Neutral Citation Number: [2026] EWCA Civ 974

Case No: CA-2025-000630; CA-2025-000642; CA-2025-000644

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE COMPETITION APPEAL TRIBUNAL
Mr Justice Marcus Smith, Simon Holmes and Robin Mason
[2023] CAT 56; [2023] CAT 57; [2024] CAT 29

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 28/07/2026

Before :

LORD JUSTICE GREEN
LORD JUSTICE ZACAROLI
and
SIR JULIAN FLAUX

- -

Between :

(1) AUDEN McKENZIE (PHARMA DIVISION) LIMITED **(2) ACCORD-UK LIMITED** **(3) ALLERGAN UNLIMITED COMPANY (formerly ALLERGAN PLC)** **(4) ACCORD-UK LIMITED** **(5) ACCORD HEALTHCARE LMITED** **(6) INTAS PHARMACEUTICALS LIMITED**	**Appellants**
- and -	
COMPETITION AND MARKETS AUTHORITY	**Respondent**

- -
- -

Sarah Ford KC and Charlotte Thomas (instructed by **Macfarlanes LLP**) for the **First and Second Appellants**
Tim Johnston (instructed by **Macfarlanes LLP**) for the **Third Appellant**
Robert Palmer KC and Laura Elizabeth John (instructed by **Linklaters LLP**) for the **Fourth to Sixth Appellants**

Josh Holmes KC, Professor David Bailey KC and Michael Armitage (instructed by **the Competition and Markets Authority**) for the **Respondent**

Hearing dates: 23, 24 and 25 June 2026

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Approved Judgment

This judgment was handed down remotely at 10.30am on 28 July 2026 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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Lord Justice Zacaroli:

Section A: Introduction, overview and summary of conclusions

1. Hydrocortisone is a medicine used for treating the replacement of cortisol in patients with primary or secondary adrenal insufficiency. Adrenal insufficiency is a chronic, rare condition that occurs when the adrenal glands fail to produce any or enough of the hormones the body needs.

2. Hydrocortisone is available in various forms including: "immediate release" tablets, where the drug is absorbed into the bloodstream rapidly after ingestion; "modified release" tablets, where the drug is absorbed more slowly into the bloodstream, known by its branded name **Plenadren**; an injectable form, known as **Hydrocortistab** (used only in exceptional cases); and soluble tablets.

3. This appeal is concerned with 10mg and 20mg immediate release Hydrocortisone tablets (respectively, **10mg IR Tablets** and **20mg IR Tablets**).

4. In a lengthy decision dated 15 July 2021 (the **Decision**), the Competition and Markets Authority (**CMA**) found various entities which at one time or another formed part of an undertaking which the CMA called "**Auden/Actavis**" guilty of two infringements of the prohibition on abuse of dominance in Chapter II of the Competition Act 1998 (**CA 1998**) (the **Chapter II Prohibition**). The CMA also found that Auden/Actavis were party to agreements with other entities which had as their object the distortion of competition in breach of s.2 of the CA 1998 (the **Chapter I Prohibition**).

5. The infringement of the Chapter II Prohibition was on the basis that Auden/Actavis sold 10mg and 20mg IR Tablets at excessive prices over the best part of a decade. For the 10mg IR Tablets, the period of infringement was 1 October 2008 until 31 July 2018. For the 20mg IR Tablets the period of infringement was 1 October 2008 until 8 January 2017. The CMA found that Auden/Actavis's prices for both forms of tablet were throughout this period excessive and unfair.

6. The CMA found two infringements of the Chapter I Prohibition. In July 2011, AM Pharma reached an agreement with an undertaking comprising Waymade plc and Amdipharm UK Limited ("**Waymade**"), under which it supplied Waymade with 1000 packs of 20mg IR Tablets a month on a heavily discounted basis, together with a cash payment (achieved by a buy-back of 80% of the product supplied to Waymade, at market rates), in exchange for Waymade agreeing to stay out of the market with its own product (the "**20mg Agreement**"). In October 2012, Auden Mckenzie (Pharma Division) Limited (**AM Pharma**) reached a similar agreement with the successor to Waymade's Amdipharm business (referred to in the Decision as "**AMCo**") in relation to 10mg IR Tablets (the "**10mg Agreement**").

7. The Decision was appealed to the Competition Appeal Tribunal (the **CAT**) (Sir Marcus Smith, Professor Simon Holmes and Professor Robin Mason). Four judgments of the CAT are relevant, to some extent, on this appeal:

   (1) A judgment dated 18 September 2023, relating to the infringement of the Chapter II Prohibition (I will refer to this simply as the **Judgment**)

(2) A judgment dated 29 September 2023, reaching provisional conclusions as regards the infringement of the Chapter I Prohibition (the **Judgment on Cartel Infringements**)

(3) A judgment dated 8 March 2024, determining the provisional findings in the Judgment on Cartel Infringements could not stand (the **Judgment on Due Process**).

(4) A judgment dated 29 April 2024, relating to a ground of appeal in respect of penalties that was left unresolved by the earlier judgments (the **Judgment on Penalty**).

8. In the Judgment, the CAT upheld the CMA's findings on abuse of dominance, and upheld the penalties imposed save in one respect which I address below in the section dealing with penalties.

9. The Judgment on Cartel Infringements and the Judgment on Due Process were the subject of an earlier appeal to this Court (Sir Geoffrey Vos MR, Sir Julian Flaux C and Green LJ). In its judgment dated 6 September 2024, [2024] EWCA Civ 1023 (***Hydrocortisone CA I***) this Court allowed the CMA's appeal, confirming the CMA's decision that the 10mg and 20mg Agreements infringed the Chapter I Prohibition.

The undertaking

10. The facts of this case are complicated by the corporate changes affecting the undertaking. Clarity is important in this respect because, while a penalty is necessarily imposed on a separate legal entity, infringement of the Chapter II Prohibition is found as against an "undertaking", which refers to an economic unit, rather than legal personality. A single undertaking may therefore comprise one or more legal entities. In *Höfner and Elser v. Macroton GmbH*, Case C-41/90201 EU:C:1991:161 at [21], the CJEU stated:

> "the concept of an undertaking encompasses every entity engaged in an economic activity regardless of the legal status of the entity and the way it is financed".

11. In this case, the undertaking includes the corporate entity that sold the drugs, being the entity with **Marketing Authorisation** to sell the drug in the UK, but also includes one or more parent company/companies within the corporate group of which the selling entity forms a part from time to time.

12. In the following paragraphs, I provide a brief summary of the various corporate entities within the undertaking. For simplicity, I will continue to use the label **Auden/Actavis** as the CMA did, to describe the undertaking as a whole from 2008 to 2018 without distinguishing between the different corporate entities within it from time to time.

13. Hydrocortisone tablets were first sold in the UK in 1955 under the brand name Hydrocortone by their originator, Merck Sharp & Dohme (**MSD**).

14. By 2007/2008, MSD concluded that it was making insufficient profit from the sale of Hydrocortisone and it decided to exit the market. On 21 April 2008 MSD sold the Hydrocortone brand and the Marketing Authorisation for both 10mg and 20mg IR Tablets to AM Pharma, the first appellant. AM Pharma took the drug off-brand and

commenced selling it as a generic drug. At the relevant times, while branded drugs were subject to price controls, generic drugs were not, since it is expected that competition between generics will keep prices down.

15. AM Pharma was an entity owned, as at April 2008, by Amit and Meeta Patel (the **Patels**). On 1 November 2012, the Patels interposed a holding company, Auden Mckenzie Holdings Ltd. On 29 May 2015 the Patels sold Auden Mckenzie Holdings Ltd to Actavis plc, which was renamed Allergan plc in June 2015 and is the third appellant (**Allergan**).

16. Within two months of that acquisition, Allergan agreed to sell its entire global generics business to Teva.

17. On 1 September 2015, AM Pharma (by now an indirect subsidiary of Allergan) transferred the Marketing Authorisation to another subsidiary of Allergan, Actavis UK Ltd (which, under its current name, Accord-UK Ltd, is the second and fourth appellant ("**Accord-UK**"). It is common ground that in these circumstances Accord-UK is the economic successor to AM Pharma and, as such, can be made liable in respect of the earlier entities' infringing activity.

18. In March 2016, in anticipation of the sale of Allergan's generic division to Teva, Actavis UK Ltd was held separate pursuant to commitments entered into between Allergan, Teva and the European Commission. This precluded Allergan from intervening in Accord-UK's day-to-day business. It is referred to in the Judgment as the **Hold Separate Regime**.

19. In August 2016, Teva acquired Allergan, becoming the indirect owner of Actavis UK Limited and of AM Pharma. The Hold Separate Regime remained in force until 9 January 2017.

20. On 9 January 2017, the sixth appellant, Intas Pharmaceuticals Limited (**Intas**), through its subsidiary, the fifth appellant Accord Healthcare Limited (**Accord Healthcare**), became the 100% owner of Actavis UK Ltd. The Hold Separate Regime ended on this date. On 5 March 2018, Actavis UK Ltd changed its name to Accord-UK.

21. In light of the corporate changes summarised above, the CAT divided the infringement period into five phases, as follows:

    (1) The **Patel Phase**, from the commencement of the infringement period (October 2008) until 29 May 2015 when the Patels sold their business to Allergan (then called Actavis plc). The undertaking at this time comprised mostly the Patels and AM Pharma (although from 2012 it included Auden Mckenzie).

    (2) The **Actavis Phase**, from 29 May 2015 until the commencement of the Hold Separate Regime on 10 March 2016.

    (3) The **Hold Separate Regime Part I**, from 10 March 2016 until August 2016 when Teva acquired Allergan.

    (4) The **Hold Separate Regime Part II**, from August 2016 until 9 January 2017, when Intas, via Accord Healthcare, acquired Actavis UK Ltd.

(5) The **Intas Phase**, from 9 January 2017 when Intas acquired Actavis UK until the end of the infringement period for 10mg IR Tablets on 31 July 2018.

22. The appellants fall into three groups, each group having brought a separate appeal.

23. The first group comprises AM Pharma and Accord-UK. These were the selling entities which held, one after the other, the Marketing Authorisation for 10mg and 20mg IR Tablets throughout the infringement period. I will refer to them compendiously (unless it is necessary to distinguish between them) as **AMP/Accord**.

24. The second group comprises Allergan alone. Allergan's involvement relates to the period commencing with its acquisition of Auden Mckenzie Holdings Ltd on 29 May 2015 until 1 August 2016 when it sold its interest in Actavis UK to Intas. Allergan relies on the fact that from March 2016 it was precluded from offering any direction to Actavis UK Ltd by reason of the Hold Separate Regime.

25. The third group comprises Accord-UK, Accord Healthcare and Intas. This group's involvement commenced on 9 January 2017 and lasted until the end of the infringement period for 10mg IR Tablets on 31 July 2018. This group is referred to as **Intas**.

Market definition and market dominance

26. There is no dispute on this appeal that the appellant undertakings were dominant in the relevant market throughout the first four phases of the infringement period. Intas disputes that it was dominant in the Intas Phase.

27. The CMA and the CAT, however, each took a different approach in defining the relevant market and arriving at a conclusion as to dominance. In order to explain their different approaches, it is necessary to say something about other related products and when they came to market.

28. From 2008 until October 2015 AM Pharma had an effective monopoly on the supply of 10mg and 20mg IR Tablets (potential competitors being kept out of the market by the 10mg and 20mg Agreements).

29. Plenadren had been granted "orphan" status by the European Commission in May 2006, in light of its modified release capability, and had been granted a European Marketing Authorisation in November 2011. Sales commenced in the UK, in relatively low numbers, at around the beginning of 2014.

30. An "orphan" drug is one that is indicated for treatment of a rare disease or condition, in the sense that the patient population is sufficiently small to render it unviable for ordinary commercial pharmaceutical development. Orphan designation is intended to enable the drug to benefit from a form of monopoly (similar to a patent). The consequence of Plenadren's orphan designation combined with its Marketing Authorisation was that no new Marketing Authorisations would be accepted for a period of 10 years (from November 2011) for the therapeutic condition "adrenal insufficiency in adults" in respect of a similar medicinal product.

31. Any similar product brought to market in that period therefore received only limited Marketing Authorisation, for treatment in children. Such products are referred to as "skinny label", as opposed to those which were authorised for treatment in children and

adults, which are referred to as "full label". The 10mg IR Tablets and 20mg IR Tablets supplied by AM Pharma were full label products, because its Marketing Authorisation preceded Plenadren's designation as an orphan drug.

32. The first entrant into the market with a skinny label product was Alissa Healthcare with a 10mg IR Tablet, in October 2015. Others (Bristol Laboratories and Resolution Chemicals) entered the market in March 2016 with 10mg and 20mg IR Tablets. AMCo launched its own 10mg IR Tablet in May 2016 and a 20mg IR Tablet in August 2017. Teva entered the market with 10mg and 20mg IR Tablets in February 2017. Genesis introduced 10mg and 20mg IR Tablets in November 2017. All of these were skinny label products.

33. I will need to return to the importance of the distinction between full label and skinny label drugs when dealing with Intas' appeal. For present purposes, it is important to note the following findings of the CMA which are not in dispute (see §3.215 to §3.245 of the Decision):

(1) Hydrocortisone was generally prescribed by doctors on an "open" basis without specifying a named brand.

(2) Pharmacists were incentivised to dispense the cheapest available, as they were reimbursed a flat amount by the NHS.

(3) Doctors may prescribe and pharmacists may dispense a drug to treat a condition not included in the therapeutic conditions listed within the drug's Marketing Authorisation (referred to as "**off-label**" use of medicines).

(4) There were no regulations or guidance on prescribing or dispensing skinny label Hydrocortisone for off-label use during the infringement period, but there was some general non-binding guidance from professional bodies such as the General Medical Council ("**GMC**") and the Medicines and Healthcare Regulatory Agency ("**MHRA**"). This recommended that healthcare professionals should usually prescribe medicines in accordance with the terms of their licence, but they could prescribe and dispense medicines for off-label use where they considered it necessary to meet the specific needs of the patient.

(5) Given the bioequivalence between full label and skinny label Hydrocortisone tablets, many healthcare professionals could have reasonably taken the view that there were no or negligible additional risks to patient safety from using the skinny label versions.

(6) The MHRA and the Chief Pharmaceutical Officers for NHS England, NHS Scotland and NHS Wales did not consider that off-label use of skinny label Hydrocortisone tablets created any risks to patient safety.

34. The CMA also made findings to the effect that, while smaller, independent pharmacies dispensed skinny label tablets in large quantities (271,654 packs in 2016 and 265,529 packs in 2017), eight of the larger pharmacies dispensed only (or virtually only) full label tablets. Of these, Boots and Lloyds between them dispensed more packs than all the independent pharmacies put together in each of 2016 and 2017. The CMA's summary conclusion at §3.282 of the Decision was that these larger pharmacies

"determined that they could not or should not dispense skinny label hydrocortisone tablets because of their assessment of a potential regulatory risk from dispensing off-label." The CMA went on to describe those pharmacies as having "no choice" but to purchase Auden/Actavis' tablets and as being "not able to switch" to skinny label tablets:

> "Accordingly, these pharmacies formed an assured base for Auden/Actavis..."

35. The CMA found that the relevant product market was the supply of 10mg and 20mg IR Tablets (including both skinny label and full label) in the UK. It found that there was a single, combined market (comprising both 10mg and 20mg tablets) prior to the entry of competing suppliers in October 2015, and separate 10mg and 20mg tablet markets from then onwards.

36. The CAT disagreed, and concluded that the relevant product market comprised (in relation to the 10mg IR Tablets as the focal product) the following products which the CAT regarded as substitutes: (1) product supplied to the market pursuant to the 10mg Agreement; (2) the 20mg IR Tablets supplied pursuant to the MSD Marketing Authorisation, and pursuant to the 20mg Agreement, and which could have been (but was not) supplied under the Waymade Marketing Authorisation; (3) Plenadren; (4) all product supplied to the market under skinny label Marketing Authorisations. It reached a similar conclusion by reference to the 20mg IR Tablets as the focal product.

37. The basis on which the CAT reached this conclusion will be important when it comes to considering the grounds of appeal relating to abuse and dominance. It did so on the basis of a "SSNIP" approach (under which the question posed is whether a small but significant non-transitory increase in price would provoke a significant number of consumers to switch to an alternative product) but with at least two critical assumptions. First, it had regard to a wholly hypothetical consumer, being a patient with a diagnosis of adrenal insufficiency who required treatment, with a responsible attitude towards dealing with that condition, with a level of knowledge about the condition and the available treatments commensurate with that of a doctor, and with an understanding of the difference between skinny and full label offerings and the regulatory regime that created that distinction. Second, it assumed (contrary to a reality in which, at the point that 20mg Plenadren came to market, its price was nearly nine times higher than 20mg IR Tablets supplied by Auden/Actavis) that all of the products which it treated as within the same market were sold at a uniform price of £10 per pack.

38. The CMA concluded that Auden/Actavis held a dominant position throughout the infringement periods in respect of both 10mg and 20mg IR Tablets.

39. The CAT preferred to analyse dominance in the market as it changed with new entrants from time to time, by reference to the five phases referred to at §21 above. It nevertheless agreed with the CMA that Auden/Actavis was dominant throughout the whole of the relevant period. There is no appeal against the CAT's findings in respect of market definition, and no appeal against its findings of dominance, save in respect of the Intas Phase.

Price increases and decreases

40. The CAT set out in table form in Annex 3 to the Judgment the selling prices for all of the IR Tablets (both full and skinny label) under the various Marketing Authorisations and Plenadren across 127 periods commencing in May 2005 and ending in July 2018. It also produced two graphs at Annex 4C to the Judgment of the selling price over time of, respectively, the 10mg IR Tablets and the 20mg IR Tablets supplied by Auden/Actavis from May 2005 to March 2020.

41. The following headline points, so far as the prices charged by Auden/Actavis are concerned, are of note:

    (1) Immediately prior to AM Pharma de-branding the drug, the 10mg IR Tablets were sold at 70p per pack, and the 20mg IR Tablets were sold at £1.07 per pack.

    (2) AM Pharma launched the de-branded 10mg IR Tablets at a price of £4.54 per pack, and the 20mg IR Tablets at a price of £5.14 per pack.

    (3) By 1 October 2008 (the commencement of the infringement period) 10mg IR Tablets were being sold for £22.28 per pack and the 20mg IR Tablets were being sold for £23.74 per pack. The CMA explained in the Decision that for pragmatic reasons they defined the infringement period as commencing on 1 October 2008, even though there had been enormous price rises prior to that.

    (4) While there was some fluctuation in the price at which Auden/Actavis sold the tablets on a month-to-month basis, the overall trend thereafter was a relatively small but steady increase in price until about April 2014 when the rate of increase quickened, reaching a peak of just over £72 per pack for both the 10mg and 20mg IR Tablets.

    (5) At the start of the Intas phase (on 9 January 2017, which is also the end of the infringement period for 20mg IR Tablets), the price was £54.21 per pack of 10mg IR Tablets and £51.28 per pack of 20mg IR Tablets.

    (6) The price of 10mg IR Tablets then fell steadily, returning to £20.23 by the end of the infringement period in July 2018. By the time of the Decision the price of 10mg and 20mg IR Tablets had reduced below the levels at the time of their launch by AM Pharma in 2008.

42. The CAT vividly described the shape of the pricing graph, given its steep upward slope and similarly steep downward slope, as the "Matterhorn". I will use the same shorthand.

43. As to the prices of other products:

    (1) Plenadren was sold in 5mg and 20mg packs. Upon entry into the market, the former was sold for £212 and the latter for £350. They remained at this price until June 2016, when they increased to around £240 and £390 respectively, where they stayed apart from some short-lived variations in 2017, until the end of the infringement period.

    (2) Skinny label products entered the market at prices slightly below those of Auden/Actavis (the first, Alissa Healthcare's 10mg IR Tablet, was priced in October 2015 at £67.52, compared to £67.74 charged for Auden/Actavis's 10mg IR Tablet as at that date).

(3) Thereafter, the prices of all competing IR products fell quickly and steeply, more quickly and steeply than Auden/Actavis' tablets, so that a very significant price differential was maintained with Auden/Actavis's tablets throughout the remainder of the infringement period. By the time of the Decision, the competing products were selling for about half the price of Auden/Actavis' tablets.

The issues in outline

44. The issues on this appeal fall into three groups:

(1) Issues concerning the CAT's finding of abuse of dominance. The appellants contend that the CAT applied the wrong legal test, that it reversed the burden of proof, failed to determine whether Auden/Actavis' prices were justified by the economic value that the product had for customers, ignored relevant comparators and failed to incorporate within its analysis the requirement that prices must be materially and persistently above "Cost Plus" (as that term is defined below at §50). A related issue is whether the CAT was wrong to find that Auden/Actavis' prices were "imposed" on customers, at least after skinny label products entered the market.

(2) Whether Auden/Actavis remained dominant in the relevant market during the Intas Phase.

(3) Challenges to the penalties imposed on all appellants.

The law on abuse of dominance

45. The statutory prohibition on abuse of a dominant position is briefly stated in s18(1) of CA 1998:

> "…any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the United Kingdom"

46. Particular examples of abuse are set out in s.18(2). The one relevant to this appeal is in ss.(2)(a), conduct which consists in "directly, or indirectly imposing unfair purchase or selling prices or other unfair trading conditions".

47. This Court, in *CMA v Flynn Pharma* [2020] EWCA Civ 339 (***Phenytoin I***), summarised almost 50 years of European and domestic law on the test of "fairness" in s.18(1) of CA 1998, which reflects that contained in Article 102 of the Treaty on the Functioning of the European Union, including the seminal decision of the CJEU in Case C-27/76 *United Brands v Commission* EU:C:1978:22 (***United Brands***). At §97, Green LJ (with whom Sir Geoffrey Vos C and Sir Stephen Richards agreed) said:

> "(i) The basic test for abuse, which is set out in the Chapter II prohibition and in Article 102, is whether the price is "unfair". In broad terms a price will be unfair when the dominant undertaking has reaped trading benefits which it could not have obtained in conditions of "normal and sufficiently effective competition", i.e. "workable" competition.

> (ii) A price which is "excessive" because it bears no "reasonable" relation to the economic value of the good or service is an example of such an unfair price.
>
> (iii) There is no single method or "way" in which abuse might be established and competition authorities have a margin of manoeuvre or appreciation in deciding which methodology to use and which evidence to rely upon.
>
> (iv) Depending upon the facts and circumstances of the case a competition authority might therefore use one or more of the alternative economic tests which are available. There is however no rule of law requiring competition authorities to use more than one test or method in all cases.
>
> (v) If a Cost-Plus test is applied the competition authority may compare the cost of production with the selling price in order to disclose the profit margin. Then the authority should determine whether the margin is "excessive". This can be done by comparing the price charged against a benchmark higher than cost such as a reasonable rate of return on sales (ROS) or to some other appropriate benchmark such as return on capital employed (ROCE). When that is performed, and if the price exceeds the selected benchmark, the authority should then compare the price charged against any other factors which might otherwise serve to justify the price charged as fair and not abusive.
>
> (vi) In analysing whether the end price is unfair a competition authority may look at a range of relevant factors including, but not limited to, evidence and data relating to the defendant undertaking itself and/or evidence of comparables drawn from competing products and/or any other relevant comparable, or all of these. There is no fixed list of categories of evidence relevant to unfairness.
>
> (vii) If a competition authority chooses one method (e.g. Cost-Plus) and one body of evidence and the defendant undertaking does not adduce other methods or evidence, the competition authority may proceed to a conclusion upon the basis of that method and evidence alone.
>
> (viii) If an undertaking relies, in its defence, upon other methods or types of evidence to that relied upon by the competition authority then the authority must fairly evaluate it."

48. Accordingly, while the overall test is that of "unfairness", the guiding principle in a case of excessive pricing is that the dominant undertaking has imposed prices that could not have been achieved in conditions of workable competition.

49. As the CJEU observed in *United Brands* at §251 to §252, one of the ways in which to establish unfairness is to compare the selling price of the relevant product with its cost

of production, which discloses the amount of profit margin. Abuse may be found where the following two-limb test (the *United Brands test*") is satisfied:

Limb 1: is the difference between the costs actually incurred and the price actually charged excessive?

Limb 2: is the price imposed unfair, either in itself or when compared to competing products?

50. Under Limb 1, the established approach in determining whether the price is excessive is to identify the direct and indirect costs of production and a reasonable rate of return. This is referred to as **Cost Plus**.

51. When applying the *United Brands* test, it is important not to lose sight of the fact that the principal evaluative exercise occurs at the second stage, where the overall question is asked whether there is a reasonable, justified, relationship between the price charged and the economic value of the goods or services in issue: see the recent decision of this Court in the second appeal in the *Phenytoin* case, *Pfizer Incorporated and ors v Competition and Markets Authority* [2026] EWCA Civ 765 (***Phenytoin II***) at §36, citing with approval the simplified approach adopted by the CAT in *Le Patourel* at §53.

Summary of conclusions

52. The bare facts of this case can be simply stated. Setting aside the complications of the changes of parent entities within the undertaking, Auden/Actavis acquired a long off-patent, branded Hydrocortisone drug, selling (so far as the 10mg IR Tablets are concerned) at 70p per pack, re-launched it as a generic medicine at £4.54 per pack then steadily increased the price to a peak of £72.14 (an increase of 1600% above the re-launch price). It is common ground that this was vastly in excess of Cost Plus, and that there was no investment or innovation in the medicine that might explain that excess.

53. Throughout the period of price increases Auden/Actavis had a monopoly. It preserved the monopoly when others sought to compete, by entering into unlawful cartel agreements with them. When competitive products did enter the market, competition was distorted by two things: first, the orphan designation granted to Plenadren, which ensured that Auden/Actavis had an effective monopoly in the supply of full label 10mg and 20mg IR Tablets; second, the risk-averse attitude in fact adopted by most major pharmacies (who represented approximately 50% of the purchasers) who continued to purchase full label drugs notwithstanding the availability of much cheaper skinny label alternatives.

54. Following skinny label entry, prices of Auden/Actavis' products, and those of competitors, fell steadily, until eventually they reached a plateau at around or less than Cost Plus. In the meantime, however, as the risk-averse attitude of the major pharmacies continued, Auden/Actavis was able to charge a very substantial premium over its competitors throughout the remainder of the infringement period.

55. This is a pricing pattern which is wholly out of sync with what is to be expected of an off-patent de-branded drug, where the price, having already reduced over time, is expected to remain low as a result of competition between generic suppliers.

56. Competition law is not a means of regulating prices *per se*. The key question is whether Auden/Actavis has used its dominant position to reap benefits that would not have been reaped in conditions of sufficiently workable competition. The facts as I have summarised them cry out for an explanation. The CMA and the CAT both reached the clear conclusion that the explanation was indeed that Auden/Actavis had abused their dominant position.

57. For the reasons developed below, none of the arguments advanced on this appeal get near, in my judgment, to being grounds for interfering with that conclusion. Nor is there any material error in the CAT's conclusion that Auden/Actavis remained dominant during the Intas Phase, or that the abuse continued during that period.

58. I have, however, reached a different conclusion in relation to the appeal against the penalties imposed on each of the appellants. That is not because I am persuaded of the merit of the numerous arguments advanced by the appellants (beyond accepting that these are respectable arguments), but because I accept their core complaint that the arguments that were advanced before the CAT are not adequately addressed in the CAT's judgment.

59. Although the outline facts and my core conclusions can be briefly stated, unfortunately, as with many cases in this area, the fuller reasons take longer to explain. The CMA undertook an extremely thorough investigation, leading to a decision which (with annexes) extends to over 1200 pages. The two most relevant judgments of the CAT (on abuse of dominance and cartel infringement) run to a further 323 pages. Given the nature of the appellants' arguments, it will be necessary to set out in some detail parts of the conclusions and reasoning in the Decision and the Judgment.

Section B: Appeal against the findings of abuse

The CMA's conclusions on unfair pricing

60. The CMA summarised its conclusions on unfair pricing at §5.1 to §5.20 of the Decision. It found that Auden/Actavis's prices for 10mg and 20mg IR Tablets were excessive and unfair throughout the whole of the respective infringement periods.

61. There is no issue taken with the CMA's calculation of Cost Plus. It is worth noting, however, the following points arising from the CMA's calculation of the reasonable rate of return (i.e. the "Plus" element of Cost Plus):

    (1) It used a return on capital employed (**ROCE**) method.

    (2) Capital employed included working capital and fixed assets. In using the actual working capital figures, the CMA recognised that this was generous to Auden/Actavis because the required working capital was inflated by the high prices charged. It nevertheless made no adjustment to account for that (§5.161 to §5.164).

    (3) It arrived at a reasonable rate of return of 8%, which was informed by the rate used when Allergan acquired AM Pharma, given that the 10mg and 20mg IR Tablets were the most significant products in terms of revenue at the time (§5.201). This achieved the aim of ensuring that Accord-UK was sufficiently compensated for the

risk and investment undertaken when entering and participating in the market (§5.206).

(4) Its conclusion was that Cost Plus for 10mg IR Tablets was between £2.17 and £4.50 per pack, and for 20mg IR Tablets was between £2.91 and £5.20 per pack (§5.5).

62. As to Limb 1 of the *United Brands* test, the CMA concluded that the prices were excessive on a Cost Plus basis. The difference between those values and the prices at which the drugs were sold was sufficiently large to be deemed excessive (§5.218).

63. At §5.223 the CMA noted that Cost Plus already included a reasonable rate of return, but that it had *not* made a finding that any price above Cost Plus was excessive. For administrative reasons, the lowest price at which the CMA made a finding that the prices were excessive was £20, which already exceeded the upper bounds of the Cost Plus calculation by 285%.

64. It then had regard (at §5.229 to §5.242) to a "substantial volume" of real-world evidence that corroborated its conclusion that Auden/Actavis' prices were excessive:

(1) The prices Auden/Actavis initially set for the sale of the 10mg and 20mg IR Tablets in April 2008 (respectively, £4.54 and £5.14);

(2) The current prices (the weighted averages from February 20 to April 2021) of competing Hydrocortisone tablets, following a prolonged period of competition (£1.34 per pack of 10mg skinny label tablets; £1.85 per pack of skinny label 20mg tablets; and £1 to £4 per pack of Waymade 20mg full label tablets for the period May to July 2020);

(3) Auden/Actavis' current prices (£2.99 per pack of 10mg IR Tablets and £1.19 per pack of 20mg IR Tablets); and

(4) The prices which Allergan projected, in January 2015, would be achieved within three years if competitors entered the market that year, namely £5.20 per pack for 10mg IR Tablets and £6.10 per pack for 20mg IR Tablets.

65. As to Limb 2, the CMA found that the excessive prices were unfair in themselves, and unfair when compared to competing products.

66. The prices were unfair in themselves because (§5.296):

(1) There were substantial disparities between the prices and Cost Plus;

(2) The prices were not justified by any feature of the IR Tablets: they were long off-patent and in the third stage of the drug lifecycle where competition is expected to drive prices of generic drugs down, even where they are essential;

(3) There was no improvement to the tablets, or their production or distribution, and no innovation or investment to justify higher prices;

(4) The features of the relevant markets meant they were incapable of functioning in a manner likely to produce a reasonable relationship between price and economic value;

(5) The adverse effects that the prices had on the end customer and patient welfare, in view of the enormous increase in NHS spending with no associated benefits; and

(6) The lack of independent or objective justification for the prices.

67. It took into account, among other things:

(1) The fact that price increases were from time to time falsely claimed by Auden/Actavis to be the result of increased costs (§5.299 to §5.304).

(2) The features of the market which enabled Auden/Actavis to maintain its high prices were: it was the monopoly supplier and, when other entrants threatened to compete, it entered into anticompetitive agreements to preclude that from happening; the orphan designation of Plenadren enabled Auden/Actavis to maintain its high prices; the way that the Drug Tarriff price was calculated meant that Auden/Actavis faced a reduced constraint on prices; and customers were not able to constrain its pricing conduct. (§5.323).

68. At §5.365 to §5.400 the CMA considered unfairness by way of comparison with competing products. It concluded (§5.371) that all competing Hydrocortisone tablets (whether full or skinny label) are sufficiently similar to allow for a meaningful comparison. It noted that full and skinny label tablets are bioequivalent, fully interchangeable and used to treat the same conditions. This was reflected in expert opinion (including the Chief Pharmaceutical Officer of NHS England, who advised Mr Patel in May 2014 that there were no risks to patient safety from off-label supply, and the MHRA) and the NHS pricing system, which treated them collectively as one product. The CMA used current prices because they were no longer inflated by the exercise of Auden/Actavis' significant market power.

69. At §5.401 to §5.429 the CMA assessed whether Plenadren or soluble Hydrocortisone tablets were meaningful comparators and concluded that they were not.

(1) They were both innovative products, and their suppliers had incurred development costs which they may still be seeking to recoup.

(2) They both had only niche uses and consequently very low volumes. Plenadren was developed for adult sufferers who do not do well on IR Tablets; its orphan designation required it to demonstrate a significant benefit over the IR Tablets. Soluble tablets were not readily interchangeable with hard tablets, being limited at a clinician level, with a prescription needing to specify that a patient required the soluble form.

(3) The market conditions in which their prices were set were fundamentally different. There were sole suppliers for each. There was no evidence of the prices being set in conditions of effective competition. There was little evidence that Plenadren exerted a competitive restraint, there being no discernible switching away from Hydrocortisone tablets.

(4) Their weakness as comparators was emphasised by the strength of competing Hydrocortisone tablets as comparators.

70. The CMA dealt with Hydrocortistab as a possible comparator only briefly. At §3.135 of the Decision it found that injectable forms of Hydrocortisone are only used in exceptional circumstances where oral medication is not tolerated, for example when a patient is going through an adrenal crisis, in cases of severe illness, pre- or post-major procedures, or where the patient is "nil by mouth". Hydrocortistab itself was not used to treat long-term adrenal insufficiency, but was used to treat arthritic conditions. At footnote 1842 to §5.402 of the Decision, the CMA concluded that Hydrocortistab was not a meaningful comparator, concluding: "There is no evidence that its price is set in conditions of [effective] competition: it is a single-supplier product and, like Plenadren, is in Category C of the Drug Tariff, the category used when there is no competition for the supply of the product. There is no evidence to suggest that there is any competitive interaction between Hydrocortisone tablets and Hydrocortistab."

71. At §5.430 to §5.460 the CMA considered economic value, which it defined as "an economic concept which describes what it is that users and customers value and will reasonably pay for" (citing *Phenytoin I* at §171). It concluded that there were no economic benefits *that were not already factored into its Cost Plus calculation*. It relied on: the age of Hydrocortisone tablets and their position in the drug lifecycle; the current prices of competing tablets; and the erosion of Auden/Actavis' prices. At §5.446 it observed that the prices of competing tablets included "proxy evidence of the economic value of patient benefit", citing *Phenytoin I* at §172.

72. Auden/Actavis had argued that the CMA failed to take into account the therapeutic benefit of Hydrocortisone tablets, and had wrongly found it was negated by patient dependency. The CMA rejected this, at §5.466 to §5.470, noting the stage in the life cycle of the drug. It reiterated that any value attributed to this was reflected in the price of current competing tablets: "If there was some additional value due to patient benefit, such value would be expected to be reflected in the prices of all tablets regardless of which supplier sold them, since all hydrocortisone tablets are bioequivalent." It also observed that since (a) the competing prices were significantly less than Cost Plus and (b) it had in any event only regarded as excessive prices in excess of £20, this allowed for considerable additional value if there were any.

73. At §5.471 to §5.479, the CMA addressed Auden/Actavis' contention that its tablets had greater economic value by virtue of factors such as its full label Marketing Authorisation, greater security of supply, a superior delivery service and a wider range of products. The CMA found that there was no evidence that these factors (or others) justified a higher economic value for Auden/Actavis' product. It again pointed to the evidence of its prices following entry and the fact that they had, by the time of the Decision, reduced below even the lowest bound of cost plus. That would not have occurred if its products had greater economic value than those of competitors. It also rejected the notion that those pharmacies who continued to buy Auden/Actavis' products made a "free choice", noting the fact that the larger pharmacies had reached the view that they could not switch to skinny label products, thus giving Auden/Actavis an assured customer base.

The CAT's conclusions on unfair pricing

74. The CAT addressed the appellants' arguments on abuse of dominance at §298 to §355. The appellants mount a root and branch attack on the legal test applied by the CAT, and it is therefore necessary to set out the CAT's conclusions in some detail.

75. Auden/Actavis' grounds of appeal to the CAT were, in short summary, as follows: (1) the CMA's finding based on a comparison between Cost Plus and the actual prices charged was wrong in law; (2) the CMA failed to take account of the prices of comparator products; (3) the CMA failed to take into account the economic value of 10mg and 20mg IR Tablets, and the fact that pharmaceutical products are priced in portfolios; (4) the CMA failed to take account of the fact that prices were falling on the "downward slopes" of the "Matterhorn"; (5) prices were not "imposed" on customers because customers exercised a choice on the basis that Auden/Actavis' products had additional value for them; (6) the prices could not be abusive because the Secretary of State had not intervened to limit prices; and (7) Auden/Actavis could not have known they were abusing a dominant position, in view of the uncertainty in the law, when prices were declining rapidly, there was widespread market entry and extensive switching.

76. The CAT began its analysis with an uncontroversial reference to *United Brands*. It then set out to define two terms which it used throughout the rest of the Judgment: "consumer surplus" and "producer surplus". It defined the former as a measure of the additional benefit which an individual consumer receives because it pays less for something than what they would have been prepared to pay. It defined the latter as the difference between how much a supplier would be willing to accept for a product versus how much they can receive by selling the product at the market price. It turns on two factors: relative efficiency between producers and the extent to which a producer can differentiate itself from its competitors, through product differentiation, and thus induce customers to pay more for its product.

77. Having discussed the concept of consumer surplus in the context of "perfect competition", it turned to consider "the real world and producer surplus". It offered three reasons why price might exceed Cost Plus (the CAT used the term "Cost" here, but it had defined that as "Cost Plus" as used by the CMA, at footnote 427 to §333), which it termed Case 1, Case 2 and Case 3.

    (1) Case 1 is relative inefficiency amongst sellers. An efficient seller, who *could* sell for less than the inefficient seller, might choose to set a price similar to that of the inefficient seller, giving rise to an element of producer surplus for it. Price therefore exceeds the Cost Plus of the most efficient seller.

    (2) Case 2 is the generation of additional value through the provision of distinctive value. This is where "Sellers can maximise producer surplus by providing to the market products that Buyers wish to purchase and for which they will pay a premium i.e. more than they would for an alternative or substitute product." Case 2 is defined very broadly by the CAT (at §322(2)), deliberately eschewing the term "product differentiation" in favour of the provision of "distinctive value", representing "something that Buyers wish to purchase from that Seller in contradistinction to the offerings of other Sellers; and for which the Buyer will pay a premium". The breadth of the term is illustrated by the recognition (see §322(2)(iv)) that "the ability to supply an otherwise undifferentiated product when others cannot is, in our view, the provision of distinctive value, even if it is not a form of "product differentiation"."

(3) Case 3 is where the Seller possesses market power that does not generate additional value in Buyers. In such cases, there is likely to be a correlation between the Seller's market power and the ability to exclude competition.

78. At §323, the CAT observed that it is the function of competition law (as opposed to economic theory) to distinguish between Case 2 and Case 3, and that line is often difficult to draw. It then turned to consider in more detail the case law following *United Brands*. It cited *Attheraces Limited v The British Horseracing Board Limited* [2007] EWCA Civ 38, noting the application by the Court of Appeal in that case of the *United Brands test*, and drew from it the following:

> "(i) The object of competition law is to protect competition, and not seek to impose an outcome that is inconsistent with properly operating market forces.
>
> (ii) Sellers of Product are entitled to the maximum price they could command in "normal and sufficient competitive" conditions. In other words, 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.
>
> (iii) The approach of the Court of Appeal in *Attheraces* is consistent both with the approach in *Flynn Pharma* (which we have described) and with the approach described by the Tribunal in *Napp*. In *Napp Pharmaceutical Holdings Ltd v. Director General of Fair Trading*, the Tribunal cited with approval the following statement regarding what is or might be an excessive price:
>
> "…if it is above that which would exist in a competitive market and where it is clear that high profits will not stimulate new entry within a reasonable period. Therefore, to show that prices are excessive, it must be demonstrated (i) that 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.""

79. It also cited *Humber Oil Terminals Trustee Ltd v Associated British Ports* [2012] EWCA Civ 36 for the proposition that the manner in which a market operates – including the legal regime governing that market – can be highly relevant both to dominance and abuse.

80. At §330 to §331, the CAT referred to the fact that there is no single method for ascertaining whether a price is unlawful, stressing the importance of comparators and the inter-relationship between price and cost. Referring to *Napp*, it identified the following approaches to establishing excessive pricing:

> "i) comparing price charged with cost incurred; (ii) comparing price charged with the costs of the next most profitable competitor; (iii) comparing the prices charged by the

> undertaking in question with those of its competitors; and (iv) comparing the prices charged by the undertaking across different markets. As the Tribunal noted, other methods will also no doubt exist, in particular analyses of price changes over time, where there is no corresponding change in the operation of the market itself."

81. At §336 to §355, the CAT applied these principles to the facts of this case. I summarise its conclusions as follows:

(1) It was "plain to the point of irrefutability" that Limb 1 of the United Brands test was met, where the margin between Cost Plus and price was so large as to be inexplicable by relative inefficiencies between sellers, and where there was no real competition.

(2) It regarded as a "red herring" the contention that the CMA failed to take into account the value placed on Hydrocortisone by patients. While it substantially agreed with the criticism that the CMA failed sufficiently to take economic value into account "so far as it goes", it rejected the contention that medical, societal and personal benefits provided by Hydrocortisone justified any excess of price over Cost Plus. While patients of course valued life-saving medicaments, that fact did not justify sellers charging more. Where such a product has no, or few, substitutes, a seller's market power is exacerbated and the ability to price above cost is enhanced, but that does not mean that consumer surplus is maximised. Instead it is diminished.

(3) In addressing whether there was economic value provided in this case, the CAT asked what explanation would be given to the interested party "on the Clapham omnibus" for the "Matterhorn". Whilst normal market inefficiencies will explain some excess (i.e. Case 1), where there is a level of price substantially exceeding Cost Plus "then (absent an articulated pro-competitive explanation) any excess will be abusive."

(4) An important point was that the five phases were "bookended" by periods of prices that were already well in excess of Cost Plus.

(5) 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.

(6) While the shape of the "Matterhorn" is not "indicative of whether the situation falls within Case 2 or Case 3", there was an absence of features such as a sudden or unexpected increase in demand, but the prices rose (during Phases 1 and 2) and the duration of increasing prices persisted for months or years, during which there was no sign of new entry and no legitimate expectation for its failure to emerge.

(7) Phases 1 and 2 were "*par excellence*" cases where the prices charged throughout were abusive, and the CAT did not consider that the downward trend of prices in Phases 3, 4 or 5 altered that position.

(8) The CAT then dealt with other points that arose, the first of which was comparators. At §348, it said this:

> "In this case, there were a number of products – notably Plenadren – which sold at prices far higher than the Focal Products in this case, which were (we remind ourselves) the 10mg and 20mg Focal Products. We do not consider such comparables to be of assistance in the present case. For reasons that we have given at length in this Judgment (Abuse of Dominance Infringements) the prices of medicinal products in the market were not competitive prices, but were distorted for reasons that we have given. Nothing can be learned from them."

(9) On the other hand, the 10mg and 20mg IR Tablets acted as their own comparators on a temporal basis, referring to the comparison it had already undertaken between the prices before and after the "Matterhorn", which approached Cost Plus much more closely.

(10) Finally, it rejected briefly the arguments based on portfolio pricing (there being no detailed justification on the facts of this case) and a perceived lack of clarity in the law.

AMP/Accord's grounds of appeal in respect of unfair pricing

82. AMP/Accord's grounds of appeal largely fall into two parts: First, it contends that the CAT's novel Case 1, 2 and 3 taxonomy is contrary to binding authority and is wrong in law, and that it led to the CAT reversing the burden of proof, failing to measure economic value through an investigation of buy-side factors, and failing to have regard to comparators, specifically Plenadren and Hydrocortistab. Second, it failed to conclude that any unfair pricing abuse ended in May 2015. I address the latter point in section D below together with Intas' appeal against the finding of abuse of dominance.

Did the CAT apply the wrong legal test?

83. I have set out in some detail the passage in the Judgment where the CAT set out its definition of producer surplus and consumer surplus, and its three-case taxonomy.

84. That passage was the subject of comment by a differently constituted tribunal (Waksman J, Eamonn Doran and Derek Ridyard) in *Le Patourel v BT Group Plc and others* [2024] CAT 76 ("***Le Patourel***"), at §82-§83. While the tribunal in that case saw the usefulness of sketching out different scenarios where distinctive value is either offered or not offered, it cautioned against too prescriptive an approach, noting that the distinction between Case 2 and Case 3 was not easy to draw and some cases could straddle both. It nevertheless adopted the concept of "distinctive value" as a useful yardstick by which to measure the value in a product which is different to its cost.

85. In refusing permission to appeal in *Le Patourel*, this Court saw no error in the tribunal's formulation of "distinctive value", rejecting the contention that by endorsing what was said by the CAT in this case, it fell into the error of placing too much reliance on product differentiation: see [2025] EWCA Civ 1061, per Green LJ, with whom Newey LJ agreed, at §78.

86. The arguments advanced on this appeal illustrate the risk of attempting to formulate in this area a new classification of circumstances which do or do not amount to abusive

pricing. It can generate complexities, uncertainty and scope for much argument about whether the tribunal's conclusion fits with, or offends, established legal principles. The three-case taxonomy is not something which should be used as a framework for analysis in the future. The ultimate question is whether the CAT in this case applied the correct legal test in reaching its conclusion. In my judgment, for the reasons which follow, it did.

87. The overarching submission of Ms Ford KC, on behalf of AMP/Accord, was that the law requires (but the CAT failed to carry out) a multi-factorial assessment of fairness, inquiring into what consumers actually value and will reasonably pay for the product in question. She submitted that the CAT instead rigidly (and wrongly) applied its three-case taxonomy as a way of distinguishing legitimate reasons for pricing from illegitimate ones. She submitted that it forced the existing case law into the straitjacket of its own taxonomy. In so doing, it failed to have regard to comparators, and to the following buy-side factors: the intrinsic value of the medicine; the fact that 10mg and 20mg IR Tablets would not have been on the market at all unless AM Pharma had saved MSD's Marketing Authorisation from being deleted; the fact that it was full, not skinny, label; and portfolio pricing.

88. While the way in which the CAT expressed its reasoning lends support to AMP/Accord's case, I consider that it both had well in mind, and ultimately applied, the correct legal test.

89. The first point to note is that the three-case taxonomy was not put forward as a legal test. It appears in a section discussing economic, not legal, concepts as a way of explaining *why* price might exceed Cost Plus. That is demonstrated by the fact that, having set out its explanation of economic value, the CAT set out the applicable legal principles, citing the post-*United Brands* case law. No issue is taken with its summary of those principles.

90. Second, while it is true that the CAT repeatedly referred to Cases 1, 2 and 3 in explaining the distinction between legitimate and illegitimate pricing, it twice made the point that the dividing line between legitimate and illegitimate pricing is determined by competition law, and not competition economics: see footnote 402, and §323.

91. Third, I do not accept that the three-case taxonomy re-writes or excludes any of the relevant legal principles. Most importantly, Case 2 – which essentially encapsulates all cases where price is legitimately in excess of Cost Plus (aside from Case 1 which is confined to relative inefficiencies between sellers) – is very widely drawn. As I have noted above, at §77(2), it includes every form of distinctive value, representing something that buyers wish to purchase from the seller in contradistinction to the offerings of other sellers.

92. There is certainly nothing in that taxonomy which excludes the requisite multi-factorial analysis of fairness, or the consideration of relevant comparators or buy-side factors on which AMP/Accord relies.

93. The critical issue, as Ms Ford recognised, is whether, having adopted this taxonomy, the CAT was in fact led into error in any of the ways that AMP/Accord contends. I turn to address these in turn: burden of proof; comparators; and buy-side factors.

Burden of proof

94. It is common ground that the burden of establishing abuse lies on the CMA. The CAT recognised this at §34(5) of the Judgment. It is not for the alleged infringer to show that their prices were legitimate or justified: see for example *Phenytoin I* at §115.

95. Ms Ford referred to various passages in the Judgment which she characterised as an impermissible reversal of the burden of proof. The most egregious examples were said to be in the section beginning at §341 of the Judgment, headed "Was economic value provided in this case". The CAT said: "The question is not, at this stage, "Does Price exceed Cost?", but rather "Why does Price exceed Cost?". Ms Ford pointed to various parts of §342, where the CAT said that prices in a Case 3 case are abusive because they cannot be justified by Case 1 and "no competitive reason for the excess consumer surplus can otherwise be articulated", and where it considered it to be significant that "none of the Appellants advanced any explanation for the excess that was consistent with a competitive market or which justified a producer surplus". These, she submitted, indicated that the CAT was proceeding on the basis that pricing above cost was problematic unless there is some "pro-competitive" justification advanced by the defendant.

96. I do not accept these criticisms of the CAT's approach. The legal burden rests on the CMA throughout. But that does not preclude the alleged infringer being subject to an evidential burden (i.e. the requirement to produce some credible evidence which if left uncontradicted and unexplained could be accepted as proving a relevant fact in issue) on various points as they arise in the course of the analysis. That such a burden may rest on an undertaking being investigated was made clear by this Court in *Phenytoin I* at §114, and the various cases cited there. That explains, for example, why the CMA need only evaluate such comparators and evidence as are adduced by the undertaking under investigation, and why the extent of the duty on the CMA to evaluate evidence adduced by an undertaking is affected by the quality of that evidence.

97. In this case, the starting point is the fact pattern I have summarised in the summary of conclusions above. Against that background, I see nothing objectionable either in the CAT asking *why* such high prices could be charged, or in regarding the appellants as being under an evidential burden in this respect, i.e. to offer some explanation for the high prices that was consistent with lawful competition (I accept Mr Holmes' explanation for the CAT's reference to "pro-competitive" justifications being a short-hand for reasons unconnected with the exercise of market power). It cannot be said that it involves a reversal of the burden *of proof*.

98. I also reject the contention that the CAT's focus on its three-case analysis caused it to adopt a Cost Plus test without more. It explicitly said, at §334, that pricing in excess of Cost Plus is a necessary but insufficient finding. It did not, in my view, contradict this in reaching its conclusion.

Comparators

99. As this Court recently stated in *Phenytoin II*, at §249, the value of comparators generally depends upon three matters: the product characteristics (e.g. where the comparator has features that are of materially greater value to the consumer than the index product, then its probative value is reduced); the extent to which the price of the

comparator arises in workably competitive conditions; and, where the comparator's price is affected by market power, the decision maker will need to consider evidence before it which enables it to adjust or regress the price to remove that element of the price which derives from the exercise of market power.

100. The CAT emphasised the importance of comparators at §331(1) of the Judgment. It identified the critical question as being whether anything probative can be derived from the comparator in question. The fact that the comparators relied on by AMP/Accord were dismissed in a few short paragraphs, in a section headed "other points that require determination", does not mean that the CAT failed to apply the correct legal test.

101. As to the substance of the point, I have little doubt that the CAT was correct to regard the two comparators which AMP/Accord relies on in this appeal as having no probative value.

102. Although the CAT stated its reasoning for rejecting Plenadren as a comparator in very brief terms at §348 (namely the price at which it was offered was distorted and not the product of a competitive market) it relied on the reasons it explained elsewhere in the Judgment. That was a reference to the following matters earlier in the Judgment (see in particular the following paragraphs: §139 (citing with approval the Decision at §3.130, §3.131, §3.133 and §4.52), §243(8)(iv)&(v) and §348):

(1) Plenadren is given only to a very small number of adrenal insufficiency patients, and is not recommended or endorsed for use in Scotland and Wales;

(2) Restrictions imposed on GPs by clinical commissioning groups materially limited the use of Plenadren;

(3) There were few clinical benefits to Plenadren – save for those few patients with severe compliance problems at whom it was targeted: the same biological rhythm could be obtained by taking IR Tablets two or three times a day;

(4) Plenadren was not recommended by either the National Institute for Health and Care Excellence or the specialist clinical reference group for endocrinology;

(5) In light of factors such as those set out above, its producer changed its sales and marketing strategy from seeking to expand sales to only serving customers when they proactively seek orders; and

(6) Its price was produced in an atypical market, with a protection for orphan drugs almost equivalent to a patent, such that it "is certainly not a market price".

103. As against this, Ms Ford referred to the CAT's finding (which she described as "foundational") that Plenadren was in the same market as Auden/Actavis' 10mg and 20mg IR Tablets, because of their clinical similarities. She relied on the fact (as the CAT emphasised in the section of the Judgment dealing with market definition) that the advice to doctors not to prescribe Plenadren was on price grounds. The CMA had not appealed the CAT's conclusion that Plenadren and Auden/Actavis' 10mg and 20mg IR Tablets were in the same market. On this basis, she submitted that Plenadren was clearly a comparable product, which competed on price with Auden/Actavis' products.

104. This significantly overstates the relevance of the CAT's findings on market definition. The CAT was careful to take the price of Plenadren out of account when considering market definition – basing its conclusions on the unreal assumption that it was offered for sale at £10 a pack. The suggestion that Plenadren competed with Auden/Actavis' product on price flies in the face of the evidence. It entered the market with a price that was many multiples that of Auden/Actavis' IR Tablets. It never made any attempt to adjust its prices relative to the prices of the IR Tablets. Its producers were content to service only the very small cohort of patients which it had managed to capture. Moreover, as the CMA submitted, the suggestion that Auden/Actavis' IR Tablets competed on price with Plenadren is belied by the fact that upon Plenadren's launch Auden/Actavis' price increases intensified, without any evidence of switching to Plenadren.

105. The reasons given by the CMA (see §69 above) and those of the CAT (see §102 above) amply justify the conclusion that Plenadren is not a relevant comparator.

106. AMP/Accord contend, however, that it was not open to the CMA (or the CAT) to dismiss Plenadren as a comparator *altogether*, just because it did not exist in circumstances of workable competition. I accept that the fact that a particular comparator's price is the consequence of an exercise of market power does not necessarily mean that there is no value in it as a comparator. That is recognised by the third point made in §249 of *Phenytoin II*. Ms Ford submitted that the burden lay on the CMA to carry out a regression analysis to identify that part of Plenadren's price that *would* be an appropriate comparator.

107. I do not accept that it was the CMA's duty to undertake such an investigation. The point made in *Phenytoin II* is that the decision maker should undertake such an analysis where it had the evidence before it. The burden on the CMA depends heavily on the nature and quality of the evidence as to comparators placed before it. Where, as here, no attempt at all was made by the appellants to indicate what, if any, fairly comparable price for Plenadren could be extracted by a regression analysis, and how that might be done, the burden did not lie on the CMA to do it for itself.

108. As the CMA submitted, this is a case where there is available the best evidence of the prices that could be achieved for Auden/Actavis' 10mg and 20mg IR Tablets in conditions of effective competition, namely the prices in fact charged following a period of such competition. No-one suggested that that there was any difference in terms of the nature of the products being offered, or that there were any different features in the market save for the presence or absence of effective competition, between January 2016 when (in the absence of effective competition) Auden/Actavis' 10mg IR Tablets sold for over £72 per pack and the time of the CMA decision (when there was effective competition) when they sold for less than Cost Plus.

109. In the face of such clear evidence that the prices achieved during the "Matterhorn" constituted "trading benefits which [Auden/Actavis] would not have reaped if there had been normal and sufficiently effective competition" (*per United Brands* at §249), there was no obligation on the CMA to undertake a regression analysis on the prices of Plenadren so as to attempt to strip out from the prices actually charged that which might not have been the consequence of market power.

110. It is a fair criticism of the Judgment that it does not deal expressly with Hydrocortistab when discussing comparators. At §348, the CAT rejected as comparators "a number of products (notably Plenadren) which sold at prices far higher than the Focal Products in this case." Read together with §303(1), where it recited the appellants' argument that the CMA had failed to take account of comparators "(notably, Hydrocortistab and Plenadren)" which were priced well above Auden/Actavis' 10mg and 20mg IR Tablets, the conclusion in §348 would appear to cover Hydrocortistab.

111. As against that, later in §348, the CAT explained the reason for its conclusion that the prices of these other medicinal products "in the market" were not competitive prices. The fact that it had earlier found that Hydrocortistab was not in the *same* market might suggest that it was not including Hydrocortistab in its conclusion on comparators. On balance, I do not think that is so. Having expressly referred to Hydrocortistab at §303(1), it is more likely that "the market" in §348 was used as an imprecise reference to the market in Hydrocortisone drugs, as opposed to the specific market identified by the CAT in the section on market definition.

112. I have no doubt, in any event, that the reasons the CAT gave in §348 for its conclusion that the comparators relied on by the appellants were not of probative value (assuming that was limited to those in the same market) applies with equal force to Hydrocortistab. The CAT made reference to Hydrocortistab earlier in its Judgment, both when explaining other forms of Hydrocortisone and when defining the relevant market. At §44, it cited with approval §3.135 of the Decision (see above at §70). At §256(5), in explaining why Hydrocortistab was not in the same market, the CAT concluded that the mechanism of delivery was a "substantial point of differentiation" between it and the 10mg IR Tablets, concluding that there would be a marked reluctance on the part of consumers to move from tablets to injections. This reflects the reasoning of the CMA in footnote 1842 (also referred to at §70 above).

113. In light of these considerations, the conclusion that Hydrocortistab is not probative as to the unfairness or otherwise of Auden/Actavis' pricing is in my view clearly correct. Its characteristics are materially different, and its price was not set in conditions of effective competition.

Buy-side factors

114. The first two buy-side factors which AMP/Accord say the CAT disregarded relate to patient benefit: the intrinsic value of the 10mg and 20mg IR Tablets and the fact that at least some customers (specifically the larger pharmacies) perceived a benefit from its full label authorisation.

115. It is clear that patient benefit may translate into some economic value, and thus may need to be factored into the reasonable price of a drug *at some point*, even where there is an element of dependency: see the decision of the CAT in *Phenytoin I* [2018] CAT 11 at §419, endorsed by this Court at [2020] EWCA Civ 13 at §165 to §167. It might be factored in within Cost Plus, or some other way: *Cinven Capital Management (V) General Partner Limited v Competition and Markets Authority* [2025] EWCA Civ 578 (***Cinven***) at §184.

116. The fact that customers pay what is demanded for a life-saving drug is not however an indication of its economic value. Of greater relevance is what customers would be

reasonably willing to pay under conditions of workable competition: see *Phenytoin I* at §155:

> "the simple fact that a consumer will or must pay the price that a dominant undertaking demands is not therefore an indication it reflects a reasonable relationship with economic value. But a proxy might be what customers are prepared to pay for the good or service in an effectively competitive market"

117. The CMA was accordingly right to submit that many life-saving drugs are sold for very little, and the fact that customers have in fact been willing to purchase the drug at high prices is not determinative.

118. In this case, there is the clearest evidence of what customers are prepared to pay for Auden/Actavis' IR Tablets in conditions of sufficiently workable competition: see above at §108.

119. AMP/Accord criticises the CAT's conclusion at §339 that the appellants' contentions did not justify any excess of price over Cost Plus. The CMA suggested that this was to be read as precluding an open-ended excess over Cost Plus, but Mr Holmes KC (for the CMA) realistically accepted that this was a difficult reading when the paragraph is taken as a whole. It is important, however, to note that the CAT was referring to the contentions summarised in the preceding paragraph, and that these were addressing the CMA's conclusion (at §5.432) that there were no non-cost related factors that increased the economic value of Auden/Actavis' IR Tablets "beyond that already reflected in Cost Plus".

120. The CMA's conclusion that economic value was already factored into Cost Plus was based on the matters enumerated in §5.433: the age of Hydrocortisone and the stage in its lifecycle; the current prices of comparators; and the current prices of Auden/Actavis' IR Tablets themselves. This was an unobjectionable application of the point made in *Phenytoin I* at §155, quoted above.

121. The CAT's comments at §339, therefore, must be seen in the context that the economic value including the value of patient benefits was sufficiently recognised within Cost Plus, having regard in particular to the best evidence of comparators in this case. I do not read it as saying that in no case can the value patients place upon a particular drug justify a price higher than Cost Plus. If that is wrong, the conclusion that economic value arising from patient benefit was sufficiently reflected in Cost Plus on the facts of this case is itself a sufficient answer to AMP/Accord's point.

122. The same point is an answer to the objection that the CAT failed to take account of the fact that Auden/Actavis' IR Tablets had full label authorisation. In theory, where the market is presented with a choice between two options, a full label and a skinny label product, then the fact that one is priced higher than the other might well reflect their respective economic value. The market simply values one more than the other, notwithstanding their bio-equivalence.

123. The CMA's finding that the larger pharmacies perceived that they had no practical choice, given their particular sensitivity to regulatory concerns, than to dispense full label IR Tablets is not, *per se*, challenged, albeit that Intas challenges whether that

remained the case into the Intas Phase (see section D below). The impact of that finding is that the holder of full label authorisation had an advantage that was the product of the regulatory regime, not the product of workable competition.

124. The question is whether the price differential, in circumstances where there is not in fact a free choice between the two, reflects their respective economic values. The answer to that is best provided by observing what happened when there was workable competition. At that point, it is fair to say that the full label products still achieved a higher price than the skinny label products. Assuming in the appellants' favour that this was not the result of a continuing perception of lack of choice, the prices obtained by Auden/Actavis were nevertheless below Cost Plus. This reinforces the conclusion that whatever economic value there was in the full label designation was sufficiently reflected in Cost Plus.

125. The third buy-side factor upon which AMP/Accord relies is that 10mg and 20mg IR Tablets would not have been on the market at all unless AM Pharma had saved MSD's Marketing Authorisation from being deleted.

126. AM Pharma launched the 10mg IR Tablets at £4.50 per pack, significantly more than the price charged by MSD (70p per pack). Whatever patient benefit lay in this drug continuing to be on the market is reflected in the price at which AM Pharma was prepared to bring its product to market. Subsequent price increases to 16 times that level cannot be explained by the patient benefit in this drug being saved from deletion. In any event, the fact that MSD was going to delete the product does not mean that *without Auden/Actavis* the drug would have been lost to patients. The very fact that others were prepared to obtain their own Marketing Authorisation for bio-equivalent drugs undermines that assumption. For these reasons, I accept the CMA's submission that, while it is true the CAT did not expressly address this point, there is nevertheless nothing in it.

127. The final buy-side factor relied on is portfolio pricing. Ms Ford submitted that like most pharmaceutical companies Auden/Actavis approached its pricing on a portfolio basis, such that excessive profits in respect of one drug may not be seen as unfair when viewed in context. The CAT rejected this proposition, saying that portfolio pricing cannot automatically justify a higher price: see §352 to §353 of the Judgment. Ms Ford submitted that it was not AMP/Accord's case that it *automatically* justified a higher price, but that it was one factor together with others which made it particularly important for the CAT to give proper consideration to potential comparators.

128. The CAT's comment that portfolio pricing did not "automatically" justify higher prices was made in the context that the contention was unsupported in this case by any contemporaneous or factual evidence: see footnote 434 to §342 of the Judgment. That was an unimpeachable conclusion. Ms Ford's submission therefore falls at the first hurdle. Without any evidence to support the contention that there was in fact portfolio pricing during the infringement period, the point is theoretical only. In any event, for reasons I have set out elsewhere, the CAT did give proper consideration to comparators, so the submission falls also at the second hurdle.

129. For these reasons, I reject AMP/Accord's case that the CAT erred in law either in its formulation or application of the test for abuse of dominance.

Section C: Dominance in the Intas Phase and abuse post-2015

The law on dominance

130. The parties were agreed that the basic test for dominance is that set out in *United Brands* at §65:

> "The dominant position referred to in [Article 86] relates to a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers."

131. The importance of market share appears from the decision of the ECJ in *Hoffmann La Roche v Commission* Case 85/76 (EU:C:1979:36), at §41:

> "An undertaking which has a very large market share and holds it for some time, by means of the volume of production and the scale of the supply which it stands for — without those having much smaller market shares being able to meet rapidly the demand from those who would like to break away from the undertaking which has the largest market share — is by virtue of that share in a position of strength which makes it an unavoidable trading partner and which, already because of this secures for it, at the very least during relatively long periods, that freedom of action which is the special feature of a dominant position."

132. This was reinforced in the decision of the General Court in Case C-457/10 P *AstraZeneca v Commission* (EU:C:2012:770), at §242:

> "although the importance of market shares may vary from one market to another, the possession over time of a very large market share is in itself, save in exceptional circumstances, evidence of the existence of a dominant position"

133. The General Court went on to say that market shares of more than 50% were "very large market shares", while a share of between 70%-80% was "in itself a clear indication of the existence of a dominant position." The CJEU in the same case at §176 said that holding a very large market share (which it too described as over 50%) over a long period was "proof" of dominance, but since it was merely citing *Hoffmann La Roche* for that proposition, I do not read much into the different wording.

134. Intas places particular reliance on §71 of *Hoffmann-La Roche*:

> "However, the fact that an undertaking is compelled by the pressure of its competitors' price reductions to lower its own prices is in general incompatible with that independent conduct which is the hallmark of a dominant position."

The CMA's conclusion on dominance

135. As I have noted above, the CMA did not address separately dominance in the Intas Phase. While its conclusion referred simply to dominance throughout the infringement period, however, in its reasoning it distinguished between pre- and post- entry of skinny label competitors (see §4.227).

136. Its conclusion that Auden/Actavis was dominant throughout (see §4.230), was based on (1) Auden/Actavis' market share; (2) its pricing behaviour, including charging significantly more than competitors in the post-entry period; and (3) the market context, which included (a) the 10mg Agreement and the 20mg Agreement, (b) the orphan designation granted to Plenadren which "created a barrier to expansion and provided Auden/Actavis with an assured customer base for 10mg hydrocortisone tablets and thereby preserved its ability to behave to an appreciable extent independently of its competitors, its customers and ultimately consumers", and (c) the absence of countervailing buyer power.

137. Figures 4.13 and 4.14 in the Decision illustrate market shares for 10mg IR Tablets throughout the infringement period. Auden/Actavis' market share (by volume) was 100% until the entry of skinny label tablets in 2015. It then fell sharply to just over 50% by about April 2016. For the first few months of the Intas Phase it fell further, reaching a trough of around 30% in September 2017, before climbing back to above 50% by October 2017, and remaining around about that level for the remainder of the period. The figures for revenue produced broadly the same shape: upon the entry of skinny label products, Auden/Actavis's market share fell to about 60%, but then increased again, and fluctuated between 70% and 80%. At the start of the Intas Phase it fell sharply to a trough of around 60%, but then climbed quickly back. By the end of the Intas Phase it had reached around 85%.

138. Figure 1.4 in the Decision illustrated (among other things) the price of Auden/Actavis's 10mg IR Tablets over the entire infringement period (and beyond) and the average selling price of competitors from their entry into the market in 2015. So far as the Intas Phase is concerned, there was a relatively sharp and steady reduction in price of Auden/Actavis' 10mg IR Tablets from around £54 to just below £20. This significantly lagged behind, however, the average selling price for the skinny label competitors, which fell from around £20 to around £4 during the Intas Phase.

139. Throughout the Intas Phase, therefore, Auden/Actavis's 10mg IR Tablets were selling at a substantial premium to the skinny label products. For most of the period the differential in relative terms was between 200% to 300%. In fact, by the end it had risen to £15 in absolute terms, and 450% in relative terms.

140. Specifically concerning the period post-entry of skinny label competitors, the CMA reached this conclusion, at §4.274 to §4.275:

> "Actavis's market share declined initially at a time when the absolute and relative premium between its price and that of its competitors was growing (particularly for 10mg hydrocortisone tablets). However, Actavis's market shares then stabilised, at a time when its competitors' prices continued falling faster than its own prices. This is direct evidence that Actavis was not losing any market share despite its competitors' tablets becoming relatively cheaper in relation to its own, and provides a strong

> demonstration that Actavis retained an ability to price above competitive levels, thereby demonstrating its market power.
>
> As the number of entrants increased and competition intensified within both the 10mg and the 20mg hydrocortisone tablets markets, Actavis's price premium increased relative to its competitors. This is not the pattern that would be expected if competitors were able to appreciably constrain Actavis's conduct: instead, it would be expected that as more competitors entered, competition would become more intense between all suppliers and erode Actavis's ability to charge a premium over its competitors' prices. The increasing premium in the face of entry therefore demonstrates Actavis's ability to act appreciably independently of its competitors."

141. I have referred above (at §34) to the CMA's finding that the larger pharmacies' perception that they had no choice but to dispense full label IR Tablets provided Auden/Actavis with an assured customer base. In its section on dominance post-entry of skinny label products, the CMA characterised this "barrier to expansion" as a key factor contributing to Auden/Actavis' ability to charge significantly above its competitors' prices (see §4.288 of the Decision). It commented (at §4.295) that the fact that customers continued to purchase full label tablets despite their substantial premium was a strong demonstration that Auden/Actavis retained dominance in the post-entry period. It noted (at footnote 1460) Auden/Actavis' argument that its position was nevertheless precarious because – had the two largest pharmacies switched – its share would have fallen to 13%, but rejected this as a hypothetical scenario, whereas the evidence showed they did not switch.

The CAT's conclusion on dominance in the Intas Phase

142. The CAT's consideration of dominance is at §258 to §297 of the Judgment.

143. It first set aside the CMA's determination that Auden/Actavis was dominant throughout the infringement period, concluding that the CMA ought to have considered dominance separately in relation to the five separate phases: §263 to §266.

144. It cautioned against placing much weight on the ability to price at will when considering the question of dominance, in a case where the abuse alleged is excessive pricing. It observed that dominance can arise through circumstance (in this case the deficiencies in the regulatory regime which created opportunities in the form of suppressing competition), as well as through the efforts of the dominant undertaking.

145. At §277, it set out its approach, "against the background of what would appear to be uncontrolled prices and an ineffectual scheme of regulatory control in a market where demand is inelastic because it is based on medical need". It described these as background factors to be accorded secondary weight.

146. At §278, it explained its approach was to consider dominance "by reference primarily to market share on a phase-by-phase" basis, both by reference to volume and revenue. It did so separately for each phase. As to the Intas Phase, the CAT found:

(1) Auden/Actavis' market share at the commencement of the Intas Phase was 52.58% by volume, and 69.1% by revenue.

(2) Its share at the end of the Intas Phase was 50.1% by volume and 64.51% by revenue.

(3) Its average share across the Intas Phase was 40.5% by volume and 63.2% by revenue.

147. These figures differ from those used by the CMA because the CMA's definition of the market was narrower, excluding Plenadren from its calculations. Plenadren sold in very low volumes (although at much higher prices).

148. Its conclusion, at §291, was that there was dominance during all five phases.

149. It first gave three reasons relating to price: (1) the ability of the holder of the relevant Marketing Authorisations to raise the price of 10mg and 20mg IR Tablets substantially; (2) in circumstances where demand did not fall away as a result of such price increases; and (3) where constraints on the holder (whether competitive or regulatory) appear to have been either minimal or non-existent.

150. It is common ground that these have no application to the Intas Phase. It explained at §292, however, that as these related to price it was cautious about placing too much weight on them. Instead, it had primary regard to market share. As to that, it concluded at §293 that the relevant market shares (by volume and by revenue) "clearly denoted dominance", a conclusion that was inevitable from the data it set out above. That was the data I have summarised at §146 above, and which derived from the Figures in the Decision referred to at §137 above. It continued:

> "In Phase 1 it was 100% but it was rarely (if ever) less than 50% whether by volume or revenue. Furthermore, the remaining share of the market was highly fragmented amongst a number of other competitors."

151. At §294 and §295 it concluded:

> "294. It is also significant that many of these competitors (namely, those selling "skinny label" products) will have laboured at a competitive disadvantage when compared to the holder of the Merck, Sharpe & Dohme MA. We have described the nature of that disadvantage already, but its effect will have been twofold:
>
> (1) First, such competitors will have sold at lower volumes than if they had a "full label" product to sell.
>
> (2) Secondly, to the extent that there was demand, that demand responded to a significant discount in the price of "skinny label" products relative to "full label" products.
>
> 295. Thus, even when there was competition, it was of limited effect, and that is reflected in the market shares that we have recorded."

152. At §296 to §297 it stated that, while it appreciated that its approach was different to that of the CMA, it did not consider it was "materially disagreeing*"* with the CMA's decision in this regard. Its disagreement with the CMA was over the approach not the result. The difference in approach was driven by its different analysis of market definition and its decision to address each phase separately. It was not, however, "because of any material error by the CMA in regard to its assessment of dominance."

Intas' arguments in outline

153. Mr Palmer KC, on behalf of Intas, submitted that the CAT made the following five errors of law:

(1) Having correctly said (at §268) that it is necessary to ask *why* Auden/Actavis's prices were at the level they were, the CAT failed to do so with specific reference to the Intas Phase;

(2) The CAT failed to give reasons for dismissing Intas' case: it is impossible to understand what the CAT decided in respect of the submission at the heart of Intas' appeal;

(3) Had the CAT asked itself the necessary question, it would have concluded that Auden/Actavis' prices were falling because of the constraint exerted by its competitors;

(4) The CAT erred by focusing predominantly on market shares, which are not sufficient to establish dominance; and

(5) The CAT was wrong to conclude that other features of the relevant market supported a finding of dominance.

154. Much of his oral argument was focused on the extent to which, if at all, the CAT upheld the CMA's analysis that Auden/Actavis had an assured customer base, as a consequence of the larger pharmacies' perception that they had no choice but to dispense full label tablets. His argument on this point is in three parts: first, the CAT had rejected the CMA's finding that there was such an assured customer base; second, if that was wrong, the CAT had certainly not *endorsed* that finding; third, even if the CAT endorsed the CMA's conclusion, that could not stand in light of the fact that it had simply ignored the substantial and lengthy arguments Intas had advanced before the CAT to the effect that there was no assured customer base.

Analysis

155. It will be apparent from the summary I have set out above of the CMA's reasoning and conclusions on dominance, that although it reached a single conclusion as to the whole of the infringement period, it had regard to the different features of the market in the periods before and after the entry of skinny label products. Much of its reasoning relating to the latter period is applicable specifically to the Intas Phase.

156. The CAT's own conclusions as to the Intas Phase were relatively briefly stated (see §149 to §151 above). Leaving aside the three points made in §291 which do not relate to the Intas Phase, the CAT's reasoning can be summarised as: (1) Auden/Actavis' market share was rarely below 50% by value or volume; (2) the remainder of the market

was highly fragmented; (3) competitors were disadvantaged by two consequences of their skinny label authorisation, because they will have sold at lower volumes and at a significant discount in price; (4) accordingly, the competition was of limited effect, reflected in the market shares.

157. It is important to understand precisely what aspects, if any, of the CMA's reasoning on dominance the CAT endorsed. Mr Palmer submitted that the CAT jettisoned most of the CMA's conclusions and reasoning on dominance, so that "very little of the CMA's analysis concerning dominance in the Intas Phase remains".

158. I do not accept this. The CAT was explicit about the extent of its disagreement with the CMA: see §152 above. The ambit of disagreement was limited to two aspects of the approach taken, and not because of any material error in the CMA's assessment of dominance.

159. Mr Palmer submitted that the CAT was wrong to place such emphasis on market shares, both because that is wrong in law and because this was not a case of very large market shares, given Auden/Actavis' market share by value averaged only 40% during the Intas Phase.

160. I have set out the relevant law above which, while acknowledging that a very large market share (generally regarded as 50% or more) is not conclusive of dominance, firmly establishes that where it is maintained over time it is, other than in exceptional circumstances, in itself evidence of a dominant position.

161. I do not accept Mr Palmer's submission that Auden/Actavis did not have a very large market share. It is overly simplistic to rely on the CAT's conclusion that the average over the Intas Phase was 40%. The reality is more nuanced than that. Auden/Actavis' market share at the beginning and the end of the Intas Phase was approximately 50%. The fact that the average is nearer 40% is explained by the fact that the decline from 100% which began with new skinny label entrants in October 2015 continued through the first few months of the Intas Phase, but was then reversed. Such competition as there was did not prevent Auden/Actavis from *increasing* its market share, such that it stabilised again at around 50% from October 2017 onwards. This constitutes, in my view, a very large market share (on the basis of volume) sustained over time.

162. I have so far used the metric (volume) that is most favourable to Intas. All parties accepted that both metrics are relevant. On the basis of revenue the percentages are 20% to 30% higher. I would not go so far, however, as Mr Armitage (who took the lead for the CMA on this aspect) suggested, to say that revenue matters more. He relied for that proposition on a passage in the decision of the European Commission in *AstraZeneca* COMP/A.37.507/F3, recital 394, but that was said specifically in relation to a market consisting of products differentiated in terms of, e.g., dosage forms, pack sizes and strength, none of which applies here.

163. It is also highly relevant that the remainder of the market was highly fragmented. The remaining 50% of the market was shared roughly equally among the five (then six) skinny label entrants.

164. Intas is able to point to the fact that Auden/Actavis' prices continued to fall during the Intas Period. Mr Palmer cited the Judgment on Cartel Infringements, in which the CAT

described, at §115(3)(v), the "inevitable downward pressure" on both skinny label and full label prices as a result of actual market entry from 2015 onwards (a finding endorsed by the Master of the Rolls in *Hydrocortisone CA I* at §114). The CMA's own expert witness, Professor Valletti, accepted that Auden/Actavis was unable to resist reducing its prices following the entry of the skinny label products.

165. That, Intas contends (with the language of §71 of *Hoffmann-La Roche*, above at §134, in mind), is inconsistent with a dominant position. Again, however, the picture is more nuanced. The question so far as dominance is concerned is the extent to which the allegedly dominant undertaking is able to act to an *appreciable* extent independently of the market.

166. Notwithstanding the fact that Auden/Actavis' prices fell about 25% between March 2016 and February 2017, there is no challenge by Auden/Actavis to the conclusion that dominance continued throughout that period. As Mr Armitage submitted, while competition with the skinny label producers undoubtedly imposed pressure on Auden/Actavis to reduce its prices, in doing so it maintained if not increased a very substantial premium above the skinny label prices throughout the Intas Phase.

167. That, as the CMA recognised (see §4.274 to §4.275 of the Decision), is an important indicator that an allegedly dominant undertaking is able to act independently of the market to an appreciable extent: see also the decision of the General Court in *Astra Zeneca* at §266:

> "the ability of AZ to maintain higher prices than those of its competitors, while retaining a much higher market share, shows that it was able to exercise market power in respect of price, since neither competing producers, nor social security systems, which bore the cost of the medicines, nor indeed patients, were able to force AZ to bring its prices into line with those of competing products".

168. The General Court went on, at §267, to note that a finding of market power was not dependent on showing that the undertaking had made use of that market power so as to prevent effective competition from being maintained.

169. I turn to consider the principal focus of Mr Palmer's oral submissions relating to the CMA's finding of an assured customer base. I did not understand Intas to dispute that when the skinny label products first became available, the larger pharmacies took the view that the risk of dispensing off-label outweighed the economic advantages of dispensing the much cheaper skinny label IR Tablets. He submitted, however, that the CMA erred in failing to appreciate two points. First, as time passed and more and more smaller pharmacies opted to switch to skinny label tablets, with no adverse consequences, the larger pharmacies were likely to review their assessment of the risk to them, and thus reconsider their decision to dispense only full label tablets. Second, in consequence, Auden/Actavis could not regard the larger pharmacies as an "assured" customer base, but must increasingly compete on price if they wanted to maintain their market share.

170. The question of the extent to which – if at all – the CAT rejected or endorsed the CMA's conclusion that Auden/Actavis had an assured customer base is in my view something

of an unhelpful diversion. The CAT appears deliberately to have eschewed referring to the phrase "assured customer base" (making only one passing reference to it in the whole of its Judgment, compared with the 20 or so references in the CMA's Decision). Instead, it undertook its own analysis, based on the evidence before it, of the extent to which Auden/Actavis' ability to price at a substantial premium over competitors derived from its full label authorisation.

171. I have set out §294 to §295 of the Judgment at §151 above. The CAT there concluded that even where there was competition (i.e. after the entry of skinny label competitors) it was of limited effect, relying on the fact that those selling skinny label products laboured under the competitive disadvantage which it had described earlier in the Judgment. To understand this, it is necessary to see where, earlier in its judgment, it addressed that competitive disadvantage. It did so primarily in the context of describing the regulatory context and in the section on market definition.

172. At §80-§83, §88, §90 and §240, it made the following (among other) findings. First, discussing an example drawn from the facts of this case, where drug A and drug B are essentially the same but one has Marketing Authorisation for children, the other for adults, but one is priced significantly below the other, it found that while a pharmacy would act rationally in dispensing the cheaper drug, even against the Marketing Authorisation, there would have been a "strong prudential motivation" amongst pharmacists to dispense the age-appropriate drug (according to its Marketing Authorisation) even if not legally obliged to do so.

173. Second, it found that there was a sense within the body of UK pharmacies that in the case of an open prescription, the preferred course was to dispense the product that was – on the face of the Marketing Authorisation and associated documentation – most appropriate for the patient; and that this was particularly so among risk-averse pharmacies.

174. In the section on market definition, at §235, it found that "…despite a really quite material price differential, a significant part of the market did not switch to skinny label. That was due to non-price considerations, of the sort we have described." At §243(8)(v)(c), it found that the larger pharmacies regarded skinny label as a different and non-substitutable product, commenting: "This is the distortive outcome of a market that is not, in any real sense of the word, a competitive market but a highly regulated market."

175. Accordingly, in finding that dominance continued post-entry of skinny label products, while at no point labelling this as an "assured customer base", the CAT relied on its findings as to the perception among the larger, risk averse, pharmacies as borne out by the fact that throughout the infringement period for the most part they did not switch to skinny label products, notwithstanding that nearly all the smaller independent pharmacists had done so by the start of the Intas Phase.

176. Mr Palmer referred to Intas' written opening submissions and lengthy written closing submissions (including a 100-plus page annex) at trial, addressing the CMA's finding as to an assured customer base. The thrust of these submissions was that the CMA was wrong to refer to the customer base as "assured" because the evidence clearly showed that all customers had a choice to switch to skinny label products, that different customers took into account different considerations, and that many exercised it by

switching to skinny label products. It contended that the CMA's case that customers were "unable" to switch ignored the fact that wherever a customer chose to purchase from one supplier, it remained free to change its decision at any time.

177. Thus, Intas' conclusion, having summarised the extensive evidence analysed in the annex to its closing submissions, was as follows:

> "This key pillar of the Decision – its characterisation of Accord-UK's customers as having "no choice" and "no ability" to switch to skinny labels from the full label and therefore comprising a "captive" customer base – is on analysis without foundation. The CMA has failed entirely to adduce the "sufficiently clear, precise and consistent evidence" of an inability to switch that would be required to discharge its burden of proof in respect of this key pillar of the Decision. Once it is removed, the CMA's conclusions on dominance can no longer be sustained."

178. This point was developed at length by reference to each of the major pharmacies which had refrained from switching to any material extent to skinny label tablets. It accepted that *one* of the factors which influenced the pharmacies' decision was "perceived regulatory risks", but submitted that the degree to which they maintained their preferences varied between different pharmacies and over time. All of this negated the CMA's conclusion that pharmacies had "no choice".

179. I need not summarise Intas' treatment of all of the major pharmacies' decision-making processes, but the point consistently made was that each of them was exercising a choice. For example, it noted that Superdrug had switched to skinny label products in June-September 2016 but then switched back, having explicitly weighed the financial advantages against the "perceived regulatory risks". Well's choice was also made by weighing the same factors. Intas quoted Rowland's decision to refrain from dispensing skinny label tablets: "because of the complexity and legal risk involved with dispensing products outside of their licensed indications, we only use fully indicated hydrocortisone where possible…" Intas contended that this shows it was not "outright prevented" from switching because of the orphan designation, but only that it was "a key reason" for its choice.

180. The two largest pharmacies by volume of Hydrocortisone tablets purchased were Boots and Lloyds. Between them, they accounted for more than the volume purchased by all the smaller pharmacies (most of whom switched to skinny label) put together. Intas referred to Lloyds' decision as being based on a balance between the potential benefits from switching to skinny label products and the hassle switching would entail but having acknowledged that "this may change if the price differential grows". It referred to Boots' decision to dispense full label tablets as being based on its "misconception" over regulatory risk conducted at the outset, to the fact that it was open to Boots to change its mind, but it had not conducted another review. Intas submitted that this does not demonstrate that it was "unable" to switch.

181. While the CMA did at times refer in the Decision to the larger pharmacies having no choice but to purchase full label tablets and being "unable" to switch to skinny label tablets (see, for example, §3.282), it is clear from a fuller reading of the Decision that it referred to an "inability" to switch as a shorthand for its longer explanation that these

customers *perceived* there to be a regulatory risk in doing so, even though there was in fact no actual impediment, and that the reference to "no choice" was driven by the fact that the only supplier of full label tablets was Auden/Actavis. Accordingly, to some extent at least, Intas' arguments on this point were an unfair over-simplification of the CMA's conclusions.

182. More importantly, however, much of the force of Intas' complaint that the CAT failed to address this material falls away in light of the CAT having avoided the labels of "no choice", an "inability" to switch or an "assured" customer base. Its own findings of fact (summarised above) are unaffected by Intas' criticisms of the terminology used by the CMA. On the contrary, taking Intas' arguments as set out in their written closing arguments at trial at their highest, they reinforce the CAT's analysis that there was a strong prudential motivation among larger, risk-averse pharmacies to dispense Hydrocortisone in accordance with Marketing Authorisation, and that it was for this reason that the larger pharmacies regarded themselves as restrained from switching to skinny label products and in fact did not do so. All that is borne out by the summaries Intas provided of these pharmacies' decision-making processes.

183. That leaves the point emphasised by Mr Palmer in oral submissions before us, namely that just because a pharmacy had once decided not to dispense skinny label products did not mean that it might not change its mind, particularly if the price differential became too great, as Lloyds expressly acknowledged, and *from Auden/Actavis'* perspective it could not be *assured* that the major pharmacies would not change their mind. While that is a relevant objection to characterising the larger pharmacies as an *assured* customer base, if that is understood to mean that it could be guaranteed, it is not an answer to the conclusion that, for as long as the pharmacies maintained that view, Auden/Actavis was able to take advantage of it by pricing at a significant premium over the products of skinny label competitors.

184. When combined with the other factors on which the CAT relied, particularly Auden/Actavis' ability to maintain and even increase market share during the Intas Phase, I find the CAT's conclusion that Auden/Actavis had – throughout the Intas Phase – the power to behave *to an appreciable extent* independently of its competitors is unimpeachable. Although it would have been better for the CAT to acknowledge explicitly that it had taken into account but rejected Intas' detailed arguments on dominance, I do not find it a material failing on the part of the CAT not to have done so.

Abuse of dominance post-entry of skinny label competitors

185. AMP/Accord contends that if there was any abuse of dominance it ceased by about 2015 when it was apparent that there would soon be effective competitive pressure to bring prices down. Intas contends that, even if that is wrong, it had ceased by the beginning of the Intas Phase on 9 January 2017.

186. Intas made the running on this part of the case. Its arguments are in summary as follows:

(1) Auden/Actavis' prices were not "imposed" on customers within the meaning of s.18 of CA 1998.

(2) The CAT erred in dismissing Intas' argument that there was normal and sufficiently effective competition during the Intas Phase.

(3) The CAT erred in concluding that Auden/Actavis' prices were within Case 3 rather than Case 2 during the Intas Phase; and

(4) The CAT erred in dismissing Plenadren as a relevant comparator. This last point adds nothing to AMP/Accord's arguments, which I have rejected above.

187. I have set out above at §81 the CAT's conclusions on abuse. Although it purported to adopt a phase-by-phase consideration (see §342 of the Judgment) it is fair to say that its treatment of the phases encompassing the downward slope of the "Matterhorn" is very brief. It simply said (at §342(4)) that the downward trend of prices in Phases 3, 4 or 5 did not affect its conclusion that, throughout, the prices were abusive. It recognised that "prices containing substantial producer surplus will – absent some barrier to or inhibition on market contestability – attract new market entrants, who will compete with the incumbent sellers", and that would be so whether the situation falls within Case 2 or Case 3. However, "the situation before us – whatever phase is under consideration – falls within Case 3 and it follows that even if prices are falling, provided they sit above [Cost Plus] they infringe the Chapter II prohibition."

188. The key question, however, is whether AMP/Accord's and Intas' arguments advanced before us should have led the CAT to a different conclusion.

189. AMP/Accord's overarching contention is that, assuming the prices of 10mg and 20mg IR Tablets were abusive in 2015, they ceased to be so at that point because it was apparent that there would soon be effective competitive pressure to bring prices down. I accept that Auden/Actavis perceived that this would be the effect of skinny label competition. That is made clear by a slide presentation dated December 2014 outlining Allergan's strategy in acquiring Auden Mckenzie Holdings Ltd. It referred to its Hydrocortisone tablets (which comprised 40% of sales) as benefitting from "a unique orphan drug exclusivity", which was "expected to erode in the near term", but as constituting a "near term cash cow". What was meant by "near term" is explained by its modelling which assumed competitors entering the market in 2015 and being dispensed off-label, and then a price erosion of 90% over three years.

190. The contention that any abusive conduct ceased when it was apparent that there soon would be effective competition is in my judgment hopeless. Auden/Actavis' response to that possibility was to impose rapid and heavy price increases, from a price of around £50 in December 2014, to the peak of over £72 in April 2016. While prices then began declining in response to competitive pressure, the prediction in Allergan's strategy paper turned out to be pessimistic: the anticipated 90% erosion took a further four years, the price settling around Cost Plus in December 2020. Moreover, as described above in the section on dominance in the Intas Phase, Auden/Actavis kept its prices substantially higher (mostly between 200% and 300% higher throughout the remainder of the infringement period) than those of its competitors.

191. That leaves the contention (which is sufficient for Intas' purpose) that any abusive conduct ceased in about April 2016 when Auden/Actavis began reacting to increasing competition by reducing prices. AMP/Accord and Intas accept that it can be said that the *effects* of the abuse continue during the following three or four years when the prices

were still higher than that which they eventually achieved following a period of effective competition. They further accept that this might be an answer to the argument that prices *after* the abuse has ended are necessarily reflective of a competitive price. Such an argument was rejected in *Cinven* at §82, which recognised that prices can remain "contaminated" by prior abuse for some period after the abuse ends. In that case, the CMA had not sought to argue that the abuse itself continued into the period when prices started to decline. Accordingly, the case says nothing about whether abuse can continue notwithstanding prices are declining in response to competition.

192. In my judgment, the fact that, as here, a dominant undertaking reacts to competition by reducing its prices does not necessarily mean that its behaviour has ceased to be abusive. The argument has to be seen in the context that it has already been found that Auden/Actavis engaged in an abuse of dominance by the massive increases in prices from £20 to £72.14 between October 2008 and April 2016. If it was abusive to charge £72.14 in April 2016, it does not automatically cease to be abusive the following month because there is a reduction of, say £2, in the price in response to a new entrant in the market. More broadly, if it was abusive to charge all the prices above £20 on the upward slope of the "Matterhorn", the abusive conduct does not necessarily cease because the same prices are later charged in the context of the downward slope. The question is whether Auden/Actavis was during that time still unfairly exploiting its market power to charge excessive prices.

193. Turning to the detailed arguments advanced by Intas, Mr Palmer's first argument is as follows: s.18 of CA 1998 requires the prices to have been "imposed" by the dominant undertaking; a seller can only be said to impose a price on a customer if the customer has no choice but to pay; following entry of the skinny label products, customers were free to choose another product; therefore Auden/Actavis did not impose their prices on customers.

194. In his oral submissions, Mr Palmer relied on the recent decision of the CAT in *Gutmann v First MTR Southwestern Trains Limited* [2025] CAT 64. That was not a case about unfair pricing, but concerned the alleged failure of rail companies to make "boundary fares" sufficiently transparent. These fares enabled the holder of a travelcard to purchase a ticket to a destination outside the travelcard zone as if the journey commenced at the last station on the journey within the travelcard zone. Mr Gutmann's complaint was that passengers were in effect paying twice for part of the journey, and this had not been made clear in the terms and conditions. In the course of its judgment, the CAT (chaired by Sir Peter Roth), at §83, discussed the concept of an unfair contractual term being "imposed" on a customer, noting that in two earlier cases mentioned earlier in the judgment (*Deutsche Telekom AG v Commission*, ECLI:EU:C:2010:603, and *Duales System Deutschland*, EU:C:2009:456) the customer wishing to use the service had "no practical alternative to paying the impugned charge" and that in *Meta Platforms v BKA*, ECLI:EU:C:2023:537), the consumers wishing to use the Facebook social network had no alternative but to "consent" to the terms entitling Meta to broad access and use of their digital data. In the following paragraph, it was recognised that "imposition" can be *de facto*.

195. The fact that in the cases cited in *Gutmann* the customer had no choice, or *de facto* no choice does not lead to the conclusion that there can be no "imposition" of an unfair price without such a finding. That it cannot be correct to say that there is no imposition without depriving the customer of choice is demonstrated by the fact that, taken to its

logical extreme, it would preclude a finding of abusive pricing in any case other than that of a monopoly supplier.

196. In my judgment, the meaning of "imposed" is coloured by the legal principles that have been developed to explain when an undertaking is dominant and when it is taken to have abused its dominance (as summarised above). Specifically, a dominant undertaking extends beyond a monopolist and includes an undertaking with a very high market share as a result of which it is able to behave to an appreciable extent independently of the market. And the touchstone of abuse, *per United Brands*, is where a dominant undertaking "reaps trading benefits which it would not have reaped if there had been normal and sufficiently effective competition." As *United Brands* makes clear, abuse can consist of charging prices that are unfair in comparison with the price of competing products.

197. In this case, (as I have already found) Auden/Actavis was able to behave independently of the market, notwithstanding prices fell post-entry of skinny label competitors, by charging 200% to 300% more than them. It was able to do this, at least in part, because of the regulatory quirk created by Plenadren's orphan designation combined with the risk-averse approach of the major pharmacies. It was well aware of the opportunity to charge higher prices as a result of "a unique orphan drug exclusivity", but that this opportunity was likely to be eroded within about three years following competitive entry. Its conduct thereafter was to take advantage of that market power in order to continue to achieve prices far higher than its competitors could charge, until such time as the extent of competition led to conditions of sufficiently effective competition. That, in my view, is sufficient to constitute "imposing" such prices on customers.

198. Intas' second argument is that the CAT was wrong to dismiss the argument that there was normal and sufficiently effective competition during the Intas Phase. It was common ground that by the time of the Decision the relevant market *was* competitive and that the only structural difference between then and the start of the Intas Phase was that the number of competitors in the market had increased. There were no effective barriers to entry and prices fell by more than 60%.

199. The answer to this is similar to that just given in relation to the "imposition" issue. Accepting that Auden/Actavis could not be "assured" that the major pharmacies would not at some point reverse their decision to dispense only full label 10mg IR Tablets, nevertheless, as Allergan correctly anticipated, the advantage derived from the "unique orphan drug exclusivity" would only be eroded over a period of time measured in years not months or weeks. That delayed the arrival of sufficiently workable competition, and that delay lasted at least until after the end of the infringement period.

200. The third argument relates to the CAT's conclusions that the situation falls within Case 3 not Case 2. Intas agrees with the CAT's analysis as to what is required, in terms of "distinctive value" to fall within Case 2 (see §77(2) above), but contends that the CAT failed to analyse various aspects of Auden/Actavis' offering to its customers that provided economic value.

201. A number of the points made by Intas under this head reflect arguments made, and addressed above, by them and the other appellants, and I need not repeat the answers given to them: namely, its contention that the CAT failed to appreciate the significance of there being no "assured customer base"; the additional economic value in its full

label authorisation, so that customers freely chose to purchase from Auden/Actavis; and the economic value of its products as a cheaper alternative to Plenadren.

202. Intas next contends that the CAT wrongly concluded that there was no normal and sufficiently competitive market in the Intas Phase for the flawed reason that, in such a market, prices would have dropped immediately to Cost Plus (whereas it is well established that in pharmaceutical markets prices normally follow a "glidepath" after competitive entry). I do not accept this criticism of the Judgment. I have explained at §192 and §197 to §199 above how the market continued to be distorted during the Intas Phase, so as to delay the arrival of sufficiently workable competition.

203. Finally, Intas contends that the CAT failed to address the unchallenged evidence from its witness, Dr Burt, who set out a number of indisputably pro-competitive reasons why customers valued Accord-UK: including its reliability as a full-range supplier, its wide range of products and adaptable logistics, packaging design, market leading sales and customer service teams, product quality and complimentary training to customers. These generic factors, unrelated to the 10mg IR Tablets themselves, may well provide reasons why customers choose to deal with Accord-UK, but the answer to Intas' reliance on them – indeed a compelling answer to the appellants' reliance on factors said to provide economic value to customers – is that a valuable proxy for assessing such economic value is what customers are prepared to pay for the particular product in a sufficiently competitive market. And, as I have already observed, the prices in fact charged for these exact products and their competitors following a period of effective competition (which reflected the price at which AM Pharma was prepared to re-launch the products in 2008) is compelling evidence of that.

204. Pulling together the above strands, I conclude that the CAT was entitled to conclude, in agreement with the CMA, that there was unfair pricing abuse throughout the Intas Phase. This period saw the continuation of the strategy which Allergan outlined in December 2014, of reaping, until it was eroded by effective competition, the benefit of the cash cow created by the "orphan drug exclusivity". That was achieved by taking advantage of the lack of effective competition to charge a very substantial premium above the prices charged by competitors. Although the parent entities changed (which is relevant to the question of penalties) the undertaking was the same throughout. The conduct during the Intas Phase may properly be characterised as the continuation of the abuse commenced in the earlier periods.

Section D: Penalties

205. The power for the CMA to impose a penalty on an undertaking for an infringement of the Chapter I and Chapter II Prohibition derives from s.36(1) and (2) of CA 1998. An appeal (on the merits) lies to the CAT under s.46(1) and (2). A further appeal to the Court of Appeal lies under s.49(1)(a): such an appeal is not limited to points of law.

206. There are important qualifications on the power to award a penalty, of which the following are relevant here: (1) a penalty may only be imposed if the infringement was committed intentionally or negligently: s.36(3); (2) no penalty may exceed 10% of the turnover of the undertaking: s.36(8); (3) the CMA and the CAT must have regard to the statutory guidance prepared by the CMA with the approval of the Secretary of State (the **Guidance**): s.38(8); and (4) the CMA must have regard to the seriousness of the infringement concerned and the desirability of deterring both the undertaking on whom

the penalty is imposed and others from entering into agreements which infringe the Chapter I prohibition and engaging in conduct which infringes the Chapter II Prohibition: s.36(7A).

207. The Guidance (published in April 2018) provides for a six-step analysis, which the CMA followed in this case in order to reach the following conclusions.

Step 1: The starting point is to apply a percentage rate of up to 30% of the undertaking's turnover in the last year of infringement.

Step 2: An adjustment for the duration of the infringement (with a further adjustment so as to hold each parent entity only liable for their respective distinct periods of ownership).

Step 3: An adjustment for aggravating factors (in this case the involvement of directors and senior management) and/or mitigating factors (in this case compliance activities).

Step 4: An adjustment for specific deterrence and proportionality (directed at each entity within the undertaking on which the penalty is imposed).

Step 5: An adjustment to prevent the maximum penalty from being exceeded and to avoid double jeopardy.

Step 6: Application of reductions for leniency, settlement or voluntary redress.

208. The CMA addressed penalties at length, covering 132 pages from p.969 of the Decision. For the purposes of determining this aspect of the appeal to this Court there is no need to do more than set out in the briefest terms its overall conclusions.

209. The CMA analysed the conduct as resulting in four separate infringements by Auden/Actavis: (1) abuse of dominance in relation to 10mg IR Tablets; (2) abuse of dominance in relation to 20mg IR Tablets; (3) the 10mg Agreement; and (4) the 20mg Agreement.

210. It found that the infringements in this case were "committed intentionally or at the very least negligently" (§10.8 of the Decision). As the economic successor to AM Pharma, Accord-UK was found liable in respect of the whole infringement period.

211. It imposed the following penalties:

(1) For the Chapter II infringement:

(a) For the 10mg IR Tablets abuse: AMP/Accord was solely liable for a penalty of £28.4 million (this was capped at this amount pursuant to the statutory cap); Allergan was solely liable for a penalty of £74.3 million and Intas (i.e. the entity Intas together with Accord-UK and Accord Healthcare) was solely liable for a penalty of £44.4 million.

(b) For the 20mg IR Tablets abuse: AMP/Accord was solely liable for a penalty of £6 million and AMP/Accord and Allergan were jointly liable for a penalty of £2 million.

(2) For the Chapter I infringement:

(a) AMP/Accord was solely liable for a penalty of £28.4 million (this was also capped at this amount pursuant to the statutory cap) in respect of the 10mg Agreement and a penalty of £2.8 million in respect of the 20mg Agreement.

(b) Allergan was solely liable for a penalty of £34.8 million in respect of the 10mg Agreement.

212. Each of the appellants mounted an extensive attack before the CAT on the level of the penalties imposed on them. Following the hearing in this Court, the parties provided a table of the arguments which were advanced before the CAT. I summarise these arguments – in so far as they were reflected in the arguments advanced on the appeal to this Court – in the following paragraphs.

213. AMP/Accord:

(1) The CAT, in the Judgment on Cartel Infringements, had found that there was no intention or negligence on the part of Accord-UK after 29 May 2015, following the departure of Mr Patel, but inconsistently concluded that the infringement of Chapter II by Accord-UK was intentional or negligent throughout the period.

(2) The uplift for specific deterrence was disproportionate (more than 400% for parts of the period), given in particular that Accord-UK was fined (in relation to the 10mg Agreement) only as the economic successor of AM Pharma, the 20mg Agreement ceased before Accord-UK could have been responsible, it did not instigate the conduct, and far from Accord-UK receiving much of the financial benefit, it *paid* sums representing at least some of that value when it acquired AM Pharma from the Patels.

(3) The imposition of four separate penalties was wrong in principle and disproportionate. It was wrong (and inconsistent with other precedents) to treat the 10mg and 20mg infringements as separate, given in particular that the two strengths formed part of the same market. Further, the 10mg and 20mg Agreements formed part of the conduct giving rise to the same abusive conduct for which AMP/Accord was penalised for the Chapter II Prohibition.

214. Allergan:

(1) The CMA's finding of intention or negligence was wrong. Allergan was unaware that Auden/Actavis was dominant. Upon its acquisition, it expected a rapid loss of market share, and a reduction in price due to competitive pressure. That is inconsistent with the findings of intentional or negligent abuse.

(2) The uplift of 1000% for specific deterrence was wrong and disproportionate, given Allergan's limited involvement and its expectation that market share and prices would fall. 12 pages of Allergan's amended notice of appeal were taken up with detailed arguments on these points. These included that, immediately upon Allergan's acquisition, it had agreed to sell the business to Teva, and within nine months was subject to the Hold Separate Regime. There was no historic conduct or culpability and no basis for deterrence as to the future given that Allergan no longer

marketed or distributed generic drugs. Notwithstanding these points Allergan was liable for over 50% of the total fine in relation to excessive pricing.

215. Intas:

(1) The CMA was wrong to rely on evidence relating only to earlier periods to find that Intas was intentional or negligent. Intas advanced detailed arguments on this point over 18 paragraphs in its amended notice of appeal.

(2) The starting point of 30% was excessive in itself when applied to Intas, as compared with the other entities, as the Intas Phase was associated only with decreasing prices in response to competitive entry and was untainted by the 10mg and 20mg Agreements. It made much of the same arguments that it made in relation to dominance and abuse. I note that while I have rejected that part of Intas' appeal, the same points have a different perspective and potentially different force in the context of penalty. Numerous other points were made in Intas' amended notice of appeal in support of this proposition.

(3) No uplift, or at least an uplift of less than 15%, should have been applied in relation to senior management involvement, again because it was applied by reference to the whole infringement period, rather than being focused on Intas itself. A greater discount than 5% should have been made for compliance activities, and there were substantial other mitigating factors that should have been reflected in a further discount.

(4) The uplift of 400% at step four was unfair and disproportionate. It was unfair on its own terms, and relative to other periods, given the materially different circumstances during the Intas Phase. It was disproportionate in that it comprised 24% of Intas' annual worldwide profit, compared with the much lower percentages in relation to the previous parent entities. Numerous further points were taken against the uplift for specific deterrence including that the rationale for the uplift (that the penalty must exceed the financial benefits by a material amount) was wrong in law and on the facts; it was not justified by the nature of the infringement during the Intas Phase (including the fact that this consisted of a failure to discontinue the undertaking's conduct), nor by the size of the Intas appellants.

216. Having summarised the CMA's conclusions on penalties, the CAT referred to the appellants' challenge that the fines were excessive and/or disproportionate in a single sentence, at §373, noting that they focused in particular on the 30% starting point at step 1, the 15% uplift and 5% credit at step 2, and the uplifts applied at step 4, as well as the issue of intention/negligence.

217. At §374 the CAT identified the approach it would adopt, being that taken in previous cases: reviewing the CMA's application of its guidance then making its own "broad brush" assessment. It said:

> "We have, of course, taken full account of the submissions made by the Appellants. We do not set them out in any detail because – as we have stated – our starting point is the CMA's approach and whether that approach is or is not defensible."

218. The CAT's conclusion is stated at §375:

> "Taking the case as a whole, we see nothing in the CMA's approach amounting to a material error. Furthermore, it is important to bear in mind that these are infringements that are (i) extremely serious, (ii) protracted, (iii) resulting in significant economic harm to the wider community and (iv) resulting in significant economic benefit to the Appellants. In short, this is a case where a substantial penalty is to be expected."

219. It expanded on this at §376. It was *ad idem* with the CMA on the seriousness of the infringements. It did not accept that the law in the area was unclear. As to the "monolithic" approach of the CMA to the Auden/Actavis undertaking, it said this:

> "We did consider whether the CMA's "monolithic" approach to the "Auden/Actavis" undertaking, which is not the same as our phased approach, requires a reviewing of the CMA's approach. We have concluded that it does not. The CMA's approach on penalty adopted a phasing and temporal approach that is as defensible (considering penalty only) as the approach we would have taken using our five phases, and we see no justification in re-doing the entire exercise when it is clear to us that the CMA's approach is not affected, in this regard, by material error. In short, whilst we would have preferred our approach, we consider that that is no reason for us to re-do an exercise that the CMA has done properly."

220. The CAT did, however, allow Allergan's appeal in one respect. It concluded that the CMA had been wrong to hold Allergan responsible for the undertaking as from the start of the Hold Separate Regime. It accordingly reduced the penalty imposed on Allergan in respect of the 10mg IR Tablets abuse from £74.3 million to £49.3 million.

221. The principal ground of appeal in this Court – on which Intas took the lead – is that the CAT failed to engage at all with the numerous and varied arguments advanced to it (in particular those summarised above) and in so doing failed to provide adequate reasons for its decision.

222. Professor Bailey KC, who dealt with this aspect of the appeal on behalf of the CMA, submitted that the CAT's Judgment on penalties had the triple virtues of being clear, concise and correct. He recognised, as he had to, that the CAT had not explored the CMA's approach in a granular manner but that it should be taken to have endorsed and adopted the CMA's reasoning and conclusions. I accept that this is a fair interpretation of the CAT's decision: it specifically endorsed the CMA's exercise as "done properly" and found no material error in it.

223. I do not accept, however, that it is an adequate answer to the appellants' complaint on this appeal. As Green LJ pointed out during the hearing, the CMA is not a court and in order to respect the rights of the appellants under Article 6 of the European Convention on Human Rights, it is essential that there is effective supervision by the CAT. Further, on an appeal against a ruling of the CAT on penalties this Court has full jurisdiction which it can only properly exercise if it knows what the CAT actually considered. As

matters stand the appeal against the CAT judgment has been relegated to an appeal against the findings of the CMA. I endorse in this respect the comments of the Competition Commission Appeal Tribunal (chaired by Sir Christopher Bellamy) in *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* [2002] CAT 1 at §499:

> "the Tribunal has a full jurisdiction itself to assess the penalty to be imposed, if necessary regardless of the way the Director has approached the matter in application of the Director's Guidance. Indeed, it seems to us that, in view of Article 6(1) of the ECHR, an undertaking penalised by the Director is entitled to have that penalty reviewed ab initio by an impartial and independent tribunal able to take its own decision unconstrained by the Guidance. Moreover, it seems to us that, in fixing a penalty, this Tribunal is bound to base itself on its own assessment of the infringement in the light of the facts and matters before the Tribunal at the stage of its judgment."

(Note that the *Napp* case predated s.38(8) of CA 1998, which requires the CAT also to have regard to the Guidance.)

224. That does not mean that the CAT cannot in an appropriate case adopt for itself the conclusions and reasoning of the CMA. But it does mean that, in any case where the infringing undertaking presents at least respectable arguments challenging the CMA's decision, the CAT must address those arguments and, if they are to be dismissed, do so with adequate reasoning.

225. In response to the table of arguments advanced by the appellants before the CAT, the CMA's response to most of them is that the CAT sufficiently addressed them by (1) referencing compendiously the relevant paragraphs in the amended notices of appeal, at footnote 473 to §373, and its confirmation, at §374(2), that it had taken full account of the submissions.

226. In my judgment, that is not a sufficient response. The appellants advanced a number of arguments against the CMA's conclusion which raised, at their lowest, serious points of concern. I highlight for example, first, the points made by Intas (and to a lesser extent Allergan and AMP/Accord) as to the lack of differentiation between the nature of the infringing conduct in the different Phases of the infringement period, and the need to relate factors going to specific deterrence to the particular entities which, from time to time, owned the undertaking. Second, I highlight the arguments relating to the need to step back from the detail and consider the proportionality of four separate penalties, irrespective of whether the conduct can properly be characterised as four infringements. These are not addressed at all in the Judgment.

227. As Mr Palmer submitted, it is not possible to tell what his clients' complaint to the CAT was, or why it was dismissed, so his clients are left without an understanding of why they have been held responsible in equal measure for conduct going back to 2008, when the nature of their involvement was substantially different, and more limited than others, and why there is a need for specific deterrence as against them on such a large scale.

228. This aspect of the case will need, therefore, to be remitted to the CAT for a fuller reconsideration of the penalties imposed. In those circumstances, I do not address the substance of the specific arguments made by the parties before us. I make only the following comments which either dispose of discrete points or offer limited guidance as to the approach to be taken.

229. First, there was a debate before the hearing of the appeal as to whether AMP/Accord had permission to appeal the level of penalty in the Judgment on Cartel Infringements (and a protective application for permission to appeal out of time was made by AMP/Accord shortly before the hearing). No point was taken against this by the CMA at the hearing, however, and for the avoidance of doubt the issues remitted to the CAT include the level of penalty imposed in respect of the infringements of the Chapter I Prohibition.

230. Second, there was some discussion as to what had to be "intended" for the purposes of a finding of intentional infringement of the Chapter II Prohibition. In the end I did not detect any real disagreement between the parties on this point. In *Ping Europe Ltd v Competition and Markets Authority* [2020] EWCA Civ 13, Rose LJ (with whom Sir Geoffrey Vos, Chancellor, and Flaux LJ agreed) said that an infringement of the Chapter I Prohibition is committed intentionally "if the undertaking must have been aware, or could not have been unaware, that its conduct had the object or would have the object of restricting competition" and that "Ignorance or mistake of law does not prevent a finding of intentional infringement".

231. As applied to a case of infringement of the Chapter II Prohibition, that means that the infringement is intentional if the undertaking is aware or must have been aware of the underlying facts that as a matter of law meant that it was dominant and that its conduct was an abuse of that dominance. The fact that it did not appreciate that these facts amounted in law to a finding of dominance and/or abuse of dominance is irrelevant.

232. Third, there was also some discussion as to *whose* state of mind was relevant in order to establish intention, given that liability for infringement falls on an undertaking, whereas penalties are imposed on specific entities within the undertaking from time to time. I did not understand Mr Johnston (who, on behalf of Allergan, principally raised this point) to dispute that since liability is imposed upon the *undertaking*, a penalty can in principle be imposed upon each legal entity within the undertaking provided that at least one of the entities within the undertaking had the requisite intention. He submitted, however (and I agree), that when it comes to assessing the level of penalty to be imposed on a specific legal entity within the undertaking (such as Allergan as parent company), a lack of intention or negligence on the part of that entity might be a highly relevant factor, particularly as regards adjustments to take account of senior management or director involvement, uplifts for specific deterrence, and when standing back and considering the proportionality of the overall penalty.

233. Fourth, I would accept in principle the broad submission advanced by all the appellants that, irrespective of whether the conduct in this case is characterised as one infringement, or two or four, it is important to take account of the relationship between the four infringements, their degree of overlap and the extent to which there is a risk of double counting when standing back and considering the proportionality of the overall penalty imposed on each entity.

234. I am not to be taken as suggesting that the CMA failed in any of the above respects. These are simply points which are relevant for the CAT to take into account in conducting its own review of the penalties imposed in light of the appellants' arguments.

Section F: Disposal

235. For the above reasons, I would dismiss these appeals on all grounds except those relating to the penalties imposed on all appellants, as to which the matter must be remitted to the CAT for further consideration.

Sir Julian Flaux

236. I agree.

Lord Justice Green

237. I also agree.