition of a penalty on Actavis in respect of the period after 29 May 2015. It should have concluded (as in fact appears to have been its intention so far as the 10mg Agreement was concerned) that the necessary statutory threshold condition for the imposition of a penalty was not met after this date. **[Core/17/615]**

76. For the avoidance of doubt, this point applies in respect of the Unfair Pricing Abuses as well (or at least the 10mg Unfair Pricing Abuse). By the time of Actavis's period of ownership, excessive prices were being maintained by the presence of the hidden 10mg Agreement (which was preventing generic entry). As a subsequent purchaser, Actavis could not have known this. Actavis inherited the prices that Auden had been charging, which within a matter of months began to fall with the new entry. The fundamental change in the facts on the ground which occurred with the departure of Mr Patel means that there is no discernible intention or negligence after 29 May 2015.

E2. The specific deterrence uplift (Ground 3, first point)

77. Auden/Actavis appeals in respect of each penalty imposed by the CMA, but also says that each penalty must be assessed in light of the totality of the penalties imposed. The Tribunal must consider whether the overall penalty is disproportionate or excessive, making its own assessment on the merits, and, if it considers that it is, it should examine the CMA's approach in order to determine where error has crept in.[15] In carrying out this exercise the Tribunal is not seeking to identify an abuse of discretion on the part of the CMA, but is exercising its "*undoubted jurisdiction to reach its own independent view as to what is a just penalty in the light of all the relevant factors*".[16]

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[15] ***Kier Group v OFT*** [2011] CAT 3, [74]-[77]. **[Auth/24/701-703]**

[Auth/24/702-703] [16] ***Kier Group***, [76]. The Tribunal observed in ***Roland v CMA*** [2021] CAT 8 at [32] that this is consistent with the requirement to examine liability on the merits. **[Auth/50/1333]**

78. In particular, the CMA's uplifts at 'Step 4' in the name of specific deterrence are disproportionate and should be set aside. The uplifts have been described at §40 above. They are nothing short of extraordinary. There is a 116% uplift for Periods A1 and A3; a 457% uplift for Period A2; a 400% uplift for Period A4, including the component for which Intas is jointly and severally liable; and a 100% uplift for Period B2.

79. The increases reflect the 400% uplift applied to Pfizer in the CMA's phenytoin decision about which the Tribunal expressed scepticism in ***Flynn/Pfizer*** (at [461]: "*…we would likely have regarded the very substantial uplift for deterrence applied to Pfizer as, on its face, difficult to justify and not required by the CMA's own penalty guidance…*"). In particular, the Tribunal noted in ***Flynn/Pfizer*** that the need for specific deterrence had anyway been reduced owing to the new price control powers conferred on the DHSC. **[Auth/39/ 1084-1085]**

80. In ***Liothyronine*** [2023] CAT 52 at [488], the Tribunal observed, in relation to substantial uplifts imposed on penalties in another pharmaceuticals excessive pricing case: "*The fundamental issue raised in relation to the deterrence uplift is whether an uplift is necessary in order to deter them from anti-competitive conduct in the future.*" In that case, the penalty sums reached at Step 3 were already enough to deprive the appellants of the financial benefits calculated by the CMA. The CMA gave no specific reason to think that the appellants were at risk from infringing competition law again in the future, and indeed the DHSC possessed specific powers enabling it to control prices. In the absence of a need for individual specific deterrence, the uplift could not be justified ([489]-[496]). **[Auth/53/ 1602]** **[Auth/53/ 1602-1603]**

81. This is not a case which requires any specific deterrence at all in respect of Actavis (as opposed to general deterrence), the entity actually being fined (and not Auden):

    (a) The DHSC undoubtedly possesses relevant price control powers in this case: Hydrocortisone 1, [100]-[104]. **[Core/16/340-341]**

    (b) In respect of the 10mg Agreement, and as set out under Ground 2, Actavis is being fined only as Auden's economic successor and not on the basis of its own conduct (since it did not itself possess any intention or negligence in respect of its period of ownership of Auden). The 20mg Agreement likewise ended before 29 May 2015 and so before Actavis can have been responsible.

    (c) As to the Unfair Pricing Abuses, and even assuming Actavis acted intentionally or negligently after 29 May 2015 *contra* Ground 2 above, Actavis did not instigate the

conduct in question and imminent generic entry to rapidly erode prices was anticipated. At most, Actavis failed to bring prices down even quicker.

(d) The idea that Actavis itself received significant financial benefit is also misconceived. Actavis paid money to purchase what it thought was a profitable business and thus paid sums representing the value of future expected financial benefit when it purchased Auden. It did not of course benefit from sums received by Auden before 29 May 2015. Further, because of its portfolio pricing approach, by which profits from hydrocortisone tablets were used to cover lower prices on other drugs, looking only at the financial benefit from hydrocortisone tablets gives an unfair picture overall. The financial benefit figures which the CMA used do not therefore in any sense reflect sums received by Actavis which can be disgorged.

(e) The CMA gives no specific reason for thinking that Actavis will engage in any further breaches of competition law in the future (nor could it plausibly do so).

82. The Tribunal ought therefore to have set aside the penalty imposed by the CMA and either directed the CMA to retake it, or retaken it itself, on the basis that:

(a) The <u>total</u> penalty (across all four infringements) should not have been uplifted to a level materially in excess of the financial benefit purportedly received by Actavis; and

(b) The financial benefit received by Actavis should have been calculated taking into account its actual position, including the points identified in the preceding paragraph.

E3. The imposition of four separate penalties (Ground 3, second point, and Ground 4)

83. It is wrong in principle and disproportionate for the CMA to fine Actavis four times over in respect of what ought to be regarded as a single course of conduct concerning the same drug (exceeding its statutory cap multiple times) and ultimately relating to the same harm. The CMA's approach imposes an excessive burden on Actavis and therefore fails to achieve the purpose of the statutory cap under s.36(7) of the Competition Act 1998.[17] In particular, the Tribunal erred in holding, at [15(1)] of Hydrocortisone 4, that it was appropriate for the CMA to impose penalties for each separate infringement, and at [15(4)] in finding that this approach did not obviate the statutory cap. **[Auth/67/ 2244-2245]** **[Core/18/ 624-625]**

[17] ***Eden Brown v OFT*** [2011] CAT 8, [57]; ***FP McCann Ltd v CMA*** [2020] CAT 28, [94].

[Auth/27/744] **[Auth/49/1310]**

84. **First**, the CMA's decision to treat the 10mg and 20mg infringements as separate (and the Tribunal's endorsement of that decision) is wrong. There was in essence one course of conduct. At trial, for example, the CMA's case was that the 10mg Agreement was an "*extension*" of the 20mg Agreement (Defence, paras. 49-56). **[RSupp/9/500-502]**

85. Further, the Tribunal has now found (in Hydrocortisone 1) that the two strengths formed part of the same product market throughout (contrary to the CMA's approach). The Tribunal's approach to penalties should have reflected this finding. It was wrong in principle to find two separate infringements in relation to conduct concerning two strengths of the same drug on the same product market. It was also contrary to the CMA's April 2018 Penalty Guidance,[18] which assumes that an infringement will be found on a particular product market. It provides a definition of "*relevant turnover*", applicable under Step 1, in which context it specifically refers to the statutory cap calculation (at para. 2.13). Referring to *Market Definition* OFT43 (i.e., the usual competition law approach to market definition), the CMA says at para. 2.11: "*The relevant turnover is the turnover of the undertaking in the relevant product market and relevant geographic market affected by the infringement in the undertaking's last business year.*"

[Auth/82/2462-2489] **[Auth/82/2476]** **[Auth/77/2352-2378]** **[Auth/82/2475]**

86. **Second**, the CMA's decision to treat the Unfair Pricing Abuses and the Agreements as comprising distinct courses of conduct meriting distinct fines was wrong. The Agreements would have had no purpose had the goal not been to protect the high prices being charged by Auden/Actavis for hydrocortisone tablets. Accordingly, they formed part of the same essential course of conduct and caused the same harm (and obtained the same financial benefit). The CMA itself acknowledges that each Agreement "*sustained a separate Unfair Pricing Abuse*" (Decision, para. 10.153, final bullet), and that the financial benefits obtained through each infringement were one and the same (Decision, para. 10.311). It gives no sensible reason for why Actavis's fine should exceed its statutory cap so substantially where the conduct in respect of which it is being fined is so closely connected.

[Core/23/1669] **[Core/23/1722]**

87. The approach taken in other cases has been to impose a single fine in respect of conduct (or indeed multiple types of conduct) affecting multiple strengths of a drug. For example:

    (a) In ***Napp***, the OFT treated as one single infringement for penalty purposes a case combining both exploitative (excessive pricing) and exclusionary (predatory pricing)

[18] See fn 7 above. The December 2021 edition is unchanged on this point: see para. 2.10. **[Auth/85/2507]**

abuse relating to oral sustained release morphine tablets and capsules, across all strengths – notwithstanding the OFT's express recognition that Napp targeted its pricing strategies differently across different strengths because it faced different competitive pressures in respect of each: see [2002] CAT 1, [36]. **[Auth/7/345]**

(b) In ***Flynn/Pfizer*** the CMA found four separate infringements – one in respect of each affected strength of phenytoin: see Decision in Case CE/9742-13, paras. 2.2 and 2.5. **[Auth/73/2289-2290]** However, recognising that, in each case, "*all four [of the relevant infringements had] taken place in the same relevant product and geographic market*", the CMA issued a single fine: paras. 7.60-61. The CMA took the same approach in the retaken Decision **[Auth/73/2291]** in Case 50908, at paras. 9.81-9.82. **[Auth/75/2348]**

(c) In ***Paroxetine***, the CMA's decision concerned GSK's drug Seroxat which was sold in 20mg and 30mg tablets and a 20mg oral liquid formulation: see Decision in Case CE-
[Auth/72/2279] 9531/11, para. 3.22. Different price trends were observed in each case (paras. 3.387- **[Auth/72/2284-2287]** 390). Further, the effect of each infringing 'pay-for-delay' agreement was to postpone generic entry in respect of each strength: see Table 3.3 at para. 3.383. However, the **[Auth/72/2281]** CMA did not find separate infringements in respect of each strength.

88. The CMA does not even begin to establish why a different approach is merited in this case, not least given that it results in Actavis being fined at over twice its statutory cap just for the periods prior to 9 January 2017, and nearly four times overall including Period A4. The Tribunal was wrong to endorse that approach, in particular given its conclusion that 10mg and 20mg tablets were in the same product market. It is contrary to the purpose of the legislation which imposes the statutory cap. The CMA has no discretion to exceed the statutory cap in relation to any individual penalty[19] and it is wrong in law for the CMA to seek to circumvent that hard limit by technically finding four separate infringements. In any event, for the same reasons, it results in a disproportionate outcome because it imposes an excessive burden which the Tribunal ought to have remedied.

F. CONCLUSION

89. This Court is respectfully invited to uphold Auden/Actavis's appeal on all grounds.

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[19] ***Napp v DGFT*** [2002] CAT 1, [501]; ***Aberdeen Journals v DGFT (No 2)*** [2003] CAT 11, [489]. **[Auth/7/392-393]**

[Auth/8/412]

SARAH FORD KC

CHARLOTTE THOMAS

Brick Court Chambers

18 March 2025