IN THE COURT OF APPEAL (CIVIL DIVISION) **Appeal Nos. CA-2025-000630**

CA-2025-000642

CA-2025-000644

ON APPEAL FROM THE COMPETITION APPEAL TRIBUNAL

Sir Marcus Smith, Professor Simon Holmes, Professor Robin Mason

[2023] CAT 56; [2023] CAT 57; [2024] CAT 29

AUDEN MCKENZIE (PHARMA DIVISION) LIMITED & OTHERS

(together "Auden")

ALLERGAN UNLIMITED COMPANY (formerly ALLERGAN PLC)

("Allergan")

INTAS PHARMACEUTICALS LIMITED & OTHERS

(together "Intas")

Appellants

-and-

THE COMPETITION AND MARKETS AUTHORITY ("CMA")

Respondent

THE CMA'S SKELETON ARGUMENT

References to the appeal bundles in this case are in the following format:
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- To the Reference Supplementary Bundle: [RS/Tab/Page]
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A. INTRODUCTION AND SUMMARY OF THE ISSUES ON THESE APPEALS

1. This is a case in which an undertaking (Auden/Actavis) acquired the licence to sell hydrocortisone tablets ("**HTs**"), an essential drug for the treatment of a life-threatening condition, and then introduced a series of massive price increases, from 70p per pack (the price being charged by the previous supplier in 2008) to a peak of £72 per pack (in 2016). It is common ground that those price increases – which were borne by the National Health Service - were not based on any increase in costs, or any investment or innovation in respect of the drug concerned. The price increases were imposed in a landscape where Auden/Actavis initially had a monopoly over the supply of HTs. Even after some competitive entry occurred in 2015, Auden/Actavis remained dominant and continued to impose unfairly high prices, charging its captive customer base a significant price premium compared to the prices charged by competing suppliers of bioequivalent versions of the same drug.

2. By its decision dated 15 July 2021 in Case 50277 (the "**Decision**") **[CB/23/649-1749]**, the CMA found that Auden/Actavis' conduct, lasting almost a decade, amounted to excessive and unfair pricing within the meaning of the CJEU's seminal judgment in *United Brands v Commission* [1978] 1 CMLR 429 ("***United Brands***") **[AB/1/8-87]**, as authoritatively considered by this Court in *CMA v Flynn Pharma and Pfizer* [2020] EWCA Civ 339, [2020] Bus LR 803 ("***Flynn CA***") **[AB/48/1228-1302]**. The Decision imposed substantial financial penalties on the corporate entities that were members of the undertaking that committed the abuses.

3. By its judgment dated 18 September 2023 (referred to herein as "**H1**"[1]), the Tribunal upheld the CMA's core findings that Auden/Actavis was dominant and had engaged in abusively high pricing, and affirmed the penalties imposed by the CMA in respect of the abuses. In so doing, the Tribunal vividly described the pattern of Auden/Actavis' pricing as the "Matterhorn", as illustrated (for example) in the graph at Annex 4A of the H1 judgment **[CB/16/516].**

4. In essence, the Tribunal agreed with the CMA that there was no legitimate explanation for the "Matterhorn"; rather, as the Tribunal found in H1 at [376(2)] **[CB/16/472]**, Auden/Actavis'

1 Distinguishing it from subsequent judgments of the Tribunal in the same case dated 29 September 2023 [2023] CAT 57 ("**H2**") **[CB/17/522-616]**, 8 March 2024 [2024] CAT 17 ("**H3**") **[AB/56/1615-1709]** and 29 April 2024 [2024] CAT 29 ("**H4**") **[CB/18/617-626]**.

prices reflected the unlawful exploitation of its market power.

5. This is a classic case of a finding by a specialist tribunal with which the Court of Appeal should be slow to interfere, all the more so when that finding was made following a trial of several weeks' duration, by reference to a range of factual and expert evidence and extensive written and oral submissions: cf. *National Grid Plc v Gas & Electricity Markets Authority & Ors* [2010] EWCA Civ 114, [2010] UKCLR 386, per Richards LJ at [22] – [26] **[AB/20/643-645]**. Given the extreme and largely undisputed facts of the case, the CMA's overall submission on these appeals is that the Tribunal was not only entitled but correct to uphold the CMA's findings in respect of Auden/Actavis' pricing.

6. It should be noted that the Decision additionally found that Auden/Actavis and certain other undertakings had engaged in related anti-competitive agreements (one concerning 10mg tablets, and another concerning 20mg tablets) designed to preserve Auden/Actavis' monopoly over the supply of HTs. The CMA's findings in respect of the 10mg agreement were overturned by the Tribunal on procedural grounds, but were subsequently considered and upheld by the Court of Appeal.[2] There was no appeal against the CMA's substantive findings regarding the 20mg agreement.

7. Against that background, the present appeals are brought by various corporate groups who were members of the Auden/Actavis undertaking and held liable for the abuses of dominance during their respective periods of ownership. The Appellants' grounds of appeal (which overlap in various respects) divide into infringement issues and penalty issues.

8. As respects the **infringement** issues, all of the Appellants challenge aspects of the Tribunal's analysis of unfair pricing. Intas also advances a discrete challenge in respect of the Tribunal's analysis of dominance, during the so-called "Intas Period" only. The CMA's case is that there was no material error of law in the Tribunal's analysis of the relevant issues. However, to the extent necessary, the CMA also submits that the Tribunal's decision to dismiss the appeals against the CMA's findings of abuse should in any event be upheld for different/additional reasons from those set out in H1: see the CMA's Respondent's Notice **[CB/4/57-75]**, and the evidence and findings from the Decision referred to therein. The findings in question were

[2] *Allergan plc & Ors v CMA ("Hydrocortisone CA")* [2024] EWCA Civ 1023 **[AB/57/1710-1749]**. The infringing parties' applications for permission to appeal against the Court's order were refused by the Supreme Court on 15 January 2025.

either not disputed before the Tribunal or were endorsed by the Tribunal in H1.

9. The **penalty** issues comprise a range of challenges to different aspects of the Tribunal's decisions affirming the penalties imposed by the CMA. The challenges involve a mixture of points of principle (for example, concerning the meaning of an intentional infringement, and the factors that are relevant to the adjustments made for specific deterrence) and specific complaints about the calculation of the penalties imposed on the Appellants. In the CMA's submission, all of the many complaints advanced by the Appellants should be rejected for the reasons given in H1 and H4 and (to the extent necessary) in the CMA's Respondent's Notice.

10. The remainder of this skeleton argument is structured as follows:

    a. **Section B** summarises the relevant factual background to these appeals, by reference to the some of the key findings in the Decision.

    b. **Section C** summarises the relevant parts of the Tribunal's judgment in H1.

    c. **Section D** deals with the Appellants' challenges to the Tribunal's findings on the infringement issues.

    d. **Section E** addresses the penalty issues raised by the Appellants.

B. FACTUAL BACKGROUND AND KEY FINDINGS IN THE DECISION

11. The following points are taken from the Decision and, unless otherwise indicated, are not in dispute for the purpose of these appeals.

12. HTs are an essential life-saving medicine on which tens of thousands of patients depend for the treatment of adrenal insufficiency, including conditions such as the life-threatening Addison's Disease.[3] They were first sold in the UK in 1955, under the brand name *Hydrocortone*, and the relevant patents had all expired by the 1970s. The drugs had thus long ago entered the 'third stage' of the drug lifecycle, where the price of even essential drugs is expected to be kept low by competition.[4] In 2007, over 50 years after they were first sold, the price of HTs was less than 70p per pack of 10mg tablets, and £1 per pack of 20mg tablets.[5]

13. In April 2008, Auden/Actavis purchased the licences to sell HTs from the company that first

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3 Decision, §1.8 **[CB/23/659]**.

4 Decision, §1.16 **[CB/23/660]**; see also H1, [152(3)(ii)] **[CB/16/360]**.

5 Decision, §1.16 **[CB/23/600]**.

brought them to market in 1955. Within days, Auden/Actavis discontinued the brand, thus removing the drug from price regulation, and instead launched generic versions of the drug.[6] Over the next eight years, Auden/Actavis introduced hefty price increases for both 10mg and 20mg tablets, as summarised at Decision, §§1.22 – 1.23 and Figures 1.1 and 1.2[7] **[CB/23/662-663]**.

14. Auden/Actavis initially staved off competitive entry from rival suppliers of generic HTs by entering into anti-competitive arrangements, paying certain suppliers in return for their agreeing to stay out of the market.[8] As noted above, the CMA's findings that these arrangements infringed the Chapter I prohibition have already been upheld following appeals to the Tribunal and the Court of Appeal.

15. From October 2015 onwards, other generic suppliers began to enter the market.[9] Auden/Actavis initially continued to raise their prices. Even when prices began to fall from their apex, Auden/Actavis continued to charge prices at a substantial premium above the prices charged by rival suppliers, while retaining significant market share, and continuing to make large profits. It was able to do so due to a quirk of the regulatory regime. In particular, due to an "orphan designation" granted to a different and innovative hydrocortisone product called Plenadren, no new licences for the treatment of adrenal insufficiency in adults could be granted for a ten-year period after November 2011. Auden/Actavis had nothing to do with the orphan designation granted to Plenadren. Yet, because Auden/Actavis already held a "full label" licence, it was the only supplier able to market 10mg HTs for adrenal insufficiency in adults, and one of only two suppliers able to do so for 20mg tablets (in circumstances where 10mg tablets account for 96% of all HTs dispensed: Decision, §1.46 **[CB/23/667]**), until the expiry of Plenadren's orphan designation. In contrast, new entrants were only able to obtain so-called "skinny label" licences, meaning that they could not market their (bioequivalent) tablets as being for the treatment of adrenal insufficiency in adults. While some customers were prepared to switch to purchasing skinny label tablets, wholesalers and pharmacies accounting for around 50% of purchases of HTs by volume were not, based mainly on their

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6 Decision, §§1.17 – 1.18 **[CB/23/601]**.

7 Decision, §1.24 **[CB/23/663]**. See also H1, [121] **[CB/16/349]** and Annex 3 at pages 188 – 204 **[CB/16/481-497]**.

8 As summarised at Decision, §§1.26 – 1.33 **[CB/23/663-665]**.

9 Decision, §3.180(a) **[CB/23/740]**.

assessment of the regulatory risks of "off-label" dispensing. These customers therefore had no choice but to purchase a very large proportion of their HTs from Auden/Actavis, creating an "assured customer base" for Auden/Actavis, and conferring the market power that enabled it to continue to charge supra-competitive prices for a lengthy period following competitive entry.[10]

16. Applying the Chapter II prohibition to the facts found in the Decision, the CMA found that:

    a. Auden/Actavis occupied dominant positions on relevant markets for the supply of (i) 10mg HTs (from 1 October 2008 until 31 July 2018) and (ii) 20mg HTs (from 1 October 2008 until 8 January 2017).

    b. Auden/Actavis charged prices for both 10mg and 20mg tablets that were excessive within the meaning of Limb 1 of *United Brands*, in that they exceeded the relevant costs of supply (including an allocation of common costs and a reasonable rate of return) by 702% per pack for 20mg tablets, and by 879% for 10mg tablets.[11] The CMA's findings on Limb 1 were not challenged before the Tribunal.[12]

    c. Those excessive prices were unfair both in themselves[13] and when compared to the "current" prices of competing HTs.[14] The CMA considered that other products (including Plenadren) were not meaningful comparators for these purposes.[15]

    d. Moreover, there were no demand-side factors which increased the economic value of Auden/Actavis' HTs beyond that already captured in the CMA's cost-plus measure, having

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10 See the summary at Decision, §§1.34 – 1.46 **[CB/23/665-667]**; see also H1, at [140], [243(8)(v)(c)] **[CB/16/354, 411]**. The existence of the "assured customer base" is disputed by Intas: see below.

11 Decision, Table 5.4 **[CB/23/1090]**.

12 As recorded in H1, at [302] **[CB/16/444]**.

13 See the summary at Decision, §§5.296(a)-(f) **[CB/23/1151-1152]**.

14 See Decision, §§5.376 – 5.400 **[CB/23/1173-1180]**. "Current" prices, for the purposes of the Decision and this skeleton, mean the weighted average prices of "skinny label" tablets for the period from February to April 2021 and the weighted average prices of full label 20mg tablets supplied by Waymade for the period from May to July 2020: see Decision, §5.393 **[CB/23/1178]**.

15 Decision, §§5.401 – 5.429 **[CB/23/1181-1187]**.

regard to (i) the age of HTs and their position in the "drug lifecycle", (ii) the current prices of competing HTs and (iii) the erosion of Auden/Actavis' own prices down towards the CMA's cost-plus measure.[16]

e. Importantly, the CMA did not find that any prices above its cost-plus measure were *ipso facto* unfair. Rather, by reference to its administrative priorities, the CMA did not reach a view on whether Auden/Actavis' prices were excessive and unfair until they reached £20 per pack, which was 285% above the upper bound of the CMA's cost-plus measure (a measure which already included a generous reasonable rate of return).[17]

f. The CMA's key findings on unfair pricing are summarised at §§5.1 – 5.20 of the Decision **[CB/23/1070-1075]**. Figures 5.1 and 5.2 **[CB/23/1073]** illustrate the stark reality of Auden/Actavis' pricing for 10mg and 20mg tablets. The following table taken from the Decision summarises some of the core evidence relied on by the CMA:

Table 5.3: evidence relied on by the CMA in reaching its conclusions that Auden/Actavis's prices were excessive and unfair

	10mg	20mg
Auden/Actavis's prices during the Unfair Pricing Abuses	**£20 - £72.14**	**£20 - £72.19**
Cost Plus	£2.17 - £4.45	£2.91 - £5.20
Current average price of skinny label tablets*	£1.34	£1.85
Current price of Waymade's full label tablets**	N/A	£1.40
Actavis's current prices*	£2.99	£1.91
Auden's entry price	£4.54	£5.14
Allergan's projected prices following competitive entry	£5.20	£6.10

* Weighted average from February to April 2021
** Weighted average from May to July 2020 because Waymade made no sales after July 2020, see Document 206689, Waymade's response to question 4 of the CMA's section 26 notice dated 9 June 2021.

C. THE TRIBUNAL'S JUDGMENT IN H1

17. In H1, the Tribunal disagreed with the CMA on its approach to market definition, finding *inter alia* that the relevant product market encompassed not only HTs but also Plenadren: see

16 See the summary at Decision, §5.433 **[CB/23/1188-1189]**.

17 Decision, §§5.18 – 5.19 **[CB/23/1075]** and §5.271 **[CB/23/1145]**.

H1, Section H **[CB/16/373-417]**. This part of the judgment is not under appeal.

18. The Tribunal nevertheless upheld the CMA's finding that Auden/Actavis occupied a dominant position throughout the period covered by the Decision.[18] The Tribunal had "*primary regard*" to market shares, but also relied on the fact that skinny label suppliers laboured at a "*competitive disadvantage*" when compared to Auden/Actavis' full label licence, meaning that "*when there was competition, it was of limited effect, and that is reflected in the market shares that we have recorded*".[19] This was a reference to the Tribunal's earlier findings of fact on the "assured customer base", i.e. those pharmacies and wholesalers who were not willing to switch to skinny label suppliers despite the fact that skinny label HTs were so much cheaper than the Auden/Actavis product. Inexplicably, Intas suggests that this aspect of the Decision was not upheld,[20] despite the Tribunal's clear endorsement of the CMA's findings: see e.g. H1, [235], [236], [243(8)(v)(c)], [294] **[CB/16/404, 409-411, 442]**. While expressing caution about relying on pricing factors as evidence of dominance in an excessive pricing case, the Tribunal also regarded it as "*clearly…relevant*" that Auden/Actavis was able to increase the price of its tablets so substantially, without demand falling away, in circumstances where regulatory and competitive constraints on Auden/Actavis were "*either minimal or non-existent*".[21]

19. In relation to abuse, having affirmed the CMA's unchallenged findings on Limb 1 of *United Brands*,[22] the Tribunal turned to Limb 2 and the question of unfairness. The Tribunal focused in particular on the question of economic value:

    a. The Tribunal began by dismissing what it described as a "*red herring*", namely the Appellants' contention that the CMA had failed to take account of the value placed on HTs by patients, to whom those tablets are a life-saving drug. The Tribunal did not accept that this factor justified Auden/Actavis' pricing, for the reasons explained at H1 [339(1)-(4)]

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18 H1, at [296] **[CB/16442-443]**.

19 H1, at [294] – [295] **[CB/16/442]**.

20 Intas skeleton, §19.1 **[CB/7/136]**.

21 H1, at [291] – [292] **[CB/16/441]**.

22 H1, at [333] **[CB/16/458]**, describing the CMA's findings on the excessive limb as "*plain to the point of irrefutability*".

[CB/16/460].

b. The Tribunal then considered whether any economic value over and above the CMA's cost-plus measure was provided in this case, emphasising that the question at this stage of the enquiry is not "*Does Price exceed Cost?*" but rather "*Why does Price exceed Cost?*".[23]

c. In answering that question, the Tribunal had regard to a taxonomy of three "cases" in which prices might exceed costs.[24] Having discounted "Case 1", where price exceeds cost due to relative efficiencies between sellers, as an explanation for the excessive prices in this case (the Tribunal's finding on this point has not been challenged),[25] the Tribunal turned to consider whether Auden/Actavis' prices fell into Case 2 (involving the provision of "*distinctive value*", in the sense of something that buyers wish to purchase from a seller in contradistinction to the offerings of other sellers[26]) or Case 3 (where a seller possesses market power that does not generate additional value for buyers).[27]

d. It was in this context that the Tribunal focused on the so-called "Matterhorn", and the potential explanation for the observed patterns in Auden/Actavis' pricing. Having noted that the prices were already well in excess of cost-plus in the periods which "*bookended*" the Matterhorn, the Tribunal considered it "*telling*" that "*none of the Appellants [had] 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*".[28] The present case contained no features (e.g. a sudden and unexpected increase in demand, as in the example of the supply of face masks during the COVID-19 pandemic) which might have provided a legitimate explanation for the extreme slopes of the Matterhorn; the only credible explanation was an abuse of dominance.[29] The Tribunal considered Auden/Actavis' prices to be unfairly high throughout the period under

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23 H1, at [340] **[CB/16/460-461]**.

24 The three-case taxonomy is first set out at H1, at [322] **[CB/16/449-452]**.

25 H1, at [333] **[CB/16/458]**.

26 H1, at [322(2)] **[CB/16/450-451]**.

27 H1, at [322(3)] **[CB/16/452]**.

28 H1, at [342(2)] **[CB/Tab16/461-4622]**.

29 H1, at [342(3)] **[CB/16/462]**.

consideration, including the period where prices were falling downwards.[30]

20. The Tribunal did not consider the prices of other products (including Plenadren) to be of assistance in assessing the fairness of Auden/Actavis' prices. That is because, for reasons given "*at length*" earlier in the judgment, "*the prices of medicinal products in the market were not competitive prices, but were distorted for reasons that we have given*". In contrast, the Tribunal agreed with the CMA that the prices of Auden/Actavis' own HTs "*act as their own comparators, when considered on a temporal basis*", in circumstances where those prices were "*so low*" and "*approach[ed] Cost much more closely*" on "*either side of the "Matterhorn"*".[31]

D. THE INFRINGEMENT ISSUES

21. The various grounds of appeal on infringement issues can be conveniently grouped as follows:

    a. Auden's and Allergan's challenge to the Tribunal's "three-case" taxonomy for assessing economic value, including their argument that the Tribunal reversed the burden of proof;

    b. Arguments that the Tribunal failed to take account of patient benefit and other sources of economic value;

    c. Challenges to the Tribunal's assessment of comparators;

    d. Challenges to the Tribunal's finding of abuse during the period following competitive entry;

    e. Intas' challenge to the Tribunal's finding of dominance during the Intas Period;

    f. Other Intas-specific points concerning unfair pricing during the Intas Period, including Intas' argument that Auden/Actavis' prices were not "*imposed*" on customers within the meaning of section 18(2)(a) of the 1998 Act (part of Intas ground 2).

22. These issues are considered in turn below.

(a) Challenges to the Tribunal's three-case taxonomy for assessing economic value

23. Auden and Allergan (but not Intas: see below) characterise the Tribunal's three-case taxonomy for considering economic value as a new "*test*" for unfair pricing. Auden contends

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30 H1, at [342(4)] **[CB/16/462]**.

31 H1, at [347]-[350] **[CB/16/463]**.

that this allegedly novel approach is contrary to binding Court of Appeal authority, namely *Flynn CA* and *Attheraces v British Horseracing Board Ltd* [2007] EWCA Civ 38, [2007] Bus LR D77 ("***Attheraces***") **[AB/18/565-621]**, and that it "*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*": Auden skeleton, §§63 – 64 **[CB/5/92-93]**. A similar contention is advanced at Allergan skeleton, §29 **[CB/6/114]**. Auden and Allergan also each contend that the Tribunal's approach amounted to a reversal of the burden of proof: Auden skeleton, §65(a) **[CB/5/93]** and Allergan skeleton, §§30-36 **[CB/6/115-116]**.

24. It is understandable that Auden and Allergan should seek to characterise the Tribunal as having laid down a novel legal test for unfair pricing, given that the Court of Appeal's jurisdiction is confined to points of law only. On a proper analysis, however, the Tribunal directed itself in accordance with the prior case law. Thus:

    a. At [325], **[CB/16/453]** by reference to *Flynn CA*, the Tribunal correctly encapsulated the nature of the overall test for unfair pricing: "*the test for abusive pricing is fairness, which implies a respect for the legitimate interests of both Buyers and Sellers*" (emphasis in original).[32]

    b. At [327] **[CB/16/454]**, by reference to *Attheraces*, the Tribunal considered the nature of the two different limbs of the *United Brands* test for unfair pricing. At [327(1)], the Tribunal rightly described the first limb (whether prices are excessive by reference to costs) as a "*threshold condition*" which is necessary but not sufficient to establish unfair pricing. And at [327(2)], the Tribunal correctly stated that the central concept under the second limb of *United Brands* is not cost or profit but economic value. In that context, the Tribunal specifically recognised that "*where a competitive market would result in Prices which are significantly above Cost, then Sellers ought to be entitled to hold on to the profits that they would thereby obtain*": [327(2)(ii)] **[CB/16/455]**.

    c. The Tribunal's articulation of the relevant legal principles was thus expressly informed by, and fully consistent with, the very Court of Appeal authorities from which it is said to have departed.

25. As respects the Tribunal's three-case taxonomy, this was not presented as a legal test for unfair pricing (let alone a novel test), but rather as a set of "*reasons*" why prices might exceed

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[32] See further *Flynn CA*, §97. **[AB/48/1256-1257]**

cost in real-world markets where the conditions of perfect competition do not obtain: [322] **[CB/16/449]**. In framing the issue in this way, the Tribunal's approach was consistent with *Flynn CA*, which makes clear that the task under Limb 2 of *United Brands* is to consider whether there are any "*other factors*" which might serve to "*justify the price charged as fair and not abusive*": *Flynn CA* at [97(v)] **[AB/48/1256]**.

26. Further, *pace* Auden's and Allergan's submissions, the three-case taxonomy does not disregard demand-side value. To the contrary, as Auden effectively concedes at §64 of its skeleton **[CB/5/92-93]**, the Tribunal's "Case 2" specifically describes a situation in which the seller generates "*distinctive*" value for which buyers will pay a premium, and recognises that this constitutes, in principle, a legitimate reason why prices may exceed costs (albeit that a price may still be too high to be justifiable in this scenario too [323(1)] **[CB/16/452]**). The Tribunal's concept of distinctive value is broad, not narrow, and does not exclude *a priori* any particular aspect of the seller's offering. Rather, it covers *"any definable aspect of the Seller's offering that adds value to the Buyer*" (emphasis in original).

27. The demand-side factors identified by the Tribunal at [322(2)] **[CB/16/450-452]** as potentially justifying prices in excess of cost are also consistent with the European Commission's encapsulation of the legal position at recital (163) of its commitments decision in *Aspen*[33], where the Commission explained that the purpose of the Limb 2 enquiry is to examine whether there may be "*legitimate reasons underlying the excessive profits identified under Limb 1, in particular reasons not yet reflected in the cost analysis in Limb 1*"; such reasons may include "*superior efficiencies*" on the part of the dominant undertaking, or the fact that the dominant undertaking has "*taken risks, made investments, improved a product or innovated in a way that could render high profits, partially or entirely, a legitimate reward for pro-competitive efforts*", although it is "*important to note…that even these reasons do not legitimise the charging of a price at any high level*".[34]

28. Notably, despite professing to adopt Auden's and Allergan's criticisms of the Tribunal's three-case taxonomy (Intas skeleton, §31**[CB**/7/**140]**), Intas in fact endorses the Tribunal's concept of "*distinctive value*" (Case 2) as consistent with the Court of Appeal's description of economic value as "*an economic concept which describes what it is that users and*

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33 Case AT.40394 – *Aspen* decision dated 10 February 2021, C(2021) 724 final **[AB/74/2292-2346]**.

34 Ibid, at recital (163) **[AB/74/2324]**.

customers value and will reasonably pay for" in *Flynn CA* at [171] **[AB/48/1279]**: see Intas skeleton, §32 **[CB/7/141]**. The CMA agrees.

29. Contrary to a suggestion at Auden skeleton, §65(b) **[CB/5/93]**, the Tribunal's three-case taxonomy also does not amount "*in substance*" to the imposition of a pure cost-plus test. Auden alights on [152](5) of H1 **[CB/16/361-361]** which distinguishes between (i) a situation in which temporarily high prices attract competitive entry (as in the Tribunal's "face mask" example) and (ii) a situation in which a market is not "*properly contestable*" due to barriers to entry, such that "*the monopoly profits of the market incumbents are improperly maintained, and an abuse of dominance is more likely to exist*". But the Tribunal did not here suggest that a dominant firm is precluded from charging prices above costs merely because it holds a dominant position. At the same time, the Tribunal was obviously correct to identify the contestability or otherwise of the market as an important consideration in deciding whether prices are, in fact, unfair and abusive. See e.g. *Albion Water* [2008] CAT 31 at [266], emphasising the need to take account of the "*competitive conditions*" when "*assessing the relationship between the disputed price and the economic value of a service, and thus the potential unfairness of a price*" **[AB/19/636]**.

30. Although the Tribunal's taxonomy was not one that was suggested by the CMA, the CMA considers that it provides a useful articulation of the essential question that arises under Limb 2 of *United Brands*, namely why it is that a price materially in excess of cost has been charged, and whether this excess is legitimate. The CMA respectfully agrees with the observations concerning the three-case taxonomy made by a differently-constituted Tribunal in *Le Patourel*, which described the concept of "*distinctive value*" from H1 as a "*useful yardstick by which to measure that value in the product which is different to its cost (as established for these purposes by the relevant competitive benchmark under Limb 1) and which is something in some way different from the offerings of other sellers, but which can include the brand or other value ascribed subjectively by the consumer for the product, as distinct from the product's particular features*".[35] Contrary to §36 of Allergan's skeleton **[CB/6/116]**, this was not a "*courteous rejection*" of the Tribunal's approach in H1. Indeed, the Tribunal in *Le Patourel* at [82] **[AB/59/1778]** specifically recognised the "*usefulness of sketching out different scenarios where distinctive value is either offered or not offered*", albeit cautioning against "*too prescriptive an approach*", and citing the Tribunal's own statement at [323] of

35 *Le Patourel [2024] CAT 76*, at [83] **[AB/59/1778-1779]**.

H1 **[CB/16/452-453]** that the distinction between Case 2 and Case 3 is not easy to draw and that some cases will straddle the two.

31. In the circumstances, the Tribunal's three-case taxonomy did not involve the introduction of a novel legal test or any departure from earlier authority. Without prejudice to that point, the findings of abuse in the Decision are fully justifiable by reference to the legal principles as stated by the Court of Appeal in *Flynn CA* and the Tribunal's decision to uphold the CMA's findings should, if necessary, be upheld on that basis in any event: see §§34-40 below.

32. **Reversing the burden of proof?** Auden and Allergan also seek to contend that the Tribunal's articulation and application of its three-case taxonomy involved an impermissible reversal of the burden of proof: see Auden skeleton, §65(a) **[CB/5/93]** and Allergan skeleton, §§30-36 **[CB/6/115-116]** .

33. This contention is, again, misconceived:

    a. The focus of the complaint, as developed in particular by Allergan, is the Tribunal's statement at [341] of H1 **[CB/16/461]** that "*(absent an articulated and pro-competitive explanation) any excess [of price above cost] will be abusive*", and the Tribunal's related observation 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*", an omission that the Tribunal regarded as "*telling*": H1, [342(2)] **[CB/16/461-462]**.

    b. But the Tribunal did not here reverse the legal burden of proof. Indeed, the Tribunal recognised earlier in the judgment that the legal burden of establishing any infringement fell on the CMA.[36] Rather, what the Tribunal expected of the Appellants (but found to be lacking) was an "*explanation*" as to <u>why</u> Auden/Actavis' prices substantially exceeded the relevant costs of supply, and indeed for the vast price hikes introduced by Auden/Actavis after it acquired the relevant licences.[37] Importantly, that explanation was sought in circumstances where this pattern of pricing (a "*mountain*" of higher prices, "*bookended*" by lower prices) was "*unusual*" when compared to the typical phases in the commercialisation of a medicinal product: see H1, [152(3)(ii)] **[CB/16/360]**, citing Figure

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36 H1, at [34(5)] **[CB/16/316-317]**.

37 H1, at [152(3)] **[CB/16/359-361]**.

3.3 in the Decision **[CB/23/701-702]**.

c. The Tribunal's approach was both unsurprising and orthodox, given that the whole purpose of the Limb 2 enquiry is to ascertain whether there are any legitimate reasons for a price to exceed the costs of supply: see *Flynn CA* at [97(v)] **[AB/48/1256]** and *Aspen* at recital (163) **[AB/74/2324]**, cited above. The Tribunal's approach was also fully consistent with the Court of Appeal's emphasis in *Flynn CA* on the fact that a dominant undertaking has an exacting evidential burden when it comes to explaining allegedly unfair pricing: *Flynn CA* at [114] **[AB/48/1263]**, citing *Athens Airport* [2009] ECR I-46 and Case T-216/13 *Telefonica SA v Commission* [2018] 4 CMLR 21 ; see also *Tournier*, [38] **[AB/4/317]**, cited at *Flynn CA*, [73] **[AB/48/1247-1248]**.

d. In the present case, the Appellants have referred in general terms to factors justifying above-cost pricing for HTs (e.g. therapeutic benefits derived by patients: see further below). But the Appellants have never attempted to explain, still less evidence, how such factors could justify the "Matterhorn" pattern of (i) price increases, above levels that were "*already high and well in excess of Cost Plus*" (H1, [342(1)]) **[CB/16/461]**, after Auden/Actavis acquired and then de-branded the drug, and then (ii) Auden/Actavis' lengthy maintenance of a substantial and highly profitable price premium even after competitive entry occurred, all in circumstances where Auden/Actavis' prices ultimately eroded down towards cost.

e. Nor, contrary to §§35 – 36 of Allergan's skeleton argument **[CB/6/116]**, did the Tribunal apply any "*presumption*" that an excess price established under Limb 1 was unfair for the purposes of Limb 2. As set out above, the Tribunal was careful to distinguish between the question of whether price exceeded cost (the subject matter of Limb 1) and the question of why price exceeded costs (the key question under Limb 2): H1, [340] **[CB/16/460-461]**. The fact that the Tribunal felt able to dismiss the Appellants' arguments on unfairness in the course of a few pages in its judgment (cf. Allergan skeleton, §35 **[CB/6/116]**) was not a consequence of the Tribunal applying any presumption of unfairness. Rather, it reflects the complete absence of any plausible justification, from any of the Appellants, for the pattern of Auden/Actavis' prices.

f. In the circumstances, the Tribunal was entitled to conclude that there was no legitimate explanation for Auden/Actavis' excessive pricing, and that its prices were unfair on that basis. This was not a reversal of the burden of proof, but a rational finding by the specialist

Tribunal applying its expertise to the arguments and evidence (or lack thereof) before it.

34. **The Tribunal's overall decision should be upheld in any event.** Even if the Tribunal did materially err in its application of the legal principles on economic value via its three-case taxonomy, the CMA respectfully submits that the Tribunal's overall conclusions on economic value (and unfair pricing more generally) can and should be upheld on the basis of the following findings from the Decision, which are not in dispute on these appeals.[38]

35. **First,** by the time of the infringements, HTs were long off-patent and in the third stage of the drug life-cycle, where competition between generic manufacturers is ordinarily expected to bring prices down towards cost.[39] Nor, despite having made contrary claims in the press[40], did Auden/Actavis engage in any innovation, investment or improvement in respect of the drug.[41]

36. **Secondly**, however, there were a number of features of the market which were apt to prevent the ordinary, expected process of generic price competition from occurring during the period of the abuses. *First*, Auden/Actavis was the monopoly supplier of HTs from 2008 to 2015.[42] During that period, it took steps to preserve its monopoly by entering into unlawful anti-competitive arrangements with other potential suppliers of HTs.[43] *Secondly,* even after competitive entry occurred, the orphan designation granted to Plenadren meant that Auden/Actavis was the only supplier able to sell "full label" 10mg HTs and so benefited from an assured base of customers.[44] *Thirdly*, limitations in the way in which reimbursement prices for pharmacies were calculated under the Drug Tariff mechanism meant that the constraint on Auden/Actavis' prices that the mechanism would otherwise have provided was significantly

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38 Cf. Annex A to the CMA's Respondent's Notice, §6(a) – (f) **[CB/4/68-70]**.

39 Decision, §§5.312 – 5.316 **[CB/23/1155-1157]**.

40 Decision, §5.299 **[CB/23/1152-1153]**.

41 Decision, §§5.312 – 5.317 **[CB/23/1155-1157]**.

42 Decision, §§5.326 – 5.327 **[CB/23/1159]**.

43 Decision, §§5.328 – 5.332 **[CB/23/1159-1162]**.

44 Decision, §§5.333 – 5.336 **[CB/23/1162]**. Whether the Plenadren orphan designation resulted in an "assured customer base" for Audren/Actavis is a matter raised by Intas' appeal as addressed below: the CMA's position is that the relevant findings in the Decision were endorsed by the Tribunal.

reduced.[45] *Fourthly*, there was no material countervailing buyer power serving as a constraint on Auden/Actavis' prices, including via regulatory intervention from the NHS and the Secretary of State.[46] (The Appellants' contrary arguments on this last point were rejected by the Tribunal[47] and have not been renewed on appeal.)

37. **Thirdly**, and against the background of the market features just referred to, during the period of the abuses found in the Decision, Auden/Actavis' prices were vastly in excess of the CMA's (undisputed) "cost-plus" measure: by up to 3,100% (£70 per pack) for 10mg tablets and up to 2,400% (£69 per pack) for 20mg tablets.[48] There is no dispute that these were excessive prices within the meaning of Limb 1 of *United Brands*. The size of the differential is also a factor pointing strongly towards a finding of unfairness at the Limb 2 stage (see *Le Patourel*, [56] **[AB/59/1774]** and *Flynn CAT*, [369] **[AB/39/1058]**).[49]

38. **Fourthly,** Auden/Actavis' prices were also vastly in excess of a range of other benchmarks including:

    a. The prices at which the previous holder of the relevant marketing authorisation sold the tablets[50];

    b. Auden/Actavis' own prices both when it first entered the market and its later prices after a prolonged period of competition.[51] As to the latter, by 2021, Auden/Actavis' prices had converged at levels in line with the CMA's cost-plus measure[52];

    c. The prices that Allergan projected would emerge following competitive entry[53];

    d. The prices charged by suppliers of bioequivalent "skinny label" HTs, following a period of

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45 Decision, §§5.337 – 5.342 **[CB/23/1162-1164]**.

46 Decision, §5.343 **[CB/23/1164]**.

47 H1, at [270]-[273] **[CB/16/423-425]**.

48 Decision, §5.17 **[CB/23/1075]**. For the CMA's undisputed analysis of Limb 1 of *United Brands*, see Decision, §§5.218-5.289 **[CB/23/1128-1152]**.

49 Decision, §§5.297 – 5.310 **[CB/23/1152-1155]**.

50 Decision, §§5.347 – 5.350 **[CB/23/1165-1166]**.

51 Decision, §§5.231 – 232; 5.238 – 5.241 and 5.351 – 5.355 **[CB/23/1134; 1136; 1167-1168]**.

52 Decision, §§5.353 and 5.445 – 5.447 **[CB/23/1167; 1191]**.

53 Decision, §5.242 **[CB/23/1]**, citing documents 00706 and 30234 from the CMA's case file.

more intensive price competition[54] – which were in fact below the CMA's cost-plus measure.[55]

39. These prices resulted in NHS spending on HTs surging from £500,000 in 2007 to some £80 million in 2016, with severe detrimental effects on Clinical Commissioning Group budgets and their ability to deliver services.[56]

40. These matters clearly demonstrate that Auden/Actavis' prices were unfair in accordance with the test stated by this Court in *Flynn CA* at [97(i)] **[AB/48/1256]**. They demonstrate that Auden/Actavis' impugned pricing was unfair both in itself and when compared with competing products. And they reveal that Auden/Actavis' pricing is not referable to the provision of any economic value to its customers over and above the CMA's generous cost-plus measure, and that the Appellants' arguments to the opposite effect have been misguided (see further below).

(b) Tribunal's alleged failure to take account of therapeutic benefits and other alleged sources of economic value

41. **Therapeutic benefits**. Both Auden and Allergan contend that the Tribunal wrongly discounted their arguments (summarised at H1, [338] **[CB/16/459-460]**) that the therapeutic benefits derived by patients from these life-saving drugs constituted a source of economic value capable of justifying Auden/Actavis' excessive prices: Auden skeleton, §66 **[CB/5/93-94]** and Allergan skeleton, §§39–41 **[CB/6/116-117]**.

42. As noted above, the Tribunal described these arguments as a "*red herring*". It held that the life-saving nature of the drugs did not justify any excess of price above costs, but instead was a factor which exacerbated the seller's market power and enhanced its ability to price above cost, and that the Appellants' arguments simply amounted to the mistaken proposition that "*Because I, the Seller, can charge high prices to you, the Buyer, and you the Buyer pay them…the Seller is transferring value to the Buyer*": H1, [339] **[CB/16/460]**.

43. Insofar as the critique of this part of the H1 judgment rests on the argument that the Tribunal's three-case taxonomy represents an overly narrow approach to the analysis of economic value,

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54 Decision, §4.275 **[CB/23/1048-1049]**, referring to the intensification of competition between skinny label HT suppliers over time.

55 Decision, §§5.233-5.237 and §§5.366-5.400 **[CB/23/1135; 1171-1180]**.

56 Decision, §§5.356-5.364 **[CB/23/1168-1171]**.

the critique is misconceived for the reasons already given. As noted above, in articulating its "Case 2", the Tribunal recognised that economic value can, in principle, derive from "*any definable aspect*" of the seller's offering for which the buyer is prepared to pay a "*premium*".

44. Further, Auden and Allergan appear to interpret this part of the H1 judgment as laying down an inflexible rule that patient benefit can never justify any amount of excess of price above cost. For the avoidance of doubt, the CMA agrees that such a rigid approach would not be correct in law: cf. *Flynn CA*, [167] **[AB/48/1278]**. However, on a fair reading, the Tribunal was not saying this. Rather, the Tribunal was rejecting the proposition that the life-saving properties of the drug justified "*any*" excess of price above cost, no matter how great the excess. But that was not the end of the enquiry: at [340] of H1 **[CB/16/460-461]**, the Tribunal proceeded to consider whether economic value in excess of cost-plus was in fact provided in this case, and concluded that it was not. As already noted, that is a factual finding by a specialist Tribunal with which the Court of Appeal ought not to interfere.

45. Further, even if the Tribunal did proceed on the basis that the life-saving properties of HTs could not justify some excess of price above cost as a matter of principle, this was not a material error given the CMA's unchallenged findings as to the very large excesses of price above cost (including a reasonable rate of return) identified at Limb 1 (cf. *Flynn CA*, [173] **[AB/48/1279-1280]**) and the vast differentials between Auden/Actavis' prices and the various benchmarks relied on: see §§37 and 38 above. *Inter alia*, the alleged value attached to the life-saving properties of HTs cannot explain why Auden/Actavis' prices were so far in excess of its own prices both prior to and after the infringement period, or indeed well above the prices of skinny label suppliers, whose tablets (as is common ground) have exactly the same medicinal properties as Auden/Actavis' tablets.[57] It is also important to bear in mind that the CMA's approach to enforcement in this case (whereby it only made findings of infringement when prices reached £20 per pack, exceeding the upper bound of cost-plus by 285%[58]) afforded the parties very considerable "headroom" in respect of their pricing.

46. **Other alleged sources of economic value**. Auden and Intas also point to certain other (alleged) sources of economic value which (they contend) were "*ignored*" by the Tribunal,

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57 See e.g. Decision, §5.384 **[CB/23/1175]**, citing a 20 May 2014 letter from the Chief Pharmaceutical Officer of NHS England which stated that there were "*no material differences*" between skinny and full label products.

58 Decision, §5.18 **[CB/23/1075]**.

including:

a. The allegation that Auden/Actavis saved the drug from being "*deleted*" by the previous holder of the relevant marketing authorisation: Auden skeleton, §67(a) **[CB/5/94]**.

b. The fact that Auden/Actavis' product had a "full label" marketing authorisation, distinguishing it from the (bioequivalent) product offered by the "skinny label" suppliers: Auden skeleton, §67(b) **[CB/5/94]** and Intas skeleton, §33.2 **[CB/7/141]**.

c. The contention that Auden/Actavis approached pricing on a "portfolio" basis, meaning that "*excessive profits made in respect of one drug may not be unfair when viewed in context*": Auden skeleton, §67(c) **[CB/5/95]**.

d. Various high-level points made in a witness statement by Dr Burt for Intas, concerning Auden/Actavis' business generally (ranging from packaging design to customer service and environmental factors): Intas skeleton, §33.6 – 33.7 **[CB/7/144-145]**.

47. It is true that the Tribunal did not deal <u>in terms</u> with the first and fourth of these points. However:

a. It is well-established that a trial judge is not obliged to give "*elaborate*" reasons for his decision, nor "*reasons for his reasons*", nor to "*deal with every argument presented by counsel in support of his case*". The duty is to "*reach conclusions and give reasons to support his view, not to spell out every matter as if summing up to a jury*": see *Staechelin v ACLBDD Holdings Limited* [2019] EWCA Civ 817, per Lewison LJ at [39] **[AB/43/1177]**.

b. In the present case, the Tribunal's key reasoning for its conclusion that Auden/Actavis' prices were unfair appears at [340] – [343]. The Tribunal relied in particular on the fact that (i) the prices charged during the infringement were "*bookended*" by two periods in which prices were "*already high and well in excess of Cost Plus*" but that (ii) the Appellants had not put forward any plausible explanation, based on reliable evidence and consistent with a competitive market, for this pattern of pricing. There was no requirement for the Tribunal specifically to mention every argument and piece of evidence advanced by the Appellants. Indeed, the appeal court is "*bound, unless there is compelling reason to the contrary, to assume that the trial judge has taken the whole of the evidence into his consideration*": *Henderson v Foxworth Investments Ltd* [2014] UKSC 41, [2014] 1 WLR 2600 at [48] **[AB/34/878]**.

c. For the avoidance of doubt, the CMA disputed before the Tribunal and still disputes

Auden's proposition that the drug would no longer have existed if Auden/Actavis had not acquired it in 2008 (see Decision, §§5.486 – 5.495 **[CB/23/1201-1204]** and CMA's Amended Defence, §264 **[RS/9/573]**). Even if Auden were correct, however, this fact self-evidently could not explain, let alone justify, Auden/Actavis' pricing in light of the undisputed factual findings in the Decision as set out above. The same is true of the generic factors referred to in Dr Burt's evidence. Among other things, none of these factors is capable of explaining the manifest difference between (i) the prices charged by Auden/Actavis during the period of the abuses and (ii) the prices charged by Auden/Actavis both when it first entered the market and after a period of competition had dragged its prices down towards cost-plus.[59]

48. In contrast, the second and third points were not ignored, but rather addressed in terms in the H1 judgment. Thus:

a. As to the second point (alleged economic value associated with Auden/Actavis' "full label" marketing authorisation), it is implicit in [342(2)] of H1 **[CB/16/461-462]** that the Tribunal did not regard Auden/Actavis' full label MA as conferring economic value justifying its high prices. Further, it is important to recall that the earlier parts of the judgment include a detailed consideration of the distinction between full and skinny label supply, with the Tribunal observing that the distinction "exists not because of any difference between the products per se (they are pharmacologically identical) but because of the effect of Plenadren's recognition as an Orphan Medicine…": (emphasis in original) [205] **[CB/16/385]**. The Tribunal specifically concluded at [243(8)(v)(c)] **[CB/16/411]** that the distinction between full label and skinny label tablets was "*the distortive outcome of a market that is not, in any real sense of the word, a competitive market…*". That is a finding of fact that cannot be impugned on appeal.

b. In any event, the alleged value attached to Auden/Actavis' full label marketing authorisation does not come close to justifying the level of Auden/Actavis' prices, bearing in mind that Auden/Actavis' prices ultimately fell to a similar level to that of the skinny label suppliers.[60] The Appellants' proposition is also impossible to reconcile with the (again, undisputed) finding in the Decision that Waymade, which (like Auden/Actavis) held

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[59] A number of the factors referred to by Intas are addressed at Decision, §§5.471ff. **[CB/23/1197]**.

[60] See Decision, Figures 5.47 and 5.48. **[CB/23/1177]**

a full label marketing authorisation for 20mg tablets but (unlike Auden/Actavis) did not hold a dominant position, did not maintain any premium as compared with the skinny label suppliers.[61] To the extent necessary, the Appellants' arguments on this point should be rejected for these reasons also.

c. As to third point (alleged portfolio pricing), the Tribunal specifically considered and rejected Auden's argument at [352] – [353] **[CB/16/464]**, noting, correctly, that no detailed justification based on portfolio pricing had been advanced. This was a finding on the evidence that the Tribunal was entitled to make; it does not raise a point of law. Auden states at §67(c) of its skeleton that it did not provide any "*detailed figures*" on this issue: in fact, it did not lead any evidence at all on portfolio pricing.

(c) Challenges to the Tribunal's approach to comparators

49. The Appellants also challenge the Tribunal's approach to comparators, as set out at H1 [347] – [350] **[CB/16/463]**.

50. **Plenadren**. Both Auden and Intas challenge the Tribunal's dismissal of Plenadren as a comparator for the purposes of assessing fairness under Limb 2 of *United Brands*: see Auden skeleton, §70 **[CB/5/95-96]**; Intas skeleton, §§35 – 37 **[CB/7/146-147]**.

51. The Tribunal's overall conclusion on this issue was that the prices of medicinal products such as Plenadren were "*not competitive prices, but were distorted for reasons that we have given*": [348] **[CB/16/463]**. That conclusion is unimpeachable on appeal:

a. As a matter of law, the Tribunal was correct to proceed on the basis that products whose prices are *themselves* distorted because they were not set in conditions of effective competition will not be reliable comparators for the purposes of Limb 2 of *United Brands*. This is faithful to the logic of the Court of Appeal's observation in *Flynn CA* at [155] **[AB/48/1275]** that the price customers are "*prepared to pay … in an **effectively competitive market***" (emphasis added) may be a "*proxy*" for economic value. See also *Le Patourel*, at [93] **[AB/59/1780].**

b. As a matter of fact, the Tribunal was entitled to conclude that the price of Plenadren and other medicinal products were not set in conditions of effective competition, having regard to its detailed analysis of that issue, as summarised at H1, [243(8)] **[CB/16/409-411]**.

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61 See Decision, §5.448 and Figure 5.52. **[CB/23/1192]**

Auden's express contention that the Tribunal "*inappropriately dismissed the relevance of Plenadren*" (Auden skeleton, §70 **[CB/5/95-96]**) reveals that, in reality, its appeal on this point is simply a disagreement with a finding on the evidence. The Court of Appeal has no jurisdiction to interfere with such a finding, given there is no basis to suggest that the Tribunal's finding is perverse or irrational.

c. Intas seek to suggest that the orphan designation regime was a "normal feature of the relevant market, rather than some anti-competitive digression from it": Intas skeleton, §§33.5.2 and 35.3 **[CB/7/142, 146-147]**. As well as being nothing more than a disagreement with the Tribunal's factual conclusions, it misses the point. The purpose of the orphan designation regime (as with patent protection) is to shield designated products from competition as a reward for innovation. The CMA does not suggest there is anything "*anti-competitive*" about this *per se*. But it does mean that there was a barrier to entry and expansion in the market, and that the prices of products which benefit from such exclusivity do not provide a meaningful insight into what would constitute workably competitive prices for off-patent drugs. This is a point made in terms by the European Commission in *Aspen* at recital (200) **[AB/74/2330].**

d. Auden and Intas also argue that there is an inconsistency between (i) the Tribunal's finding that Plenadren forms part of the same market as Auden/Actavis' HTs[62] and (ii) its finding that the price of Plenadren is not a good comparator for the purpose of Limb 2 of United Brands. Properly understood, however, there is no inconsistency. The Tribunal's finding that the price of Plenadren was not a competitive price is a part of its reasoning on market definition (this was necessary to avoid making the well-known "Cellophane fallacy": see Flynn CA, [154]). It is why the Tribunal instead approached the question of market definition by considering a hypothetical price of £10/unit for both HTs and Plenadren, and considering the likely elasticity of demand between the two products at these assumed price levels: H1, [245], [256(3)] **[CB/16/412, 416-417].** The Tribunal's conclusions on market definition were therefore not based on any consideration of the actual price of Plenadren, let alone any view that those prices were workably competitive. To the contrary, the

[62] For the avoidance of doubt, Plenadren's inclusion in the same market makes no difference to the position on dominance, given that Plenadren has always accounted for less than 1% of all HTs dispensed by volume: see Decision, §3.132 **[CB/23/726]**.

Tribunal recognised that Plenadren in fact sold at a price "around 40 times higher than the price we are hypothesising": H1, footnote 332 **[CB/16/417]**.

52. **Hydrocortistab**. Auden additionally complains that the Tribunal failed to consider Hydrocortistab, an injectable form of hydrocortisone: see Auden skeleton, §71 **[CB/5/96]**. This is not a fair criticism. Quite apart from the principle that a trial judge is not obliged to expressly deal with every argument (see above), H1, [303(1)] **[CB/16/444]** specifically refers to Auden's argument that both Hydrocortistab and Plenadren were sufficiently comparable products for the purposes of the unfair pricing analysis. The Tribunal's conclusion on comparables generally is then framed in general terms at [348] **[CB/16/463]**: "*…the prices of* ***medicinal products*** *in the market were not competitive prices…Nothing can be learned from them*" (emphasis added). This clearly explains why Auden's argument by reference to Hydrocortistab was rejected. It is also important to read H1 as a whole, since the Tribunal found important differences between Hydrocortistab and HTs at [44] and [256(5)] **[CB/16/319, 417]**, concluding that (as the CMA had found) Hydrocortistab did not form part of the same product market.

53. To the extent necessary, the CMA also relies on the following undisputed findings in the Decision as further demonstrating that neither Plenadren nor Hydrocortistab are reliable comparators for the purposes of the Limb 2 analysis in this case[63]:

    a. The lack of any evidence of material substitution between Auden/Actavis' tablets and other products in the relevant "treatment area" despite the significant price increases introduced by Auden/Actavis, a point that applies to both Plenadren and Hydrocortistab[64];

    b. Further as to Plenadren: (i) unlike Auden/Actavis' tablets, Plenadren is a new and innovative "modified-release" version of hydrocortisone with clinically relevant advantages[65]; (ii) Plenadren is not routinely or commonly prescribed[66], being used by less than 1% of all patients with adrenal insufficiency[67], and is not proactively marketed in the

63 Cf. Annex A to CMA's Respondent's Notice, §6(g)(i) **[CB/4/70]**.

64 Decision, §4.72 **[CB/23/970]**.

65 Decision, §§4.51 and 5.406 – 5.412 **[CB/23/962; 1183-1184]**.

66 Decision, §4.52 **[CB/23/962-963]**.

67 Decision, §4.73(a) **[CB/23/971]** .

UK[68]; (iii) it appears in "Category C" of the UK Drug Tariff system, a category only used where there is no competition for the supply of the drug in question[69]; and (iv) the introduction of Plenadren in 2012 did not prevent increases in selling or NHS reimbursement prices for HTs or affect volume trends for HTs dispensed.[70]

c. Further as to Hydrocortistab: (i) despite claims to the contrary made in interviews during the CMA's investigation, there is no contemporaneous evidence that Auden/Actavis used Hydrocortistab as a reference for its pricing of HTs; (ii) Hydrocortistab has a different method of delivery (via injection) and a different active ingredient; (iii) Hydrocortistab is primarily used to treat certain arthritic conditions, and only used to treat adrenal insufficiency in rare cases, e.g. where a patient is 'nil by mouth'; and (iv) like Plenadren, it is in Category C of the drug tariff, reflecting the fact that there is no competition in the supply of the product.

d. For the avoidance of doubt, the CMA rejects the proposition at §31 of Auden's skeleton **[CB/5/84]** that the CMA "*declined to address Hydrocortistab as a comparator*" in the Decision. The Decision specifically considers this issue at footnote 1842 **[CB/23/1181]** (and see further the CMA's Amended Defence, §§295 – 302 **[RS/9/583-585**]).[71]

(d) Challenges to the Tribunal's findings of abuse during the period following competitive entry

54. Auden also makes a free-standing complaint about the Tribunal's findings of abuse during the period following competitive entry, alleging that by around May 2015, it was apparent that there would "*soon be effective competitive pressure to bring prices down*", and that in no circumstances can there have been any abuse after that date: see Auden ground 1(c). Allergan advances an equivalent argument as its ground 1(c). To similar effect, Intas contests the CMA's findings of abuse during the Intas Period (8 July 2017 until 31 July 2018) based on the assertion that the market was functioning "*normally and sufficiently competitively during*

68 Decision, §5.415 **[CB/23/1185]**.

69 Decision, §5.418 **[CB/23/1185]**.

70 Decision, §4.73(b) **[CB/23/971]**.

71 See also Section C3 of the "ambulatory draft", §13 **[CS/22/405].**

that period".[72]

55. Auden and Allergan found their respective arguments under this head on the Tribunal's judgment in *Napp* [2002] CAT 1.[73] They construe that judgment as establishing a substantive legal requirement that, in order to establish abusive unfair pricing, it must be shown that there is no (likely) effective pressure from new entry to bring prices down to competitive levels: see Auden skeleton, §§61 – 62 and 73 – 74 **[CB/5/92,96-97]**; Allergan skeleton, §45 **[CB/6/118]** (describing this as an "*important and well-established proviso*"). Intas also contends that the facts during the Intas Period do not correspond with the description in *Napp*: Intas skeleton, §33.8 **[CB/7/145-146]**.

56. These arguments impose an unwarranted gloss on *Napp* and do not reflect the law on unfair pricing:

    a. The Director General of Fair Trading in *Napp* had proceeded on the basis that a price will be excessive (and hence unfair) for the purposes of the Chapter II prohibition where "*(i) prices are higher than would be expected in a competitive market, and (ii) there is no effective competitive pressure to bring them down to competitive levels, nor is there likely to be*".[74] The Tribunal in *Napp* considered that this approach was "*soundly based*" in the circumstances of the case before it, but did not suggest that point (ii) was a pre-requisite for a finding of an unfair price. To the contrary, the Tribunal specifically emphasised that there may be "*other ways of approaching the issue*",[75] a point that the CJEU had also made in *United Brands* at [253] **[AB/1/82]**.

    b. Further, and contrary to Auden skeleton, §62 **[CB/5/92]**, the Court of Appeal in *Flynn CA* did not "*approve*" the Director General's approach in *Napp* as the "*test*" for an unfair price. It forms no part of the "*general conclusions from the case law about the test to be applied*" as set out by Green LJ at [97] of *Flynn CA* **[AB/48/1256-1257]**, notwithstanding that Green LJ specifically considered *Napp* as part of his detailed excursus through the unfair pricing jurisprudence. Rather, Green LJ made clear that the basic test for unfair pricing is the one

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72 See Intas skeleton, §§24-30 **[CB/7/139-140]**. Other Intas-specific points on abuse are addressed elsewhere in this skeleton argument.

73 See Auden skeleton argument, §§61-62 **[CB/5/92]**.

74 See the quotation from the Director General's decision at [390] of *Napp* **[AB/7/362-363].**

75 *Napp*, at [391] **[AB/7/363].**

laid down in *United Brands* at [249] **[AB/1/81]**, namely whether the relevant price results in the dominant undertaking reaping trading benefits that would not have been obtained in conditions of workable competition. Accordingly, as a matter of principle, the fact that there is some competitive pressure that is gradually bringing prices back down **towards** competitive levels does not prevent those prices from being characterised as abusive while they **remain** at excessive and unfairly high levels. The undisputed facts concerning Auden/Actavis' prices (see §§37 and 38 above) show that those prices were well above any reasonable benchmark for workably competitive levels – be that cost-plus, the prices charged by suppliers of medicinally identical products, or Auden/Actavis' own prices before/after the abuses - throughout the relevant period.

c. Allergan contends that "*where prices are coming down by themselves, it is far better to let the market do its work*", relying on an observation by Green LJ at [104] of *Flynn CA* **[AB/48/1258-1259]**.[76] But that observation concerns (at most) the desirability of "*regulatory intervention*" in markets where high prices act as a "*magnet to entry*". It says nothing about the substantive legal test for unfair pricing, which is set out in *Flynn CA* [97] **[AB/48/1256-1257]**, as distinct from the discretionary question of whether a regulator should intervene in any particular case.

57. For all those reasons, the Tribunal was correct (and in any event in light of the analysis and reasoning in the Decision, entitled) to find that Auden/Actavis' prices remained abusive even in the period following competitive entry, and notwithstanding that its prices started to decline during that period: see H1, [342(4)] **[CB/16/462]**. Allergan characterises this aspect of the judgment as suggesting that "*prices are unlawful until they have reverted to the norm of cost*" (Allergan skeleton, §45 **[CB/6/118]**). However, the Tribunal said no such thing. Rather, in circumstances where Auden/Actavis' own prices were already well above a cost-plus level both before and after the period in which the CMA found it to have engaged in unfair pricing, the Tribunal considered that there was no legitimate justification for the pattern of Auden/Actavis' prices during that period, notwithstanding that those prices began to decline following competitive entry.

58. For the same reason, there is no merit in this aspect of Intas' appeal. As noted above, Intas contends that the market was functioning "*normally and sufficiently competitively*" during the Intas Period, as shown *inter alia* by Auden/Actavis' falling prices: Intas skeleton, §26

[76] Allergan skeleton §22 **[CB/6/112]**.

[CB/7/139-140].

59. In a nutshell, Intas' argument is that since it was subject to some competition during the Intas Period, its prices were necessarily competitive prices: see Intas skeleton, §28 **[CB/7/140]**.

60. Insofar as this argument rests on Intas' contention that the Tribunal was wrong to find that Auden/Actavis held a dominant position during the Intas Period, it adds nothing to Intas' Ground 1, which is misconceived for the reasons given below. If Intas is wrong about dominance, it follows inexorably that the relevant market was not characterised by workable competition during the Intas Period: the very factors relied on by the CMA and endorsed by the Tribunal in relation to dominance, including during the Intas Period, show that the market during the Intas Period (or any other part of the infringement period) was not characterised by workable competition at all.

61. Insofar as this is a free-standing argument on abuse, it is misconceived in any event. Per *Flynn CA*, [97(i)] **[AB/48/1256]**, the critical question is not whether the dominant firm's pricing is subject to some degree of competitive pressure, but whether the prices it charges are **above** workably competitive levels. While Intas seeks to make a virtue of the CMA's submission that the current prices of HTs are competitive prices (Intas skeleton, §27 **[CB/7/140]**), in fact this is one of the various benchmarks indicating that Auden/Actavis' prices were substantially above competitive levels, and hence unfair at all material times, including during the Intas Period: see §38 above.

62. In any event, as already set out, the Tribunal reached a clear factual conclusion in this case that the relevant market was "*not, in any real sense of the word, a competitive market*": H1, [243(8)(v)(c)] **[CB/16/410-411]**. In the circumstances, Intas' contention in its skeleton argument (§26) that the relevant market was characterised by normal and sufficiently effective competition during the Intas Period is simply a disagreement with the Tribunal's findings of fact, and does not raise a point of law. There is similarly nothing in Intas' alternative argument (Intas skeleton, §30 **[CB/7/140]**) that the judgment gives no reasons for dismissing Intas' arguments on this issue. As noted above, there was no obligation on the Tribunal to refer explicitly to every one of the myriad arguments made by the Appellants: see *Argos Ltd and JJB Sports plc v OFT* [2006] EWCA Civ 1318 at [5] **[AB/16/513]**. But in any event, the judgment does provide clear reasons for the Tribunal's conclusion that Auden/Actavis' prices were abusive throughout the period covered by the Decision, including the Intas Period.

63. Intas also contends that, on the Tribunal's approach, Auden/Actavis' prices should have

dropped immediately to the CMA's cost-plus level following competitive entry, suggesting that such an approach would have "*startling*" implications for pharmaceutical markets generally: Intas skeleton, §33.5.3 **[CB/7/143-144]**. This submission ignores the fact that Auden/Actavis' prices prior to competitive entry had **already** been increased to levels vastly in excess of cost-plus, and remained well above those levels (and above a series of other competitive benchmarks) for a period of years even after competitive entry. The fact that the Tribunal found that this pattern of pricing was unfair, on the facts of this case, tells one nothing about what might be unfair in different pharmaceutical contexts. It also ignores the fact that the CMA for administrative reasons did not take enforcement action until prices were some 285% above the upper bound of its cost-plus measure.

(e) Dominance during the Intas Period

64. Intas claims that, regardless of any earlier finding of dominance in respect of Auden/Actavis, the CMA and the Tribunal erred in not considering dominance separately in respect of the relevant period of its ownership, 9 January 2017 to the end of the infringement period on 31 July 2018 (the last 18 months of the infringement). The Tribunal's findings on dominance in respect of earlier periods are not the subject of any appeal. Intas' argument therefore rests on such dominance having been lost by the time it acquired the infringing undertaking.

65. In support of this contention, Intas points to various factual indicators which it claims show that there was no longer dominance during the Intas Period.[77] Yet, it ignores the significant factors pointing the other way – including, in particular, market shares that were above the level at which a presumption of dominance arises – which both the CMA and the Tribunal relied upon in concluding that Auden/Actavis remained dominant throughout the infringement period.

66. In particular, the CMA found that:

    a. Market shares remained sufficiently high to give rise to a presumption of dominance throughout the Intas Period: when measured by value, the CMA's preferred metric[78], Auden/Actavis' market share for both 10mg and 20mg tablets remained above 70% even following competitive entry, and was as high as 86% (for 10mg tablets) and 78% (for 20mg

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77 Intas skeleton, §3 **[CB/7/130-131]**.

78 For the reasons given at Decision, §§4.185 – 4.190 **[CB/23/1015-1017]**.

tablets) at the end of the Intas Period.[79]

b. There was no steady decline in market shares, but a decline followed by a plateauing.[80]

c. Throughout the Intas Period, Accord-UK's market shares (by both value and volume) remained much higher, and less volatile, than those of its competitors which were also fragmented.[81]

d. There was extensive other evidence pointing towards continuing dominance during the Intas Period, including (i) Accord-UK's ability to maintain a large absolute and relative price differential,[82] (ii) Accord-UK's persistently very high profit margins, notwithstanding entry by other suppliers (unlike its competitors),[83] (iii) the orphan designation granted in respect of Plenadren, which formed a barrier to expansion by providing Accord-UK with an assured customer base of pharmacies (accounting for around 50% of total demand) who were only prepared to buy "full label" hydrocortisone tablets for the vast majority of their purchasing requirements,[84] (iv) the fact that the "Drug Tariff" mechanism did not impose a sufficient constraint on Accord-UK's pricing to prevent it from maintaining prices at levels much higher than its competitors, a point specifically acknowledged by Intas in its letter to the Department for Health and Social Care, dated 7 December 2017,[85] and (v) there was no material countervailing buyer power constraining Accord-UK's prices.[86]

e. In the premises, there were no exceptional circumstances capable of rebutting the

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79 Decision, §§4.247-4.255 **[CB/23/1034-1040]** and Figures 4.13 to 4.16 **[CB/23/1035-1038]**, in particular, see Decision, §4.249 and also §4.250 **[CB/23/1038-1039]** which confirms Auden/Actavis' market shares also remained above 50% for most of the period following competitive entry when measured by volume, and stood at 53% (for 10mg tablets) and 67%. (for 20mg tablets) at the end of the Intas Period.

80 Ibid.

81 Decision, §§4.256-4.261, Figures 4.13 to 4.16 and §§4.299-4.300 **[CB/23/1041-1042; 1035-1038; 1055-1056]**.

82 Decision, §§4.267-4.275 and §§4.301-4.306. **[CB/23/1043-1049; 1056-1057]**

83 Decision, §§4.276-4.277. **[CB/23/1049-1050]**

84 Decision, §§4.288-4.298. **[CB/23/1052-1055]**

85 Decision, §§4.278-4.287 and §§4.307-4.311. **[CB/23/1050-1052; 1058-1059]**

86 Decision, §§4.312-4.349 and Annex B. **[CB/23/1059-1069] [CB/26/1793-1798]**

presumption of dominance. To the contrary, the evidence supported a finding of dominance at all material times, including throughout the Intas Period.

67. The CMA took the view that it would be artificial to assess the Intas ownership period in isolation. The fact that Intas acquired Accord-UK (then Actavis UK) in January 2017 is not itself relevant to the assessment of Auden/Actavis' continued market power. The CMA properly considered dominance across the whole of the post-entry period, taking due account of any relevant developments that occurred in that period. There is no requirement to undertake a fresh, separate dominance analysis just because the ownership of an undertaking changes, nor would it be appropriate to ignore relevant factors such as that the undertaking had possessed a very large market share over a lengthy period prior to the change.

68. The Tribunal diverged from the CMA on whether dominance had to be assessed by reference to different time periods. It found that it had "*to parse the Matterhorn*",[87] and made clear that it considered dominance specifically by reference to different time periods, including the Intas Period.[88] Nonetheless, the Tribunal held that what it described as "*the CMA's monolithic approach*" (as contrasted with its own "*phased approach*")[89] did not amount to "*any material error by the CMA in regard to its assessment of dominance.*"[90]

69. Applying its phased approach, the Tribunal reached the same substantive conclusion as the CMA: that Auden/Actavis remained dominant throughout the infringement period. It found that "*the undertakings as we have found them to be during all five phases had a dominant position in the markets*".[91]

70. In reaching this conclusion, the Tribunal had regard to a range of evidence. In particular, it had "*primary regard*" to market shares as well as regard to other factors similar to those considered by the CMA, including pricing factors and the absence or minimal nature of competitive and regulatory constraints.[92] That evidence **included** the findings in the Decision

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87 H1, [266] **[CB/16/422-423]**.

88 H1, [289]-[290] **[CB/16/439-441]**.

89 H1, [296(2)] **[CB/16/442-443]**.

90 H1, [297] **[CB/16/443]**; see also [296(2)] **[CB/16/442-443]**; contrary to what is suggested in Intas' skeleton, §6.1 **[CB/7/132]**.

91 H1, [291] **[CB/16/441]** (emphasis added).

92 H1, [291]-[295] **[CB/16/441-442]**.

concerning the assured customer base: as explained at §18 above, Intas is wrong to submit that the Tribunal did not endorse those aspects of the Decision. The Tribunal emphasised it was considering these factors "*by reference to the various temporal phases*", which included the Intas Period.[93] Although it acknowledged that "*market share fell over time*", the Tribunal held "*that the relevant market shares (by volume and by revenue) of the undertakings in question clearly denoted dominance, and we regard this conclusion as inevitable from the data*".[94] In the light of these conclusions, the Tribunal upheld the findings of dominance in the Decision.[95]

71. In short, the CMA and the Tribunal may have taken a somewhat different approach in how they approached the dominance assessment (by express reference to different time periods, or otherwise). But this was a difference of form, not substance. On the extensive evidence before them, including market share data which "*clearly denoted dominance*" and multiple other indicators supportive of dominance, both the CMA and the Tribunal were right to find that Auden/Actavis was dominant throughout the entire infringement period, including the Intas Period. At a minimum, this was a conclusion they were entitled to reach. Intas' appeal does not even engage with the authorities establishing that market shares above 50% give rise to a presumption of dominance which can only be displaced in "*exceptional circumstances*"[96] and that a market share of 70-80% or above by value or volume is "*in itself, a clear indication of the existence of a dominant position*".[97] Instead, Intas attempts to 'salami-slice' away various factors supporting the finding of dominance.[98] For example, Intas argues that the Tribunal paid insufficient regard to the question of why prices were falling during the Intas Period.[99] Yet, the case law shows that even periods of "*very lively*" competition are compatible with a

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93 H1, [292] **[CB/16/441]**.

94 H1, [293] **[CB/16/441-442]**.

95 H1, [296] **[CB/16/442-443]**.

96 See Case C-457/10 P *AstraZeneca v Commission* EU:C:2012:770, at [176]. **[AB/30/816].** See also *Albion Water v Ofwat* [2006] CAT 36, at [118]-[123] **[AB/17/561-563].**

97 Case T-30/89 *Hilti v Commission* EU:T:1991:70, [92] **[AB/5/328]**; cf. Decision, §4.179 **[CB/23/1012-1013]**.

98 Intas skeleton, §§12-20 **[CB/7/134-137]**.

99 Intas skeleton, §§12-14 **[CB/7/134-135]**.

dominant position.[100] Moreover, Intas ignores the fact that by the end of the Intas Period, Auden/Actavis was charging over five times its competitors' average prices for 10mg tablets.[101] The law is clear that "…*the ability of [an undertaking] to maintain higher prices than those of its competitors, while retaining a much higher market share, shows that it [is] able to exercise market power in respect of price*".[102]

72. Intas' attempt to challenge the findings on dominance ignores the careful in-the-round assessment undertaken by both the CMA and the Tribunal on the evidence before them. It does not concern any error of law but amounts to nothing more than a factual disagreement with the expert regulator and expert Tribunal as to how they weighed the evidence. In the premises, there is nothing "*surprising*" about the findings of ongoing dominance[103] and there is no valid basis for the Court of Appeal to interfere with it.

(f) Intas-specific arguments on abuse

73. Intas further argues that there was no finding by the Tribunal that Accord-UK "*imposed*" prices on its "*customers*" and that the Tribunal should have quashed the Decision on this basis alone.[104] The Tribunal considered this argument at H1, [304] **[CB/16/444]**, making clear that it was dealing with it together with the other appellants' arguments on economic value.

74. The premise of this argument is that there is a discrete legal requirement that prices must be "*imposed*" (in the sense that customers have no choice but to pay the prices concerned) before they can be characterised as unfair.[105] However, there is no such requirement in law. While section 18(2)(a) uses the word "*imposing*", it is well-established that the categories of abuse are not limited to the list of practices set out in section 18(2).[106] Nor is there any authority for the proposition that only a price which a customer has no choice but to pay can be unfair.

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100 *United Brands*, [113]-[121] and [196] **[AB/1/69,76]**; see also Case T-24/93 *Compagnie Maritime Belge Transports v Commission* EU:T:1996:139, [72] and [76]-[79] **[AB/6/331-333].**

101 Decision, §§4.272-4.273**[CB/23/1047-1048]**

102 Case T-321/05 *AstraZeneca v Commission* EU:T:2010:266), [266] **[AB/22/677-678].**

103 Intas skeleton, §4 **[CB/7/132]**.

104 Intas skeleton, §22 **[CB/7/137-139]**; at §22.5 it states that "*the act of imposition by the dominant undertaking is an essential ingredient in the abuse*" **[CB/7/138]**.

105 Intas skeleton, §22.1 **[CB/7/137].**

106 *Socrates v Law Society of England and Wales* [2017] CAT 10, at [141].

United Brands itself makes clear that prices may be unfair when compared to competing products. And even the "*offer*" of an unfair price can be abusive: see *Albion Water*, cited at §29 above.

75. In any event, Intas' arguments regarding the "*imposition*" of prices are unsustainable on the facts. It claims that customers exercised choice in favour of the product because it had additional economic value to them, and that given this element of choice prices were not "*imposed*" on them. That, however, ignores the substantial body of pharmacies who considered that skinny label HTs were not a substitute for Auden/Actavis' full label HTs.

76. There was no challenge to the factual findings in the Decision concerning the existence of this group of pharmacy customers (including the two largest pharmacy chains, Boots and Lloyds), who accounted for almost 50% of total demand for HTs and who principally purchased full label tablets. They did this because of their assessment of a potential regulatory risk from dispensing off-label.[107] Intas' own witness, Dr Burt, agreed that the larger chains in particular were "*more risk-averse*" and saw it as "*important to adhere strictly to the regulatory regime, and to dispense products according to their marketing authorisation rather than stray outside them*".[108] The pharmacies concerned left very significant sums of money *"on the table*" by continuing to purchase more expensive full label tablets rather than cheaper skinny label tablets.[109]

77. In the Decision, the CMA found that such pharmacies constituted an "*assured customer base*" for Auden/Actavis.[110] As such, Intas was able to "*impose*" prices on them.

78. Intas challenged this characterisation but, contrary to its attempts to suggest that the finding was not upheld in the H1 judgment, the Tribunal reached the same essential conclusion as the CMA, albeit using different terminology: see §18 above. The Tribunal considered that "*the label "customers" is unhelpful*"[111] because it elides the different roles of doctors, pharmacies

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107 See the summary of the pharmacy evidence at Decision §3.283 **[CB/23/784-787]**.

108 Witness statement of Dr Burt, §57 **[RS/2/41]**.

109 See the CMA's note dated 25 January 2023 in response to a request from the Tribunal **[CS/24/497-499].**

110 Decision, §§4.288 – 4.298 **[CB/23/1052-1055]**.

111 H1, [73] **[CB/16/329]**.

and patients "*whose complex interaction collectively makes up the ultimate consumer.*"[112] It went on to find that pharmacies, even if they in theory had a choice in respect of which product to dispense, might have an understandable basis and "*a strong prudential motivation*" to limit that discretion as to what products they dispense – even if that entailed forsaking a financial benefit.[113] In effect, such pharmacies are a "captive" or "assured" customer base, even if the Tribunal did not employ that exact terminology.

79. Intas' own expert economist accepted in cross-examination, based on the relevant documentary evidence, that the four largest pharmacy multiples (Boots, Lloyds, Well and Rowlands) did not engage in any "*trade off*" between price and regulatory factors when making purchasing decisions: they proceeded on the basis that regulatory considerations gave them no choice but to purchase full label HTs, despite the fact that skinny label HTs were much cheaper.[114]

80. Considered in that context, Intas is wrong to suggest that there was no finding by the Tribunal which would allow a conclusion of prices being "*imposed*" on certain customers. Pharmacies which, for understandable prudential reasons, limited themselves to dispensing full label tablets would meet the definition of customers on whom Auden/Actavis could (and did) impose a price.

81. Intas' "*corollary*" to this point,[115] rests on the same misunderstanding of the Tribunal's judgment, combined with Intas' arguments that during the Intas period the relevant market was already a competitive one. It therefore falls to be rejected for the reasons set out above.

E. THE PENALTY ISSUES

82. Only a small proportion of infringing conduct is detected and leads to the imposition of a penalty. Accordingly, penalties perform an important function in signalling both the unacceptability of practices that infringe competition law and the serious consequences of engaging in such practices. The CMA submits that these penalties are necessary and

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112 H1, [75] **[CB/16/330-331]**.

113 H1, [79]-[82] and [90] **[CB/16/332-333, 338]**.

114 See the evidence cited at §264(a)-(f) of the CMA's written closing submissions for the H1 trial **[CS/23/442-444].**

115 Intas skeleton, §§24-35 **[CB/7/139-147]**.

appropriate, taking into account the seriousness of the infringements (H1 [376(1)] **[CB/16/471-472]**), the significant harm to the wider community (H1 [375(iii)] **[CB/16/471]**): NHS expenditure soared from £0.5m in 2007 to £84m in 2016;[116] and the significant economic benefit to Auden/Actavis (H1 [375(iv)] **[CB/16/471**), which totalled £145.3m.[117]

83. The CMA imposed the following penalties on the parties to these appeals for the infringements found by the Decision,[118] which, subject to one point, were upheld by the CAT:[119]

Unfair Pricing Abuses	
Auden /Actavis total penalty	**£155.2 million**
The Auden Appellants[120] are solely liable for	£28.4 million [10mg Abuse] £6 million [20mg Abuse]
Allergan is solely liable for	£74.3 million [10mg Abuse] *Reduced to £49.3m by the Tribunal*
The Auden Appellants and Allergan are jointly and severally liable for	£2 million [20mg Abuse]
The Intas Appellants[121] are jointly and severally liable for	£44.4 million [10mg abuse]
Market Exclusion Agreements	
Auden /Actavis total penalty	**£66 million**
The Auden Appellants are solely liable for	£28.4 million [10mg Agreement] £2.8 million [20mg Agreement]
Allergan is solely liable for	£34.8 million [10mg Agreement]

84. After briefly setting out the statutory scheme, Penalty Guidance, Decision and Judgments, the CMA addresses each of the Appellants' arguments in turn below, grouping the arguments

116 Decision, §§5.361-5.364. **[CB/23/1174-1175]**

117 Decision, Table 10.3. **[CB/23/1665]**

118 Decision, Table 10.1. **[CB/23/1660]**

119 H1, at [377 (2)] **[CB/16/472]**; H4, at [14] and [15] **[CB/18/624-625].** The Tribunal set aside the finding that Allergan could be fined for the period after it had entered into commitments with the European Commission not to provide direction or oversight to Accord-UK, its subsidiary, as part of a merger control process: H1, at [285] **[CB/16/432-437]**.

120 Table 10.1 **[CB/23/1660]** refers to "Accord-UK" which is in effect the same as the "Auden Appellants" since Accord-UK bears liability for the penalties imposed for the conduct of Auden Mckenzie (Pharma Division) Ltd, as its economic successor.

121 Table 10.1 **[CB/23/1660]** refers to "Accord-UK, Accord Healthcare and Intas" separately.

thematically.

The statutory scheme for penalties under the Competition Act

85. The power to impose penalties on undertakings that have infringed the Chapter I and II prohibitions is provided in primary legislation by s. 36(1)–(2) CA 1998. That provision gives the CMA (and, on appeal, the CAT) a broad discretion in relation to the imposition of penalties, which is subject to only five qualifications: (i) a penalty may only be imposed if the infringement has been committed intentionally or negligently: s. 36(3); (ii) there is limited immunity from penalties under ss. 39-40; (iii) the mandatory statutory cap on the penalty, set at 10% of the undertaking's turnover: s. 36(8);[122] (iv) under s. 38(8) the CMA and the CAT must "*have regard*" to the guidance as to the appropriate amount of a penalty published under s. 38(1);[123] and (v) the CMA must have regard both to the seriousness of the infringement and to the desirability of deterrence: s. 36(7A) of the CA 1998.

The Penalty Guidance

86. The relevant Penalty Guidance is set out in CMA73, published in April 2018 **[AB/82/2462-2489]**. As is clear from §1.4 of the Guidance **[AB/82/2468]**, in determining penalties, the CMA pursues twin objectives: (1) to impose on infringing undertakings penalties that reflect the seriousness of the infringement and (2) to ensure that the threat of penalties will deter the infringing and other undertakings from engaging in anti-competitive practices. The Penalty Guidance sets out a six-step process for calculating penalties, as set out in §87 below.

The Decision

87. The CMA's approach to penalties is summarised in [365] to [372] of H1 **[CB/16/467-470]**. The CMA found that the Auden/Actavis undertaking had committed each Unfair Pricing Abuse intentionally or at least negligently: Decision §§10.21-10.31 **[CB/23/1621-1626]**. The CMA applied the steps in the Penalty Guidance, as follows:

    a. **Step 1**: the CMA applied the maximum starting point of 30% of Auden/Actavis' turnover in the relevant UK markets for 10mg and 20mg HTs in the last business year before the infringement ended: §§10.163-10.185 **[CB/23/1672-1682]**.

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[122] The relevant order referred to in s. 36(8) is Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 SI 2000/309, as amended by SI 2004/1259 **[AB/69/2255-2264].**

[123] On departing from the guidance see *Argos Ltd v OFT* [2006] EWCA Civ 1318, [161] **[AB/16/521].**

b. **Step 2**: the CMA multiplied the Step 1 penalties by the durations of the different infringements: §§10.187-10.188. **[CB/23/1682-1683]**

c. **Step 3**: the CMA increased the Step 2 penalties by 15% for the aggravating factor of director/senior manager involvement in the abuses: §§10.195-10.198 **[CB/23/1685-1687]**, but reduced it by 5% for the compliance activities of the appellants: §§10.219-10.227. **[CB/23/1695-1698]**

d. **Step 4**: the CMA evaluated whether each Step 3 penalty for each infringement for each addressee of the Decision would be sufficient to achieve specific deterrence without being disproportionate or excessive. The CMA's Step 4 assessment is set out in detail below. Having allocated the Step 3 penalties to the different periods of ownership of Auden, the CMA estimated the minimum financial benefits obtained by the undertaking from each abuse during each period: Table 10.3. Having considered all the factors relevant to Step 4 in its Penalty Guidance, the CMA made the adjustments in §10.296 and §10.308. **[CB/23/1718; 1722]**

e. **Step 5**: the CMA capped the Auden Appellants' penalty for the 10mg Abuse at £28.4m in accordance with the statutory maximum: §10.394 **[CB/23/1741-1742]**; it did the same for the fine imposed in respect of the 10mg Agreement: §10.396. **[CB/23/1742].**

f. **Step 6**: the CMA made no adjustments for leniency or settlement: §10.416 **[CB/23/1747]**.

88. In addition, the CMA took a step back and assessed whether the *aggregate* penalty imposed on each undertaking was proportionate: §§10.155-10.161 **[CB/23/1669-1672]** and 10.405-10.415. **[CB/23/-1744-1747]**

The Judgments in H1, H2 and H4

89. In **H1**, the CAT reviewed the penalties imposed by the CMA for the Unfair Pricing Abuses: H1 at [356]-[376] **[CB/16/465-472]**. Subject to a *pro-rata* reduction for Allergan's shorter infringement,[124] the CAT affirmed the penalties: H1[377(2)] **[CB/16/472]**. In **H2**, the CAT held that it was premature to decide the appeals against the penalties for the 10mg Agreement: H2 at [159] **[CB/17/615]**. Those appeals are pending before the CAT.[125] In **H4**, the CAT rejected the challenges to the level of penalties imposed for the 20mg Agreement: H4 at [13]-

[124] The Tribunal set aside the finding that Allergan could be fined for the period after it had entered into commitments with the Commission not to provide direction or oversight to Accord-UK, its subsidiary, as part of a merger control process: H1, [285] **[CB/16/432-437]**.

[125] [2024] EWCA Civ 1023.

[16] **[CB/18/624-625]**.

Jurisdiction of this Court

90. This Court's jurisdiction is governed by s. 49(1) CA 1998 and is not limited in relation to penalty to errors of law by the CAT. An appeal against penalty is unlikely to be successful unless it can be shown either that the CAT erred in principle or that, looked at overall, the penalties imposed were disproportionate or discriminatory.[126]

Issue 1: Whether the CAT was wrong to hold that the Unfair Pricing Abuses were intentional within the meaning of s. 36(3) CA 1998

91. The appellants all challenge the CAT's finding at H1 at [376(1)] **[CB/16/471-472]** that the abuse of dominance infringements were committed intentionally.[127]

92. A penalty can be imposed only if the CMA (or, on appeal, the CAT) is satisfied that the infringement has been committed intentionally or negligently by the undertaking.[128] An infringement is committed intentionally if the undertaking could not have been unaware of the essential facts that its conduct was exploitative or anti-competitive.[129]

93. The CMA submits that the CAT was plainly entitled to find at [376(1)] that the Auden/Actavis undertaking had intentionally abused its dominant position. The CAT held that Auden/Actavis' market shares "*clearly denoted dominance*" and competition was of "limited effect": H1 at [293]-[295] **[CB/16/441-442]**; that it was "*plain to the point of irrefutability*" that the prices were excessive: H1 at [333] **[CB/16/458]** and none of the Appellants advanced an explanation for the excess consistent with a competitive market: H1 at [342(2)] **[CB/16/461-462]**.

94. The CAT held that "the record of this appeal demonstrates very clearly an illegitimate exploitation of market power to leverage price well in excess of what was fair": H1 at [376(2)] **[CB/16/472]**. None of the Appellants' arguments establishes that the CAT was wrong:

a. Auden, Allergan and Intas are wrong in law to suggest that the CAT had to determine whether Actavis, Allergan or Intas (i.e., the corporate legal entities that later acquired Auden)

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126 *Interclass Holdings Ltd v OFT* [2012] EWCA Civ 1056, at [59] **[AB/29/779-780].**

127 Auden Ground 2, Allergan Ground 2(b) , Intas Ground 3.

128 CA 1998, s. 36(3) **[AB/67/2244].**

129 *Ping Europe Ltd v CMA* [2020] EWCA Civ 13, at [117] **[AB/46/1208],** cited in Decision, §10.16. **[CB/23/1619]**

acted intentionally.[130] The correct question is whether the Auden / Actavis undertaking (of which those legal entities formed part, during their ownership periods) committed the infringement intentionally or negligently, as is clear from both s. 36(3) CA 1998 and the case-law.[131] They clearly did.[132]

b. Nor (for the same reason) is it relevant to intention whether Mr Stewart of Allergan or Dr Burt of Intas knew or should have known about the infringing conduct. It was sufficient, as a matter of law, that the Auden/Actavis undertaking included the legal entity that sold HTs at unfair prices.[133] Further, intention can be inferred from all the facts and circumstances.[134] The CAT's finding of intention is amply borne out by Auden/Actavis' knowledge of the essential facts that meant it was dominant and charging unfair prices.[135]

c. Allergan is wrong to suggest at §§55-58 **[CB/6/121-123]** that the CAT's finding of intention turns on any business person having to appreciate the CAT's analysis of abuse in this case. The stark reality was that Auden/Actavis' prices exceeded cost-plus by 879% for 10mg and 702% for 20mg tablets.[136] On those facts, the CAT rightly pointed out in H1 at [376(1)] **[CB/16/471]** that "any business person with any understanding of the pharmaceutical business would have appreciated that these margins were only defensible if there was some legitimate means of differentiating the 10mg and 20mg Focal Products from the competition."

d. Intas' claim that the Decision did not find that Intas committed the infringement intentionally is misconceived for two reasons.[137] First, it focuses on the wrong person for the

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130 Auden skeleton, §75 **[CB/5/97]**; Allergan skeleton, §§61-62 **[CB/6/125-126]**; Intas skeleton, §40 **[CB/7/147-148]**.

131 The case-law is cited in Decision, fns 3497 and 3509 **[CB/23/1618; 1620-1621]**. Ignorance or mistake of the law does not preclude an intentional infringement: Decision, §§10.14-10.16 **[CB/23/1619]**.

132 H1, at [375]-[376(1)]**[CB/16/471-472]**; Decision, §§10.21-10.29 **[CB/23/1621-1626]**.

133 Decision, §10.22 **[CB/23/1621-1622]**: AM Pharma from 1 October 2008 to 31 August 2015, and Actavis-UK (later renamed Accord-UK) from 1 September 2015.

134 *Napp*, at [456] **[AB/7/380].**

135 Decision, §§10.25-10.28, esp. §10.25(d) and §10.28(c)(ii), (d)(ii) **[CB/23/1622-1626]**; CMA's Amended Defence, §§431-433 **[RS/9/637-638].**

136 H1, at [376(1)] **[CB/16/471-472]** and Decision, Table 5.4 **[CB/23/1090]**.

137 Intas skeleton, §40.1 **[CB/7/147]**.

reason set out in §0 above. Secondly, the CMA only has to be satisfied, as a threshold matter, that the infringement was intentional or negligent.[138]

e. The issue of intention / negligence was live before the CAT and all parties had a fair opportunity to present evidence and make submissions on it during the trial. There is no basis for Intas' complaint that there was a failure of due process.[139]

95. If (contrary to the above arguments), the Court considers the CAT erred in its approach,[140] then the CMA submits that the Auden/Actavis undertaking acted intentionally or negligently because it knew or should have known the facts:

a. Auden/Actavis was dominant: in particular, that it was the sole and subsequently major supplier of HTs in the relevant markets.[141]

b. Auden/Actavis' prices for its HTs were unfair, in particular given that they: (i) soared by 1,500% from c. £4-5 per pack in April 2008 to £72 per pack in March 2016;[142] (ii) did not reflect any material increase in production costs or any investment in the tablets; (iii) exceeded any reasonable measure of costs plus a reasonable return; (iv) remained significantly above cost plus even after prices fell from 2016 onwards.[143] Moreover, Auden/Actavis was aware (or should have known) that it was able to exploit its dominant position by increasing prices.[144]

96. Allergan refers to Mr Stewart's evidence that the margins for HTs were not dissimilar to those for other parts of its business.[145] But the Auden/Actavis undertaking cannot have been unaware that its 10mg pricing was unfair regardless of the margins for other products. There is no evidence that Allergan's other products were comparators that could have suggested

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138 *Napp Pharmaceutical Holdings Ltd v DGFT* [2002] CAT 1, at [455] **[AB/7/379].**

139 Intas skeleton, §41 **[CB/7/148]**.

140 CMA Respondent's Notice, §9 **[CB/4/72-73]**.

141 Decision, §10.24 **[CB/23/1622]**.

142 Decision, §5.320 and §§5.351-5.355 **[CB/23/1157, 1167-1168]**; the surge in prices was even higher when compared to MSD's price of less than £1 per pack before April 2008.

143 Decision, §10.28(a)-(c) **[CB/23/1625-1626]**.

144 Decision, §§10.28(d)-10.29 **[CB/23/1626]**.

145 Allergan skeleton, §61.3 **[CB/6/125-126]**.

Auden/Actavis' 10mg prices were fair.

Issue 2: Whether the CAT was wrong to fail to quash the penalty for the 10mg Agreement in light of the finding in H2 at [137]

97. Auden argues that the CAT erred in failing to quash the penalty for the 10mg Agreement given its finding in H2 at [137] **[CB/17/604-605]**, namely, the corporate legal entities that acquired the holder of the Merck, Sharpe & Dohme ("**MSD**") marketing authorisation ("**MA**") did not know or should have known of the illegal aspects of the 10mg Agreement.[146]

98. The short answer to Auden's argument is that at all times the Auden/Actavis *undertaking* included the legal entity that sold HTs and entered into the 10mg Agreement.[147] What matters is not whether the acquirers of the holder of the MA for Auden's HTs were aware of the illegal aspects of the 10mg Agreement but whether the undertaking cannot have been unaware of its anti-competitive nature.[148] It plainly was.[149] As the CAT put it in H2, at [137] **[CB/17/604-605]**: "… *the acts and state of mind of Auden – because Auden was part of the same undertaking – are the acts and state of mind of these entities also. If Auden was infringing, then so were they*."

99. In any event, even if there were a question about whether the unlawful 10mg Agreement was intentional or negligent in light of H2 at [137] **[CB/17/604-605]**, that issue is pending before the CAT. Therefore it would be premature to consider the matter in these appeals.

Issue 3: Whether the CAT was wrong to uphold the uplifts for specific deterrence

100. Before turning to the appellants' specific claims,[150] a comment needs to be made about the CMA's assessment of deterrence. Section 36(7A) of the CA 1998 obliges the CMA to have regard to the seriousness of the infringement and to the desirability of deterrence. The CMA carried out a multi-factorial assessment of the factors set out in Step 4 of the Penalty Guidance for each infringement and each undertaking at the time of the Decision.[151] As the CAT rightly

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146 Auden Ground 2 and Allergan Ground 2(b) ; Auden skeleton, §75 **[CB/5/97].**

147 See §94 of this skeleton argument, above.

148 See *Royal Mail plc v Ofcom* [2019] CAT 27, at [782] **[AB/45/1203]**.

149 Decision, §§10.35-10.39, 10.43, and 10.46 **[CB/23/1626-1631, 1632-1633, 1634-1636]**.

150 Auden Ground 3, Allergan Ground 2(c), Intas Ground 4 **.**

151 Decision, §§10.251-10.308 **[CB/23/1704-1722]**.

noted in H1 at [367(6)] **[CB/16/469]**, the CMA took into account:

a. The minimum financial benefits reaped by Auden/Actavis from the abuses during the periods of ownership of the infringing entity: §§10.142-10.147 (generally) **[CB/23/1664-1666]**, §§10.258-10.264 (10mg Abuse) **[CB/23/1706-1709],** and §§10.297-10.308 (20mg Abuse) **[CB/23/1718-1722]**.
b. The serious nature and severe impact of each infringement: §§10.265-10.268 (10mg Abuse) **[CB/23/1709-1710]** and §§10.305 and 10.307 (20mg Abuse) **[CB/23/1721-1722]**.
c. The size and financial position of the undertaking at the time of the Decision: §§10.270-10.272 (Allergan) **[CB/23/1710-1711]** and §§10.279-10.280 (Intas) **[CB/23/1712-1713]**.
d. The fact that the undertakings had a significant proportion of their turnover outside the relevant market: §10.273 (Allergan) **[CB/23/1711]** and §10.281 (Intas) **[CB/23/1713]**.
e. The scale of the infringement during Allergan's ownership: §§10.274-10.277 **[CB/23/1711-1712]**.
f. The fact that Intas continued its unfair pricing even though it was aware of the CMA's investigation: §§10.282-10.283 **[CB/23/1713-1714]**.

101. It is evident from these paragraphs of the Decision that the CMA weighed the need to impose a penalty that reflected the serious and harmful nature of the infringement and the need for specific deterrence against the financial impact on each undertaking, in line with the Guidance. The CMA and, on appeal, the CAT was not required to adopt an even finer-grained approach, attaching particular 'weightings' to each consideration.[152] The CMA's overall conclusions at Step 4 in Decision §10.296 (10mg Abuse) **[CB/23/1718]** and §10.308 (20mg Abuse) **[CB/23/1722]** were by their nature a judgement in the round. The above considerations also justify the CAT's broad-brush assessment in H1, at [375]-[376] **[CB/16/471-472]**.[153]

102. The appellants all challenge the uplift imposed on each of them to achieve specific deterrence,

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152 See *FP McCann v CMA* [2020] CAT 28, at [312] and [314] **[AB/49/1316-1317];** see also, in a regulatory context, *Virgin Media v Ofcom* [2020] CAT 5, at [117] **[AB/47/1215].**

153 Respondent's Notice, §12 **[CB/4/73-74].**

and between them make six main submissions.[154]

103. First, the appellants challenge the size of the uplifts for the Unfair Pricing Abuses. The CMA submits that the necessity and size of the uplifts must be understood in light of the size and financial position of the undertaking as well as the need to deter exploitative pricing, which richly rewarded the wrongdoer and harmed the NHS:

    a. **Auden**: the Step 3 penalty for its sole liability for the 10mg abuse was £40.6m. Accord-UK's minimum financial benefit from that abuse was more than double that figure: £87.6m.[155] In principle, the fine should materially exceed the proceeds from unlawful behaviour so that violations of the law will not pay.[156] This would have meant that Auden's Step 4 penalty should have been materially more than £87.6m. However, Auden's Step 3 penalty exceeded the statutory cap of £28.4m and so no adjustment was necessary (or indeed possible).

    b. **Allergan**: the Step 3 penalty for the 10mg abuse during its ownership of the infringing undertaking was £6.8m. This would not adequately deter given (i) it was 0.02% of Allergan's worldwide turnover of £35.7 billion, 0.19% of its profit after tax of £3.6 billion and 0.07% of net assets of £9.6 billion; and (ii) it was much smaller than the minimum financial benefit obtained from the abuse of £37.9m during Allergan's ownership. In addition, monthly ASPs reached their zenith during Allergan's ownership (£72 per pack of 10mg in March 2016 and £72 per pack of 20mg in October 2015)[157] and NHS spending hit £84m in 2016.[158]

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154 It is not clear what Auden seeks to achieve by objecting to a hypothetical adjustment at Step 4: the statutory cap had the effect of reducing the Step 3 penalties for the 10mg infringements; and no uplifts were imposed in relation to the 20mg infringements.

155 Decision, §10.285 **[CB/23/1714]**.

156 Decision, §10.142 **[CB/23/1664]**. Businesspeople generally act rationally and will weigh up all their options, including the profitable illegal ones. On the relevance to fine-setting of profiting from an infringement see Cases C-189/02 P *Dansk Rørindustri v Commission* EU:C:2005:408, at [260] and [292] **[AB/12/451-452,460];** see also opinion of AG Sharpston in Case C-50/12 P *Kendrion NV v Commission* EU:C:2013:350, at [80] **[AB/31/835].**

157 Decision, §§5.83(c) and 10.275-10.277 **[CB/23/1091-1092, 1711-1712]**.

158 Decision, §10.267(a) **[CB/23/1709]**.

c. **Intas**: the Step 3 penalty for the 10mg abuse during its ownership of the infringing undertaking was £8.9m. This figure would not adequately deter given (i) it was 0.5% of Intas' worldwide turnover, 4.9% of its profit after tax and 0.9% of its net assets;[159] and (ii) it was much smaller than the minimum financial benefit obtained from the abuse of £12.5m during Intas' ownership.[160] See further issue 6 below.

104. The CMA also adjusted the Step 3 penalties for the 20mg abuse for Allergan in light of the financial benefit from that abuse and its size and financial position.[161]

105. Where a penalty is only a very small percentage of the undertaking's total turnover, the impact of the penalty on that undertaking is likely to be very limited. The Step 3 penalties for the abuse of dominance infringements are insignificant for undertakings of the size and strength of Allergan and Intas. It is only when the penalties imposed are sufficiently high to make a real impact on the undertaking that an addressee of an infringement decision is given the necessary incentive to comply with competition law in the future.[162]

106. Second, the appellants pray in aid the DHSC's price control powers.[163] However those powers have never been used. The DHSC has publicly committed to consulting on its methodology for using its powers, but it had not done so by the time of the Decision or H1 (and still has not done so). In any event, these powers only extend to the prices of individual unbranded generic medicines,[164] whereas specific deterrence applies to all activities of the infringing undertaking. Put shortly, the possibility of future regulation of an individual generic pharmaceutical product does not negate the need for deterrence.

107. Third, the appellants contend that the CMA gave "no specific reason" to think that they would

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159 Decision, §10.280 **[CB/23/1713]**.

160 Contrary to the plea in Intas' skeleton, §47.2 and §50.3 **[CB/7/151, 152],** the minimum financial benefit of the abuse does not operate as a ceiling or limit on the extent of a deterrence uplift. It is one but not the only factor when adjusting a Step 3 fine to secure specific deterrence.

161 Decision, §§10.297-10.308 **[CB/23/1718-1722]**.

162 Case T-15/02 *BASF AG v Commission* EU:T:2006:74, at [235] **[AB/13/486].**

163 Auden skeleton, §81 **[CB/5/98-99];** Allergan skeleton, §65.2 **[CB/6/127-128]**.

164 Decision, Annex F, §§79-87 **[CB/26/1870-1872]**.

re-offend,[165] referring to the CAT's decision in *Liothyronine* at [491] **[AB/53/1602]**. This contention ignores the fact that the CMA did give specific reasons, including the unduly small nature of the Step 3 penalties relative to the financial benefit of the abuse and the overall size of the Allergan and Intas undertakings. These were indications of a risk of recidivism.

108. Fourth, the Auden Appellants refer to some irrelevant considerations:[166] (i) Actavis was the economic successor to the infringing entity; (ii) Actavis bought the Auden business and (iii) Actavis did not instigate the infringing conduct. These points are misconceived:

a. As to (i), the CMA found (and Auden has not contested) that Actavis was the economic successor of AM Pharma and, as such, " *liability follows the infringing business and the gains from the Infringements and deters the entity on whom the penalty is imposed*".[167]

b. As to (ii), the purchase of a highly profitable infringing business does not preclude an uplift for specific deterrence. It does not alter Actavis' imposition of abusively high prices. Nor is Auden's assertion that it used the profits as part of an alleged portfolio pricing approach relevant. The purpose of the deterrent uplift is not simply to disgorge ill-gotten gains; its purpose is broader and takes into account all the factors in §§2.20-2.24 of the Penalty Guidance that are relevant to adjusting a penalty in order to have the desired deterrent effect.

c. As to (iii), the absence of instigation does not preclude the need for deterrence.[168] What is relevant in this case is that Actavis continued the infringing conduct.

d. None of the factors identified by Auden offset the substantial financial gains derived by it from the abuses. The potential returns from unfairly high prices are so likely and so great that (absent an uplift for a sufficient specific deterrent effect) it would be very tempting behaviour for profit-maximising dominant firms.

109. Fifth, the Allergan Appellant challenges the uplift applied in the Decision to a Step 4 penalty

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165 Auden skeleton, §80 **[CB/5/98]**; Allergan skeleton, §66 **[CB/6/128]**; Intas skeleton, §50.1 and 50.4-50.6 **[CB/7/152-153]**.

166 There was no upward adjustment for the penalty imposed for the 20mg Agreement: Decision, §§10.329-10.331 **[CB/23/1726]**.

167 Decision, §9.90 **[CB/23/1510]**.

168 Instigation is an aggravating factor under Step 3; the absence of instigation is neither a mitigating factor under Step 3 nor a factor for reducing penalties at Step 4.

of £74.3m, without acknowledging that on appeal the CAT reduced the fine to £49.3m.[169] In summary, the CMA's responses to its main arguments are:

a. The lack of historic conduct or culpability specific to Allergan plc is immaterial. This Court has held that the policy of the CA 1998 is to protect the public by imposing obligations on the undertaking.[170] The CMA and the CAT were entitled to assess whether the proposed penalty would have a sufficient deterrent effect and be proportionate by reference to each undertaking as at the time of the CMA's decision. Allergan's reference to the EU case of *Deutsche Telekom* **[AB/41/1098-1145]** is misplaced, since the CMA did not increase the fine purely by reference to a former parent company's turnover.[171] Allergan is, moreover, wrong to claim that it is not culpable: it is just as culpable as the other members of the Auden/Actavis undertaking for the infringement during its ownership period.[172]

b. Allergan emphasises that it owned and operated Auden/Actavis for 9 months and that it expected the hydrocortisone "*cash cow*"[173] would lead to market entry and falling prices.[174] Neither point negates the central fact that Auden/Actavis charged abusively high prices throughout Allergan's period of ownership.[175] Neither detracts from the need for deterrence for the reasons given in Decision, §10.288 **[CB/23/1714-1715]**. It is not necessary to show that Allergan knew or should have known about the unlawful conduct in order to adjust a penalty under Step 4 of the Penalty Guidance.

c. Allergan points the finger at the DHSC for 'letting' it charge the prices it did for HTs during its ownership of Auden/Actavis.[176] The CMA rejects this unworthy attempt to shift

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169 Allergan skeleton, §51 and §65 **[CB/6/120, 127-128]**.

170 *Safeway Stores Ltd v Twigger* [2010] EWCA Civ 1472, at [23] **[AB/23/692].**

171 See §99 of this skeleton, above.

172 Case C-882/19 *Sumal SL v Mercedes Benz Trucks España SL* EU:C:2021:800, at [42]–[43], considered in *CMA v R (VW AG)* [2023] EWCA Civ 1506, at [84]-[88] **[AB/54/1606-1609]**.

173 Decision, §10.28(d)(ii) **[CB/23/1626]**.

174 Allergan skeleton, §§59.1, 59.4 and 65.2 **[CB/6/123-124, 127-128].**

175 Allergan was the parent of Accord-UK, the infringing subsidiary, and is properly penalised for the 10mg Abuse that it is deemed to have committed itself; on the legal principle see Case T-372/10 *Bolloré v Commission* EU:T:2012:325, at [51] **[AB/28/761]**.

176 Allergan skeleton, §59.2 **[CB/6/123-124].**

the blame. The true position is that Auden/Actavis failed to comply with its special responsibility not to exploit its dominance.[177] Whilst the CAT did find that there had been a regulatory failure in this market, it also found that this did not justify the abuse, which "arose out of the illegitimate exploitation": see H1, at [351] and [376(1)] **[CB/16/464,471]**.

d. Allergan's complaint that it is being fined 50% of the total fines is misplaced. The specific deterrent effect of a fine is calibrated to the infringer's characteristics and circumstances. Thus, the uplift at Step 4 should not be affected by a comparison with the overall penalties after Step 6 (which, by definition, are imposed on all addressees in respect of all infringements found by a decision).

e. Finally, Allergan's attack on the use of global turnover is mistaken. It is a relevant criterion under Step 4 of the Penalty Guidance.[178] The fact that Allergan generates most of its turnover outside the relevant market is one of the reasons why an uplift is appropriate,[179] lest the deterrent effect of fines in the UK be unduly weakened.[180]

110. Sixth, the Intas and Allergan Appellants refer to a comment by a differently constituted Tribunal panel in *Phenytoin* that a 400% deterrent uplift applied to Pfizer's fine for excessive pricing would be difficult to justify.[181] The Tribunal's comment was *obiter*. It did not purport to lay down a hard-edged rule to be applied in all cases. Nor did the Tribunal reach a final conclusion on the deterrence uplift in that case. It follows that there was no need for the Tribunal to give reasons for not following a non-binding and non-definitive observation in an earlier case.

Issue 4: Whether the CAT was wrong to decide that the CMA was entitled to impose four separate penalties on Accord-UK for four separate infringements

111. The Auden Appellants argue that the CMA was wrong to fine Actavis four times over for

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177 Decision, §5.278 and §5.491 **[CB/23/1146, 1202].**

178 Penalty Guidance, §2.20 **[AB/82/2479]**; it is also relevant to the statutory maximum: s. 36(8) CA 1998 **[AB/82/2479].**

179 See *Eden Brown Ltd v OFT* [2011] CAT 8, at [90] **[AB/27/748]**.

180 It is irrelevant that a different jurisdiction (the USA) applying a different anti-trust law does not prohibit excessive pricing in its own territory; cp. Allergan skeleton, §65.5 **[CB/6/128].**

181 Intas skeleton, §50.5 **[CB/7/152]**; Allergan skeleton, §59.3 and again at §65.4 **[CB/6/124, 128]**.

what they consider to be a single course of conduct.[182] This, it is said, fails to achieve the purpose of the statutory cap in s. 36(8) CA 1998. Allergan adopts this ground.[183]

112. The CMA agrees with the CAT's pithy summary in H4 at [15(4)] **[CB/18/625]**: "*The CMA's approach does not obviate the statutory cap. Different penalties were imposed for different, serious, infringements*."[184] Although the Agreements delayed the emergence of competition and enabled Auden/Actavis to charge unfair prices, there were separate infringements since:[185]

1. **Objectives**: Auden/Actavis did not pursue a common objective with Waymade/AMCo in relation to its abuse of dominance.[186] The objective of the 10mg and 20mg Agreements was to eliminate potential competition from (respectively) Waymade and AMCo, thereby protecting Auden/Actavis' market position.[187] Nor did the 10mg and 20mg Agreements share a single objective, although the manner in which they were concluded was similar.[188]
2. **Participants**: Waymade and Auden were parties to the 20mg Agreement; whereas Waymade/AMCo and Auden/Actavis participated in the 10mg Agreement. Only Auden/Actavis abused its own dominant position.[189]

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182 Auden Grounds 3 and 4 ; Auden skeleton, §§83-87 **[CB/5/99-101]**.

183 Allergan skeleton, §67 **[CB/6/128].**

184 As a matter of law, separate fines can be imposed for separate infringements: Cases T-71/03 *Tokai Carbon v Commission* EU:T:2005:220, at [118] and [124] **[AB/11/443],** cited in Decision, §10.150 **[CB/23/1668]**.

185 Respondent's Notice, §13 **[CB/4/74]**; Decision, §§10.150-10.153 **[CB/23/1668-1669]** and CMA's Amended Defence, §§599-605 **[RS/9/699-701]**.

186 Decision, §10.153(a)-(b) **[CB/23/1668-1669]** ; see Case T-681/14 *Servier SAS v Commission* EU:T:2018:922, at [1289] **[AB/40/1097].**

187 Decision, §6.888 **[CB/23/1456]**.

188 Auden/Actavis NoA, §117(1) accepted that the two agreements were "separate and significantly different" from one another.

189 Decision, §10.153(f) **[CB/23/1669]**; see Cases T-71/03 *Tokai Carbon v Commission* EU:T:2005:220, at [120] **[AB/11/443]**.

a. **Timing**: the Unfair Pricing Abuses pre- and post-dated the Agreements, lasting for eight years (20mg) and nine years (10mg). The 10mg Agreement was entered into almost a year after the 20mg Agreement, albeit both lasted around three years.[190]

b. **Conduct**: the primary payment mechanism under the 20mg Agreement (sale to Waymade and resale to Auden) was different from that under the 10mg Agreement (supply of fixed volumes at a deeply discounted price).[191] Both mechanisms were distinct from Auden/Actavis' unilateral imposition of unfair prices, which, in turn, differed as between the 10mg and 20mg strengths.

113. The Auden Appellants emphasise the Tribunal's finding that the two strengths were in the same relevant product market.[192] However, the definition of the relevant market does not compel (or preclude) a finding of a single and continuous infringement.[193] Moreover, the criteria set out in §112 above all pointed against such a finding. Even if (contrary to the CMA's primary case) the Agreements and Unfair Pricing Abuses met the criteria for finding a single and continuous infringement, there is no obligation on the CMA or the CAT to do so.[194] The single and continuous infringement concept exists to help with enforcement of the law, not to hinder it.

114. In the premises, the CMA (and on appeal the CAT) was entitled as a matter of law to impose a separate fine for each separate infringement, each subject to the statutory cap.[195] The approaches taken in previous cases[196] reflect the facts of those cases and do not mandate the

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190 Decision, §7.2 **[CB/23/1475]**.

191 Decision, §§6.362-6.370 **[CB/23/1304-1306]**; *Servier*, at [1279] **[AB/40/1096]**.

192 Auden skeleton, §85 **[CB/5/100]**.

193 Case T-373/10 *Villeroy & Boch v Commission* EU:T:2013:455, at [52]-[58], and on appeal to the CJEU in Case C-626/13 P EU:C:2017:54, at [67]-[69] **[AB/37/906]**.

194 See Newey LJ in *Balmoral Tanks Ltd v CMA* [2019] EWCA Civ 162, at [31]-[32] **[AB/42/1162]**.

195 Decision, §10.151 **[CB/23/1668]** citing Case T-446/05 *Amann & Söhne v Commission* EU:T:2010:165, at [93]-[94] **[AB/21/657]**.

196 Auden skeleton, §87 **[CB/5/100-101].**

imposition of a single fine in this case.[197]

115. The CMA recognised that multiple penalties were imposed for infringements affecting the same market at the same time and took care to avoid double counting.[198] For example, the CMA only used relevant turnover from the 10mg tablet for the 10mg infringements and 20mg turnover for the 20mg infringements.[199] The CAT's market definition did not require it (and does not require this Court) to use a new measure of relevant turnover.

Issue 5: Whether the CAT made its own assessment of the penalties

116. The appellants contend that the CAT erred because, they say, it failed to form its own view on the proportionate and appropriate penalty.[200] This contention is wrong. The CAT's task on penalty appeals under the CA 1998 is two-fold and it fulfilled both tasks:

a. First, as the CAT expressly recognised, it had to reach its own assessment about the appropriateness of the penalties imposed: H1, at [357] and [374] **[CB/16/465, 471]** and H4, at [13]. The CAT said in H1 at [374(2)] **[CB/16/471]** that it had taken full account of the submissions made by the appellants and "considered on the merits" the basis on which the penalties were calculated: see H1 at [377(2)] **[CB/16/472]**; see also H4, at [16] **[CB/18/625]**.

b. Second, the CAT had to consider whether CMA had made a "material error" or adopted a "defensible approach". This is important for the CMA and the parties to know where (if anywhere) the CAT considers that the CMA has gone materially wrong: H1, at [375] **[CB/16/471]**. This is consistent with the CAT's approach in other cases.[201]

117. Despite this, Allergan and Intas claim that the CAT failed to assess the proportionality of the

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197 On the facts of the *Napp*, *Phenytoin* and *Paroxetine* cases see CMA's Amended Defence, §603 **[RS/9/700].** On the non-binding nature of previous penalty decisions see *Eden Brown Ltd v OFT* [2011] CAT 8, at [78] **[AB/27/745].**

198 Decision, §10.155 **[CB/23/1669-1670]**.

199 Decision, Annex F, §65 **[CB/26/1866-1867]**.

200 Auden Ground 3; Allergan Ground 2(a); Intas Ground 4; see Auden skeleton, §77 **[CB/5/97]** Allergan skeleton, §§54 and 59 **[CB/6/121-124]**; Intas skeleton, §42 **[CB/7/148-149]**.

201 *G F Tomlinson Group Ltd v OFT* [2011] CAT 7 at [72] (Vivien Rose: Chair) **[AB/26/729-730]**, aff'd in *Roland (U.K.) Ltd v CMA* [2021] CAT 8, at [34] (Andrew Lenon KC: Chair) **[AB/50/1334]**.

penalties.[202] If, as the CMA submits, the Tribunal's findings of liability are upheld, the question for this Court is whether the Tribunal was wrong to impose the fines it did.[203] In addressing that question, the Court must have regard to the CAT's reasons in H1, at [375]-[376] **[CB/16/471]**, which must be understood in light of its earlier findings about the harmful nature of the abuse of dominance infringements. None of those reasons can be faulted. Given the CAT showed the parties and this Court the basis on which it acted, it is not necessary for the CAT to address every argument presented by a party.[204] The CMA submits that there is no basis for interfering with the CAT's assessment of the penalties needed to mark the gravity of the infringements and to ensure proper deterrence.

118. If (contrary to the arguments set out above) the Court considers that the CAT failed to assess the proportionality of the penalties or failed to set out its reasoning fully, then the CMA asks the Court to confirm the penalties imposed by the Decision (subject to the undisputed reduction in Allergan's fine for the 10mg Abuse) under s. 15(3) of the Senior Courts Act 1981 and paragraph 3(2)(b) of schedule 8 to the CA 1998.[205]

119. The final penalties imposed for the **10mg Abuse** were appropriate:

120. **Auden**: the result of the statutory cap at Step 5 was to reduce Accord-UK's penalty to £28.4m. The cap prevented an excessive burden from being imposed on it.[206]

121. **Allergan**: the Step 4 penalty was £74.3m (reduced on appeal to £49.3m). £74.3m was only 0.2% of Allergan's worldwide turnover for the financial year ending 31 December 2020.[207] Using three-year averages, £74.3m was also only 0.3% of Allergan's worldwide turnover, 1.6% of its annual profit after tax and 1.5% of its average dividends.[208] Bearing in mind the serious nature of this abuse, its severe impact on the NHS and how Allergan gained from it,

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202 Allergan skeleton, §59 **[CB/6/123-124]** and Intas skeleton, §46 **[CB/7/150]**.

203 *Argos Ltd and Littlewoods Ltd v OFT* [2006] EWCA Civ 1318, at [230] **[AB/16/541-542]**.

204 *Argos*, [5] **[AB/16/513]** and case-law cited.

205 For an overview of the CMA's approach see Decision, §§10.139-10.160 **[CB/23/1663-1672]**.

206 *Eden Brown v OFT*, §57 **[AB/27/744]**; *FP McCann v CMA*, §90 **[AB/49/1309].**

207 Decision, §10.288(a) **[CB/23/1715]**. £49.3m is 0.14% of Allergan's worldwide turnover.

208 Decision, §10.288 **[CB/23/1714-1715]**.

this is a proportionate sum.[209]

122. **Intas**: the Step 4 penalty was £44.4m. This was 3% of Intas' worldwide turnover and 4% of its net assets for the financial year ending 31 March 2020.[210] Using three-year averages, £44.4m was 3% of Intas' worldwide turnover and 29% of its annual profit after tax.[211] Again, having regard to these financial indicators and the serious nature of the abuse, its harmful impact and Intas' financial gain from it, this is a proportionate sum.[212]

123. The CMA also submits that the final penalties for the **20mg Abuse** were proportionate for the reasons set out in the Decision.[213]

124. Likewise, the penalty of £2.8m imposed on Accord-UK for the **20mg Agreement** is both an effective deterrent to that undertaking and proportionate, having regard in particular to the fact that the penalty was just 0.2% of Accord-UK's turnover and the harmful nature and impact of that agreement.[214]

125. The CMA did not stop there. It also assessed the proportionality of the aggregate penalties imposed on each of the Auden and Allergan Appellants:[215]

    a. **Auden**: the CMA assessed the total penalty of £112m imposed on Accord-UK for the four separate violations of competition law committed by Auden/Actavis.[216] At the time of the Decision Accord-UK was part of the same undertaking as Intas and this total penalty constituted 6.3% of its worldwide turnover.[217] All four fines did not exceed the statutory cap that would apply to the Accord-UK/Intas undertaking for one infringement. Auden is

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209 Decision, §10.289 **[CB/23/1715]**.

210 Decision, §10.291(a) and (d) **[CB/23/1716]**.

211 Decision, §10.291(a) and (c) **[CB/23/1716]**.

212 Decision, §10.292 **[CB/23/1716]**.

213 Decision, §§10.301-10.308 **[CB/23/1720-1722]** (20mg Abuse).

214 H4, at [13]-[15] **[CB/18/624-625]** and Decision, §§10.322-10.327 **[CB/23/1724-1726]**.

215 Decision, §§10.157-10.160 **[CB/23/1670-1672]**.

216 Accord-UK is solely liable for £67.6m for the 10mg Abuse from 1 October 2008 to 8 January 2017, the 20mg Abuse and the Agreements and jointly and severally liable with Intas for £44.4m imposed in respect of the 10mg Abuse from 9 January 2017 to 31 July 2018: Decision, Tables 10.1 and 10.2 **[CB/23/1660, 1663]**.

217 Decision, §§10.414-10.415 **[CB/23/1746-1747]**; see also §10.293 **[CB/23/1716-1717]**.

wrong to claim in §83 of its skeleton that its total fine exceeded the statutory cap that *applies to it*; the cap applies to the penalty imposed for each infringement committed by the undertaking.[218]

b. **Allergan**: the CMA assessed the total penalty of £111.1m imposed on Allergan for the three separate violations of competition law committed by Auden/Actavis under Allergan's ownership.[219] The CMA considered that figure was proportionate, taking into account the fact that it was just 0.3% of Allergan's worldwide turnover and the serious and harmful nature of the infringements committed during its ownership of the infringer.[220]

Issue 6: Whether the CAT was right to dismiss Intas penalty appeal

126. The Intas Appellants contend that the CAT should not have upheld the penalty of £44.4 million imposed by the CMA on Intas. This section addresses Intas' arguments that the CAT failed (1) to take account of the circumstances of the period during which Intas owned and operated Auden/Actavis (Intas period from 9 January 2017 to 31 July 2018) and (2) to assess the proportionality of Intas' penalty relative to other appellants.[221]

127. **Intas period**: Intas says the market had "evolved" by the time of the Intas period.[222] The CAT had well in mind what it called "Phase 5" which was the period during which Intas controlled the Auden/Actavis infringing undertaking.[223] It recognised for example that Auden/Actavis' prices were falling (from their highest levels) during the Intas period, as can be seen from H1, at [342(4)] **[CB/16/462]**. The CAT held it was irrefutable that Auden/Actavis' prices were excessive at all times: H1, at [333] **[CB/16/458]**.[224] It had no doubt that there was no justification for the excess producer surplus: [342(1)] **[CB/16/461]**.

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218 See the opinion of AG Sharpston in Case C-50/12 P *Kendrion NV v Commission* EU:C:2013:350, at [92]-[93] **[AB/31/836]** and the CJEU judgment in Case C-50/12 P EU:C:2013:771, at [57] and [66] **[AB/32/851, 853].** The cap in s. 36(8) CA 1998 is modelled on EU law: *FP McCann v CMA* [2020] CAT 28, at [92] **[AB/49/1309-1310].**

219 Decision, Table 10.14 **[CB/23/1746]**. Following its appeal to the CAT, the total figure is now £86.1m.

220 Decision, §10.413 **[CB/23/1746]**.

221 Intas skeleton, §§46-49 **[CB/7/150-151]**.

222 Intas skeleton, §§46, 48, 49, 50 **[CB/7/150, 151, 152]**.

223 H1, at [179(5)], [289]-[290], [342(4)], [366(4)], [368] **[CB/16/372, 439-441,462,468,469]**.

224 H1, at [334] **[CB/16/458]** held that the CMA's finding of excessive prices was unimpeachable.

The CAT should be taken to have had these points well in mind when it reached its overall conclusions about the appropriateness of the penalties in H1, at [375]-[376] **[CB/16/471-472]**.

128. If, however, the CAT erred in its determination of Intas' penalty appeal, or failed to provide adequate reasons for its decision, the CMA asks this Court to uphold the penalty for the following additional reasons:[225]

a. Accord-UK retained market shares for 10mg tablets by volume and, in particular by value, which were much higher than those of its competitors.[226]

b. Although 10mg prices fell during the Intas period, Accord-UK's prices remained very high, and much higher than those of its competitors.[227] This can be seen from the differentials between Accord-UK's ASP and Cost Plus (1,524%)[228] and MSD's pre-infringement price in 2008 (4,937%).[229]

c. Accord-UK's minimum financial benefit from the 10mg Abuse during the Intas period was £12.5m, and the excess above Cost Plus was £27m.[230]

d. Intas' Step 3 penalty of £8.9m would be unlikely to deter an undertaking of its considerable size: its reported revenue in 2020 was £1.65 billion.[231]

e. Intas' Step 4 penalty of £44.4m is an effective and proportionate deterrent given its gain from the abuse, the serious and harmful nature of the abuse, Intas' size and financial position, its significant turnover outside the relevant market and that it continued the infringing conduct during the CMA's investigation.[232]

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225 Respondent's Notice, §14 **[CB/4/74-75].**

226 Decision, §§4.253-4.262 **[CB/23/1040-1042]**.

227 Decision, §4.265 **[CB/23/1043]**.

228 Decision, Table 5.24 **[CB/23/1128]**.

229 Decision, Tables 5.24 and 5.44 **[CB/23/1128, 1165]**. Accord-UK's ASP of £35.26 also exceeded the average price of competing skinny label tablets of £1.34, weighted average from February to April 2021: §5.236 **[CB/23/1135]**.

230 Decision, §5.227 **[CB/23/1133]**.

231 Decision, §10.280 **[CB/23/1713]**; see also §10.149 **[CB/23/1667]**.

232 Decision, §§10.264(c), 10.266-10.268, 10.279-10.283 and 10.290-10.292 **[CB/23/1709, 1709-1710, 1712-1714, 1715-1716]**.

f. Annual NHS expenditure on HTs was £62m and £40m in 2017 and 2018 respectively, as compared with just £0.5m in 2007.[233]

129. Intas refers to the principle that the penalty should be specific to the offender and the offence.[234] The CMA had regard to that principle when it considered the circumstances of the individual undertakings at Steps 3 and 4.[235]

130. **Comparisons with other appellants' fines**: The fine for each addressee is the result of many different choices as to what factors should (or should not) be taken into account when setting the penalty.[236] The CAT has held that "[t]*he fact that the application of these choices results in two different companies being subject to widely varying fines is not a matter for complaint or criticism by itself*." This comment is an answer to Intas' complaint about the level of its fine differing from the one imposed on Allergan.

131. As to the particular points made in §47 of Intas skeleton argument **[CB/7/150-151]**:

a. As to §47.1, the fact that Intas' penalty was 30% of the total fines imposed for the 10mg Abuse misses the point. The point is that Intas' penalty was properly set by reference to the factors set out in the Penalty Guidance and was assessed by reference to Intas' own position and individual circumstances.[237]

b. As to §47.2, the fact that Intas' penalty constituted a higher proportion of its financial benefit than for other addressees does not invalidate the level of penalty. Penalty-setting is a multi-factorial assessment which includes financial benefit, but, as noted above, also weighs up several other factors. Intas highlights one factor, but fails to appreciate the balancing of factors relevant at Step 4 of the Penalty Guidance. It cannot be sensibly

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233 Decision, §5.361 **[CB/23/1169]**.

234 Intas skeleton, §44 **[CB/7/149-150]**.

235 Decision, §10.255; §§10.134-10.137 **[CB/23/1705; 1661-1662]**.

236 *G F Tomlinson v OFT* [2011] CAT 7 (Chair: Vivien Rose), at [150] **[AB/26/731-732]**.

237 Decision, §§1.24 **[CB/23/663]**, 3.324 **[CB/23/809-810]**, 4.245-4.275 **[CB/23/1033-1049]**, 4.285 **[CB/23/1052]**, 5.227(d) **[CB/23/1133]**, 5.231 **[CB/23/1134]**, 5.236 **[CB/23/1135]**, 5.317 **[CB/23/1157]**, 5.361 **[CB/23/1169]**, 9.202(a)-(b) **[CB/23/1544-1545]**, 10.25(g) **[CB/23/1625]**, 10.28 **[CB/23/1625-1626]**, 10.264(c) **[CB/23/1709]**, 10.266-10.268 **[CB/23/1709-1710]**, 10.279-10.281 **[CB/23/1712-1713]**, 10.290-10.292 **[CB/23/1715-1716]**.

suggested that the CMA must impose an ineffective penalty to align all penalties as a proportion of illicit financial benefit.[238]

132. As to §47.3, the CMA took into account the financial measures mentioned by Intas as part of its multi-factorial assessment of proportionality.[239] It is not necessary as a matter of law for the CMA (or on appeal the CAT) to harmonise fines with a different addressee (here, Allergan) which had a different financial position and engaged in infringing conduct in different circumstances and at a different time.

Conclusion on penalties

133. In conclusion, the pharmaceutical sector is an important part of the economy of the UK. Those that have undermined the competitive process in that sector need to recognise that they have acted unlawfully and that significant penalties are warranted. The CMA asks the Court to uphold the penalties as an effective warning to the Appellants and others.

F. CONCLUSION

134. For all of the above reasons, the CMA asks the Court to dismiss the appeals.

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Prof. DAVID BAILEY
DAISY MACKERSIE

9 May 2025

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238 The purpose of penalty-setting is not simply to disgorge ill-gotten gains; on the policy objectives of penalties see §86 of this skeleton argument, above.

239 Decision, §§10.291-10.292 **[CB/23/1716]**.