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Case Nos: 1407/1/12/21
1411/1/12/21
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1413/1/12/21
1414/1/12/21

IN THE COMPETITION APPEAL TRIBUNAL

Salisbury Square House
8 Salisbury Square
London EC4Y 8AP

18 September 2023

Before:

SIR MARCUS SMITH
(President)
PROFESSOR SIMON HOLMES
PROFESSOR ROBIN MASON

Sitting as a Tribunal in England and Wales

BETWEEN:

ALLERGAN PLC

(The **Allergan Appellant**)

AMDIPHARM UK LIMITED
AMDIPHARM LIMITED
ADVANZ PHARMA SERVICES LIMITED
ADVANZ PHARMA CORP LIMITED

(The **Advanz Appellants**)

CINVEN (LUXCO 1) SARL
CINVEN CAPITAL MANAGEMENT (V) GENERAL PARTNER LTD
CINVEN PARTNERS LLP

(The **Cinven Appellants**)

AUDEN MCKENZIE (PHARMA DIVISION) LIMITED
ACCORD UK LIMITED

(The **Auden/Actavis Appellants**)

INTAS PHARMACEUTICALS LIMITED
ACCORD HEALTHCARE LIMITED
ACCORD-UK LIMITED

(The **Intas Appellants**)

Appellants

- and -

THE COMPETITION AND MARKETS AUTHORITY

Respondent

Heard at Salisbury Square House on: 22 to 25, 29 and 30 November 2022, 2, 6 to 8, 13 to 16, 19 to 23 December 2022, 25 January 2023 and 3 February 2023, with the provision of the "Annex 3" data[1] on 27 April 2023 and 15 May 2023. Judgment circulated in draft to the parties on 30 August 2023

JUDGMENT

(ABUSE OF DOMINANCE INFRINGEMENTS)

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[1] The "Annex 3" data is described in [5] of the Judgment and was provided to the Tribunal in largely agreed form on these dates by the CMA, having liaised with the other parties. There were some disputes about descriptions of the data in the notes accompanying it. These we have taken into account, and the data in Annex 3 represents (i) the data underlying the Hydrocortisone Decision, which (ii) was deployed and used by all parties on this appeal, but which (iii) has been rendered into manipulable form for the purposes of this Judgment by the parties (for which we are very grateful).

APPEARANCES

Mr Daniel Jowell, KC and **Mr Tim Johnston** (instructed by **Addleshaw Goddard LLP**) appeared for the Allergan Appellants

Mr Robert O'Donoghue, KC and **Ms Emma Mockford** (instructed by **Clifford Chance LLP**) appeared for Cinven Appellants

Ms Sarah Ford, KC and **Ms Charlotte Thomas** (instructed by **Macfarlanes LLP**) appeared for the Auden/Actavis Appellants

Mr Robert Palmer, KC, **Ms Laura Elizabeth John** and **Mr Jack Williams** (instructed by **Linklaters LLP**) appeared for the Intas Appellants

Mr Mark Brealey, KC (instructed by **Morgan, Lewis & Bockius UK LLP**) appeared for the Advanz Appellants

Ms Marie Demetriou, KC, **Mr Josh Holmes, KC**, **Mr Tristan Jones**, **Mr Nikolaus Grubeck**, **Mr Michael Armitage**, **Mr David Bailey** and **Ms Daisy Mackersie** (instructed by the **legal department of the Competition and Markets Authority**) appeared for the Competition and Markets Authority

INTRODUCTION

(1) The Hydrocortisone Decision

1. By a decision dated 15 July 2021 in Case No 50277 concerning excessive and unfair pricing and anti-competitive agreements in relation to hydrocortisone tablets (the **Hydrocortisone Decision**[2, 3]), the United Kingdom Competition and Markets Authority (the **CMA**) found that the various appellants listed above, collectively the **Appellants**, had infringed UK competition law in the various respects set out in paragraph 1.4 of the Hydrocortisone Decision. It will be necessary, in due course, to set out exactly the nature of these infringements, for they differ according to the persons against whom they are made. We shall refer to these infringements generally as the **Hydrocortisone Infringements**.

(2) The Appellants

(a) Formal addressees

2. The Appellants to the Hydrocortisone Decision, and who are addressees of that decision, fall into five groups, who we shall refer to as follows:

   (1) The **Allergan Appellant**.

   (2) The **Advanz Appellants**.

   (3) The **Cinven Appellants**.

   (4) The **Auden/Actavis Appellants**.

   (5) The **Intas Appellants**.

(b) Terms of reference and terminology

3. The various companies and/or persons comprising these groups are set out in the heading to this Judgment; and the parties who are Appellants have been set out in the preceding paragraph. There is no correlation between these descriptions, which renders them unhelpful for purposes of exposition. Moreover, there is no correlation between these descriptions and the entities who were actors over the many years that the Hydrocortisone Infringements found by the CMA are said to have taken place.

4. Before launching into any kind of explanation of the history, it is necessary to state some clear terms of reference and terminology. The importance of this can be seen in the

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[2] A list of the terms and abbreviations used in this Judgment, which are **bolded** on first use, together with the paragraph in which that term/abbreviation is first used, is at Annex 1 hereto.

[3] Documents that we refer to frequently are underlined in the text and are listed and described in Annex 2 hereto.

Hydrocortisone Decision itself. The Hydrocortisone Decision articulates the following definition:[4]

"By this Decision, the CMA finds that:

a. The following legal entities form or formed part of an undertaking, referred to for the purposes of this Decision as "Auden" or "Actavis" (or "Auden/Actavis") as appropriate in context:

i. from 1 October 2008 to 28 May 2015: AM Pharma;

ii. from 29 May 2015 to 1 August 2016: AM Pharma, Accord-UK and Allergan;

iii. from 2 August 2016 to 8 January 2017: Accord-UK; and

iv. from 9 January 2017 to 31 July 2018: Accord-UK, Accord and Intas."

The term "Auden/Actavis" thus embraces most of the Appellants, rendering it impossible to differentiate between them.[5] Given that it is central to the Hydrocortisone Decision to allocate responsibility between the various actors for the purposes of ascertaining infringement and penalty, such an all-inclusive approach renders the drawing of the necessary distinctions all but impossible. For this reason, we will eschew the term "Auden/Actavis" and, indeed, most of the other definitions of the entities that are used in the Hydrocortisone Decision as liable to obscure rather than elucidate.

5. Although it is to anticipate the factual exposition that occurs later on in this **Judgment (Abuse of Dominance Infringements)**, it is critical that our terms of reference and terminology are nailed down from the outset. Our terms of reference and terminology derive from **Annex 3** to this Judgment (Abuse of Dominance Infringements). As to this Annex:

(1) Annex 3 is in essence a chronological schedule of the prices and quantities sold of the medicinal products with which the Hydrocortisone Decision is concerned. Annex 3 comprises seven columns.

(2) Column (1) specifies the relevant date or date range for that particular row in the table. Most of the rows in Annex 3 comprise pricing data. Each of these rows of pricing data has been given, in addition to the relevant date or date range, a period reference. Thus, the first row of pricing data in Annex 3 is "Period 1" and the last row of pricing data in Annex 3 is "Period 127".

(3) Interspersed amongst the rows of pricing data are more general event descriptions which are relevant to this Judgment (Abuse of Dominance

[4] Hydrocortisone Decision/1.3.

[5] Clearly, it includes the Allergan Appellant, the Auden/Actavis Appellants and the Intas Appellants. But it also includes parties, not on the face of it appearing within the definition "Auden/Actavis".

Infringements). They will be explained in due course and are shaded grey in Annex 3. These rows do not have period references, and the format is in typical chronological form: date followed by event description.

(4) Turning to the pricing data, the information contained in Annex 3 is much more granular. In addition to the date/date range/Period in Column (1), the following data is provided:

(i) Column (2) specifies the holder of the **Marketing Authorisation** permitting the sale of a particular medicinal product. As will be described in much greater detail, it is not legally permissible to sell a medicinal product in the United Kingdom without a Marketing Authorisation. The Marketing Authorisation under which a medicinal product is sold is thus key to differentiating between medicinal products. It is perfectly possible for what is in substance the same pharmacological product to be sold under different Marketing Authorisations which (may) differ in terms of the medical indications for which they may be used.

(ii) The medicinal product lying at the heart of these appeals is packs of thirty 10mg "immediate release" hydrocortisone tablets (**10mg immediate release hydrocortisone tablets**).[6] We appreciate that this is a cumbersome and long definition, but necessarily so. Each of the elements of the definition ("10mg", "immediate release", "tablet" and "hydrocortisone") is necessary in order to differentiate this medicinal product from other medicinal products. Over and above these attributes, lies the Marketing Authorisation. It is perfectly possible for 10mg immediate release hydrocortisone tablets to be sold under multiple Marketing Authorisations and – as will be seen – this did in fact occur in the present case.

(iii) It will, therefore, be necessary to differentiate between the various Marketing Authorisations under which medicinal products were sold. Annex 3 achieves this differentiation through colour coding. Thus, 10mg immediate release hydrocortisone tablets sold under a Marketing Authorisation originally awarded to an entity known as Merck, Sharpe & Dohme is shaded yellow in Annex 3.

(iv) In fact, although Merck, Sharpe & Dohme was originally awarded a Marketing Authorisation for 10mg immediate release hydrocortisone tablets, this entity has nothing more to do with the events considered in the Hydrocortisone Decision or in this Judgment (Abuse of Dominance Infringements). That is because Marketing Authorisations are transferable. The holder of a Marketing Authorisation during any given Period is specified in Column (2) of Annex 3. Thus, for Periods 1, 2 and 3, the holder of the Marketing Authorisation for 10mg immediate release hydrocortisone tablets is specified as Merck, Sharpe & Dohme and the

[6] There were also 20mg immediate release hydrocortisone tablets. They are also relevant to the Hydrocortisone Infringements, as we will describe, but were sold in much lower volumes.

rows are shaded yellow to identify the relevant Marketing Authorisation. In Period 4, the Marketing Authorisation transferred to an entity known as AM Pharma. This change is recorded in Column (2) of the relevant row, but the row continues to be shaded yellow, to reflect the transfer to AM Pharma of the Marketing Authorisation previously held by Merck, Sharpe & Dohme.

(v) The entity holding a Marketing Authorisation is often itself a part of a larger entity. The parent or holding company or companies or persons involved are specified in Column (3) of Annex 3. We stress that the inclusion of entities in this column says nothing about whether the entities described in Columns (2) and (3) are part of the same "undertaking" or not. That is a question that was – in certain respects – controversial on these appeals, and nothing in Annex 3 is intended to pre-judge this question. The purpose of Columns (2) and (3) is simply to enable the reader to track the changes in the holder of any given Marketing Authorisation (the point considered in paragraph 5(4)(iv) above) and also to track changes in the ownership/control of that holder. By way of example, AM Pharma was originally owned and controlled by two siblings, Amit and Meeta Patel,[7] (we shall refer to them as **Mr Amit Patel** and **Mrs Meeta Patel**) with no corporate intermediary. This fact is recorded in Column (3) for Periods 4 to Period 58. From Period 59, there was a change in corporate structure, in that Auden Mckenzie Holdings Ltd was interposed between AM Pharma and Mr and Mrs Patel. That change is recorded in Column (3).

(vi) The change that occurred between Period 58 and Period 59 did not affect the economic ownership and control of AM Pharma. But changes in corporate structure can – indirectly – result in a *de facto* as opposed to *de jure* transfer of the Marketing Authorisation. An example of such a transfer occurs between Period 89 and Period 90. At this point in time, AM Pharma continues to hold the Marketing Authorisation (the row continues yellow), and Auden Mckenzie continues to be the holding company for AM Pharma. However, ownership of Auden Mckenzie itself transfers, at this point, from Mr and Mrs Patel to Actavis plc. It is at this point in time that Actavis plc first becomes involved, a point that it is important to bear in mind, and which the Hydrocortisone Decision's definition of "Auden/Actavis" obscures. Column (3) records these important changes in legal and economic responsibility for the sale of medicinal products under particular Marketing Authorisations.

(vii) Columns (4), (5), (6) and (7) contain specific pricing data for each period. It is unnecessary – at this point – to describe this data with any greater specificity. However, this data was central to the CMA's consideration of the Hydrocortisone Infringements and is central to our consideration of those infringements in this Judgment (Abuse of Dominance Infringements). We will be making considerable reference

[7] Hydrocortisone Decision/3.4.

to this pricing data, as appropriate, later on in this Judgment. The purpose of this extended description of Annex 3 is to enable precise reference to the relevant actors to be made from the outset.

(c) The notices of appeal

6. The Appellants all appeal the Hydrocortisone Decision, and they do so in notices of appeal filed with the Tribunal during the course of September and October 2021. We shall refer to these notices of appeal as follows:

   (1) The Allergan NoA.

   (2) The Advanz NoA.

   (3) The Cinven NoA.

   (4) The Auden/Actavis NoA.

   (5) The Intas NoA.

7. The CMA filed a single Defence to all of these notices of appeal on 18 March 2022.

(3) Infringements found in the Hydrocortisone Decision

8. It will be necessary to expand considerably on the infringements found in the Hydrocortisone Decision when the uncontroversial facts have been set out. For present purposes, it is sufficient to note the following.

9. In very broad terms, the Hydrocortisone Decision found infringements of both the Chapter I and the Chapter II prohibitions under the Competition Act 1998. Beginning with the abuse of dominance infringements under Chapter II (which is the logical place to start) the Decision found various abuses of dominance concerning the sale of 10mg and 20mg immediate release hydrocortisone tablets in a period between October 2008 and July 2018. We shall refer to these infringements, as found by the Decision, as the **Abuse of Dominance Infringements**.

10. Turning then to the cartel infringements under the Chapter I prohibition, the Hydrocortisone Decision found two agreements said to infringe the Chapter I prohibition. Both concerned agreements not to compete, the first in the sale of 20mg immediate release hydrocortisone tablets and the second in the sale of 10mg immediate release hydrocortisone tablets. For reasons that are obvious, these are respectively referred to as the **20mg Agreement** and the **10mg Agreement**. We shall refer to these infringements found by the Decision as the **Cartel Infringements**.

11. Although it is obvious, we should explain that **20mg immediate release hydrocortisone tablets** are identical to 10mg immediate release hydrocortisone tablets save that they are twice the strength. They are also, to be clear, not able to be sold under a Marketing Authorisation for 10mg immediate release hydrocortisone, but have to be sold under their own, distinct, Marketing Authorisation.

12. The Abuse of Dominance Infringements are all subject to appeal. Those appeals are considered and determined in this Judgment (Abuse of Dominance Infringements). So far as the Cartel Infringements are concerned, only the 10mg Agreement is the subject of any substantive appeal, although the 20mg Agreement that preceded it is of at least some relevance (and the level of fines imposed is the subject of challenge), and will need to be considered.

13. Substantial penalties were imposed as a result of the findings made in the Hydrocortisone Decision, running to many tens of millions of pounds. These – so far as the penalties relate to the Abuse of Dominance Infringements – are described, more fully, below.

(4) The structure of this Judgment

14. This is a long and complex judgment. That is partly because the subject matter is intrinsically complex, and partly because the Appellants took different, and sometimes inconsistent, positions in their Notices of Appeal.

15. The structure of this Judgment (Abuse of Dominance Infringements) is as follows:

(1) Section B sets out the relevant procedural facts; the evidence that we heard; and our approach to appeals of this sort.

(2) Section C describes the various pharmaceutical products relevant to an understanding of the Hydrocortisone Decision, their nature and their significance.

(3) Section D describes the regulatory regime as it applies to pharmaceutical products. The description in this Section seeks to explain the regime without too much reference to the pharmaceutical products described in Section C. The reason for this is that it is necessary to understand how this regime operated in the abstract, before considering the particular circumstances of this case.

(4) Section E provides a history and description of the market in general and neutral terms. This Section provides the essential factual narrative – and some of the key data – for resolving the appeals, but it quite deliberately eschews the factual and legal controversies that arose out of the appeals.

(5) Sections F, G, H, I and J consider various aspects of the Abuse of Dominance Infringements. More specifically:

(i) Section F considers, in general terms, the elements that must be shown when investigating an alleged infringement of the Chapter II prohibition.

(ii) These elements – which are fourfold: (i) factual responsibility, (ii) market definition, (iii) dominance and (iv) abuse – are then considered more specifically in the following sections: Section G (factual

responsibility); Section H (market definition); Section I (dominance); and Section J (abuse).

(6) Section K considers the penalties for the Abuse of Dominance Infringements.

16. This Judgment (Abuse of Dominance Infringements), as the title implies, does not deal with the Cartel Infringements. The appeals in relation to these infringements are determined in a second Judgment, **Judgment (Cartel Infringements)**. Since the Hydrocortisone Decision, the grounds of appeal and other pleadings and the appeal hearing itself all considered the Abuse of Dominance Infringements and the Cartel Infringements together and without differentiation, this is a course that requires explanation:

(1) The Abuse of Dominance Infringements stand entirely separate from the Cartel Infringements and can, quite properly, be determined without reaching any concluded view on the Cartel Infringements. Indeed, although it is in no way a justification for splitting the Cartel Infringements from the Abuse of Dominance Infringements, one advantage of the course we are taking is that the self-standing nature of the Abuse of Dominance Infringements is underlined and emphasised.

(2) On the other hand, whilst the Cartel Infringements in large part themselves stand separately from the Abuse of Dominance Infringements, they are – in some respects – coloured by the Abuse of Dominance Infringements. There is some sense, therefore, in permitting the determination of the Abuse of Dominance Infringements in the Judgment (Abuse of Dominance Infringements) to precede the determination of the Cartel Infringements in the Judgment (Cartel Infringements). We stress that this is an incidental benefit of the course we are taking and not a justification for doing so.

(3) The reason for splitting what was originally intended to be a single judgment dealing with all the infringements is that certain procedural concerns manifested themselves in regard to the Cartel Infringements during the course of the hearing itself. Whilst writing the judgment, it has become clear:

(i) That these questions, whatever their merits, arise out of the Cartel Infringements and are entirely separate from the Abuse of Dominance Infringements.

(ii) That these questions need to be further addressed by parties and persons present at the hearing of the appeals.

(iii) That those questions are best addressed (i) on the basis of the finally determined appeals in relation to the Abuse of Dominance Infringements (ii) by reference to a separate Judgment (Cartel Infringements). The reason why this is the case is considered not in this Judgment (Abuse of Dominance Infringements) but in the later Judgment (Cartel Infringements).

B. PROCESS AND EVIDENCE

(1) The Hydrocortisone Decision, the notices of appeal and other pleadings

(a) The Hydrocortisone Decision

17. The Hydrocortisone Decision is a substantial document. It runs to 1,101 pages plus some short annexes of 104 pages. The Hydrocortisone Decision is the most significant document in this appeal and will represent our starting point when considering any question of fact.

18. Decisions of the CMA are accorded particular significance under the law of the United Kingdom. Section 58 of the Competition Act 1998 provides that absent contrary direction by the Tribunal, a finding of fact in a decision of the CMA is "binding" on the parties in any proceedings falling within Part I of the 1998 Act. Of course, the Tribunal itself is not bound by such findings, which would render appeals such as this somewhat pointless.[8] It is incumbent upon the CMA and – in any appeal "on the merits" – this Tribunal to identify clearly those findings of fact that have been made in any infringement decision. In this case:

    (1) It is incumbent upon the Tribunal to make clear the factual basis for the material facts underlying this Judgment, particularly where many of the findings in the Hydrocortisone Decision were being challenged by the Appellants.

    (2) We also bear in mind that what constitutes a finding of fact in the Hydrocortisone Decision ought to draw on the nature of binding facts under section 58 as articulated in *Enron II*. Those findings must be clearly identifiable,[9] and it is not permissible to root around the decision in order to point to passages from which a finding of fact might arguably be inferred.[10]

    (3) In a decision the length and detail of the Hydrocortisone Decision, it is unsurprising (i) that many findings of fact are made and (ii) that it can be difficult to identify with precision all of the findings of fact actually made. This will become a matter of particular importance when we come to the 10mg and 20mg Agreements. The Appellants, and indeed, the Tribunal, are entitled to a high degree of certainty in terms of exactly what the CMA has found and what it is has not found.

    (4) In *BGL (Holdings) Limited v. CMA*,[11] the Tribunal emphasised the importance of stating clearly the evidence on which decisions are based:

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[8] As is noted in Brealey and George, *Competition Litigation: UK Procedure and Practice*, 2nd ed (2019) at [11.17], this constitutes an important "safety valve" (to use the term in *Enron II*, [2011] EWCA Civ 2 at [52]).

[9] See *Enron II* at [56].

[10] See *Enron II* at [55] to [56].

[11] [2022] CAT 36 at [226].

"…Generally speaking, decisions should draw a hard-and-fast distinction between:

(1) Evidence.

(2) Analysis of that evidence or inferences being drawn from it.

(3) Conclusions of fact drawn from (1) and (2)."

We repeat the importance of such an approach here.

19. It is not possible to list the findings made by the CMA in the Hydrocortisone Decision, and we make no attempt to do so in this Judgment (Abuse of Dominance Infringements): for one thing, not all findings are relevant to the points arising on this appeal.[12] Where, however, a fact is relevant to a ground of appeal pleaded in the notices of appeal, the course that we have adopted is to state certain facts in this Judgment and specifically reference (generally in footnotes) the source for that finding. Where the source is recorded as being the Hydrocortisone Decision and the reference is unqualified, then we are to be taken as endorsing and affirming this finding of fact. Where we are referring to parts of the Hydrocortisone Decision without affirming the finding of fact made in the decision, we make this clear by stating, after the reference "(Ref only)".[13]

(b) The notices of appeal

20. The notices of appeal are all substantial documents, running to many paragraphs and pages. We refer to them as necessary in the course of this Judgment (Abuse of Dominance Infringements), but would only observe that they are less useful to a tribunal seeking to determine a complex appeal than they might have been. In part, that is because of the lengthy and complex Hydrocortisone Decision itself. But it is also because the notices of appeal are more argument than pleading, and do not engage with much specificity with the findings contained in the Hydrocortisone Decision itself.[14] As a result, the CMA's consolidated Defence itself runs to 229 pages. Instead of defending the Hydrocortisone Decision by reference to the terms of the Decision itself, the CMA's Defence comprises in large part a re-arguing of what has already been decided in the Hydrocortisone Decision itself.

21. As will be seen, the questions considered by the CMA, dealt with in the pleadings and determined in this Judgment (Abuse of Dominance Infringements), are by no means straightforward. The manner in which the Hydrocortisone Decision and the consequent

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[12] We refer to [4.30] of the Competition Appeal Tribunal's *Guide to Proceedings 2015*, which describes an appellant's duty to make it clear whether or not primary facts are in issue: "…Parties should pay careful attention to distinguishing in the notice of appeal between disputes about primary facts and disagreements which are more appropriately characterised as ones of appraisal or assessment of those primary facts…"

[13] We should make clear that the "(Ref only)" qualification does not necessarily imply that we are rejecting a finding by the CMA in the Hydrocortisone Decision, merely that we are not endorsing and affirming the finding. In many cases, we refer to paragraphs in the Hydrocortisone Decision in order to outline the case against the Appellants or to articulate points made by the Appellants against the Hydrocortisone Decision. In such cases, the point of the cross-reference is exactly that: a cross-reference.

[14] In many cases, of course, that is because primary findings of fact are not being challenged.

pleadings are framed reflect this complexity, and we would not wish it to be thought that we are being critical of the extraordinary levels of hard work and effort that have gone into this process. But we do consider that even though appeals of this sort are important – to the CMA as the United Kingdom's competition authority; to the Appellants as the addressees of a decision of some significance; and to the pharmaceutical markets in the United Kingdom generally – it is imperative to find a way of reducing the cost and time taken on these appeals, without impairing fairness of process and ideally by improving it.

(2) Ambulatory drafts

22. At an early stage in these proceedings, the Tribunal sought to achieve a degree of consensus through the use of what came to be known as "ambulatory drafts". These documents – principally compiled by the parties, but under the supervision of the Tribunal – were intended to accurately and fully delineate "that which is not in dispute from that which is controverted".[15]

23. Compilation of the ambulatory drafts proved highly contentious, not least because, instead of articulating the points of genuine dispute, the parties sought in large part to "spin" the language of the drafts, without addressing the substance of the issue. Thus, by way of example, there are clearly a number of different hydrocortisone products on the market and – when it comes to market definition – it is important to understand the extent to which these products are or are not substitutes. A great deal of time was spent in argument about these distinctions. Elision of different hydrocortisone products under a single label is, therefore, not helpful, and this Judgment (Abuse of Dominance Infringements) is careful to avoid it. Careful distinction between the products, so as to enable a proper assessment of substitutability, is something that ought to have been possible, at an early stage in these proceedings, without "selling the pass" on market definition which (as we shall see) was properly and understandably controversial as between the various parties.

24. The ambulatory draft process thus proved something of a failure when measuring cost against benefit.[16] Nevertheless, the ambulatory drafts did provide a helpful source for factual references and have been useful in the drafting of this Judgment (Abuse of Dominance Infringements). The ambulatory drafts are not referenced in the Judgment: we have considered it more appropriate to reference the primary materials, in particular the Hydrocortisone Decision itself. However, the ambulatory drafts enabled us to collate and identify those primary materials more easily, and to that extent proved worthwhile. But the use of ambulatory drafts is an experiment that the Tribunal is unlikely to repeat. The related problems of long hearings and voluminous documentation remain.

(3) Documentary evidence

25. Given the volume of the pleadings, and the size of the Hydrocortisone Decision, the volume of documentary evidence was remarkably small. The most significant such evidence was pricing and volume data of the various hydrocortisone products that were

[15] [2022] CAT 2 at [14].

[16] Not only the parties' costs, but also those of the Tribunal. Pulling together into a single document the various drafts of the parties, and refereeing the disputes that arose, proved costly in terms of Tribunal time.

sold. This data was produced – in largely agreed form – by the CMA after the hearing, but that data informed a great deal of the material in the Hydrocortisone Decision and was available to the parties throughout the appeal. After the hearing, the Tribunal sought and obtained material that was before it in different and manipulable form. As we have described, that material appears in Annex 3 to this Judgment (Abuse of Dominance Infringements), and we should make clear that we accept this data as factually accurate.

(4) Witnesses of fact

26. Given the wealth of written material, we dispensed with oral openings, and (after housekeeping matters) proceeded to hear the oral evidence directly. In the order they were called, we heard from the following witnesses:

(1) *Mr Robert Sully*. Mr Sully was called on behalf of the Advanz Appellants. He was – until recently – global general counsel of Advanz, having joined the organisation in 2011. He gave one witness statement (Sully 1) and gave evidence on Days 1 and 2 of the appeal (22 and 23 November 2022). He gave evidence straightforwardly and clearly, and as precisely as he could given the passage of time.

(2) *Mr John Beighton*. Mr Beighton was called on behalf of the Advanz Appellants:

(i) Mr Beighton has worked in the pharmaceutical industry for around 40 years, initially with Smith Kline Beecham and then various other companies. On 15 March 2013 he was appointed the chief executive officer of Amdipharm Mercury Company Limited (**AMCo**), holding that position until the end of 2015. Until October 2015, AMCo was ultimately owned by the Cinven Appellants. In October 2015, AMCo was acquired by Concordia International Corp (**Concordia**), becoming its "International Segment". Mr Beighton served as President of Concordia's "International Segment", until he stepped back from executive involvement. Since then, he has focussed on various non-executive roles in the pharmaceutical industry.

(ii) Mr Beighton gave one witness statement (Beighton 1) and gave evidence on Days 2 and 3 of the appeal (23 and 24 November 2022).

(iii) Mr Beighton was an impressive and knowledgeable witness. He gave his evidence precisely and was extremely articulate. His knowledge of the pharmaceutical industry was both profound and detailed.

It will be necessary to return to, and expand upon, the quality and nature of the evidence of Mr Sully and Mr Beighton when we come to consider the 10mg Agreement and the Cartel Infringements in the Judgment (Cartel Infringements). It is a matter of some regret, and great concern, to us that we are unable, in brief terms, to articulate the extent to which the Hydrocortisone Decision makes findings about their involvement in the 10mg Agreement. Given that the Hydrocortisone Decision finds in terms that the 10mg Agreement infringed the

Chapter I prohibition, this is obviously not satisfactory. This is a matter addressed in the Judgment (Cartel Infringements).

(3) *Mr Wayne Middleton.* Mr Middleton was called on behalf of the Advanz Appellants. He joined a company known as Amdipharm in March 2010 in that company's supply chain team and was appointed supply chain manager by May 2011. In May 2013, as part of the merger of Amdipharm and Mercury, which resulted in the creation of AMCo, he was appointed the head of supply chain integration, performing this role until April 2014. He was senior operations manager with the Advanz Appellants until April 2022, at which time he left to run his own management consulting company. He gave one witness statement[17] dated 22 November 2022 (Middleton 1) and gave evidence on Day 4 of the appeal (25 November 2022). Mr Middleton gave evidence on the limited question of AMCo's efforts to bring hydrocortisone tablets to market, and he assisted the Tribunal to the best of his ability in this regard.

(4) *Ms Kelly Lifton.* Ms Lifton was called on behalf of the Advanz Appellants. Ms Lifton was, at the times material to her evidence, employed by Aesica Queenborough Limited (**Aesica**) as a senior regulatory affairs officer (between 2007 and 2017). Her evidence – like that of Mr Middleton – related to AMCo's attempts to bring 10mg hydrocortisone tablets to market. Ms Lifton was called by the Advanz Appellants to rebut suggestions by the CMA that there was a delay in bringing these tablets to market that was at least corroborative of the existence of the 10mg Agreement. Ms Lifton robustly refuted such allegations in her witness statement dated 22 November 2022,[18] (Lifton 1) and gave evidence on Day 4 of the appeal (25 November 2022). Because Ms Lifton was not part of AMCo, but was rather a contractual counterparty of AMCo, her evidence on this point carried particular weight. Because, in cross-examination, there was a hint that Ms Lifton's evidence was so partisan in AMCo's (and so Advanz's) favour that she must be being paid for it,[19] we should record that we regard Ms Lifton as a transparently honest witness, whose evidence we believe.

(5) *Mr Robert Stewart.* Mr Stewart gave evidence on behalf of the Allergan Appellant. He gave a single witness statement dated 14 September 2021 (Stewart 1) and was interposed to give evidence on Day 10 of the appeal (8 December 2022). Mr Stewart gave evidence in relation to the (somewhat complex) history of the acquisition of Actavis UK Ltd. We will describe the history, and its relevance, in due course. Mr Stewart assisted the Tribunal with his evidence in this regard to the best of his ability.

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[17] Which was uncontroversially updated to reflect certain changes since the statement was first made.

[18] Again, this was an updated version.

[19] See Transcript Day 4/pp.94 to 95:

> "**Q (Ms Demetriou, KC)**: Ms Lifton, can I just ask you this: are you being paid by Advanz to give evidence in this?
>
> **A (Ms Lifton)**: Absolutely not"

There were a number of witnesses who were not required for cross-examination, and whose statements were uncontroversially admitted. We do not set these out here but will refer to them, as necessary, in the course of this Judgment.

(5) The expert witnesses

27. The Tribunal heard evidence from a total of five experts. In the order they were called, we heard from the following expert witnesses:

(1) *Dr Rina Newton.* Dr Rina Newton was called on behalf of the Advanz Appellants:

(i) Dr Newton is a UK-registered pharmacist. She was the Managing Director of Complimed (now Pharmalex), a healthcare compliance agency and consultancy which advises UK-based pharmaceutical companies on compliance. She now acts as a consultant for Pharmalex. She was formerly the Compliance Leader at AstraZeneca UK. She described her expertise as relating to the ABPI Code and related matters,[20] including interpreting the MHRA's guidance on off-label prescribing and understanding how a pharmaceutical company may or may not support or encourage off-label use.[21]

(ii) Dr Newton gave evidence on the regulations relating to the promotion of medicines and the off-label dispensing of medicines. She also gave evidence on whether AMCo could have promoted its reduced indication 10mg hydrocortisone tablets for the same indications as Auden's full indication 10mg tablets (a point we will be considering in more detail in this Judgment (Abuse of Dominance Infringements)), and whether a promotional flyer published by Alissa Healthcare (another seller of hydrocortisone tablets) for its reduced indication hydrocortisone 10mg tablets was compliant with the ABPI Code.

(iii) Dr Newton produced one expert report for these proceedings dated 21 November 2022 (Newton 1), and gave evidence on Day 5 of the appeal (29 November 2022).

(iv) We found Dr Rina Newton to be a competent and credible witness. We consider that her focus on the regulations and her undoubted expertise in relation to them may have led her to overstate the compliance risks and concerns. That is in no way intended as a criticism, merely a reflection of her concern to ensure that the strict letter of the regulations be promulgated.

All of the other experts were expert economists:

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[20] Transcript Day 5/p.32.

[21] Transcript Day 5/p.36.

(2) *Mr Derek Holt*. Mr Holt was called on behalf of the Advanz Appellants. He is presently managing director at AlixPartners UK LLP. He produced one expert report (Holt 1) and gave evidence on Day 5 of the appeal (29 November 2022).

(3) *Dr Matthew Bennett*. Dr Bennett is vice-president at the consultancy Charles River Associates. He was instructed by the Cinven Appellants and produced two expert reports for these proceedings (Bennett 1 and Bennett 2). He gave evidence on Day 6 of the appeal (30 November 2022).

(4) *Mr Simon Bishop*. Mr Bishop is a partner and co-founder of RBB Economics. He was called on behalf of the Intas Appellants and produced two expert reports for these proceedings (Bishop 1 and Bishop 2). He gave evidence on Day 7 of the appeal (2 December 2022).

(5) *Professor Tommaso Valletti*. Professor Valletti gave evidence on behalf of the CMA. He is a Professor of Economics at Imperial College Business School, where he is the head of the department of economics and public policy. He was Chief Competition Economist for the European Commission (Directorate General for Competition) between 2016 and 2019. He produced one expert report (Valletti 1). He gave evidence on Days 7, 8, 9 and 10 of the appeal (2, 6, 7 and 8 December 2022).

28. We were assisted by all of the economists who, we consider, did their very best to provide their impartial and expert opinions on the somewhat abstract questions which this case involves. This level of abstraction (e.g. the question of "value" and market definition in an unusual and highly regulated market) made giving expert evidence exceedingly difficult for all, because none of the experts were able to anchor themselves in fact and provide an opinion arising out of narrow and defined factual issues. These appeals simply did not generate that sort of question for expert consideration. We therefore wish to express our gratitude for their efforts.

29. Professor Valletti was an exuberant, combative and opinionated expert. We in no way hold that against him, and our opinion of his evidence is as for the other economists (as set out in the preceding paragraph). The reason we mention Professor Valletti in particular is because his style of evidence – and his views (expressed outside these appeals, but which views were put to him in cross-examination) about "economists for hire" (not a direct quote from Professor Valletti, but certainly a fair summary of what he did say) – drew criticism from the Appellants. Thus, the Cinven Written Closing suggested that Professor Valletti's evidence "should be approached with a considerable degree of caution".[22] Particular criticism was made of Professor Valletti's own rather colourful criticisms of the economists called by the Appellants.[23] We deprecate such

[22] At [165].

[23] Thus, Professor Valletti described CRA and RBB – the economics firms acting for the Cinven Appellants and the Intas Appellants respectively – as "useful fools" (see the Cinven Written Closing at [166(1)]) and the lawyers retained by them as having a "toxic mentality" and that "they will do anything for money" (see the Cinven Written Closing at [166(2)]). We have no desire to parse all of Professor Valletti's out of court statements, nor to set them

comments, which evince a degree of naivety and a lack of understanding of the litigation process on the part of Professor Valletti. The process before this Tribunal is an adversarial one, where experts advance opposing views which are appropriately tested in cross-examination.

30. We consider Professor Valletti's criticisms of other experts both ill-advised and wrong. However, these criticisms do not go to Professor Valletti's own abilities as an expert. We consider that Professor Valletti was well-aware of his own responsibilities as an expert, and that he gave his evidence on questions of economic substance (if not on other questions) properly and in accordance with the highest standards.

(6) The Joint Expert Statement and other notes and papers

31. The experts – in addition to the reports we have referenced – agreed a Joint Expert Statement dated 22 July 2022. Furthermore, a number of notes and papers were produced by the experts during the course of the trial. We will reference these notes and papers as necessary in the course of this Judgment (Abuse of Dominance Infringements), but do not list them here.

(7) Approach to this appeal

(a) Jurisdiction

32. The Appellants appeal the Hydrocortisone Decision pursuant to section 46(1) of the Competition Act 1998. Paragraph 3 of Schedule 8 of that Act sets out the Tribunal's jurisdiction on appeals pursuant to section 46. According to these provisions:

    (1) The Tribunal must determine the appeal on the merits by reference to the grounds of appeal set out in the notice(s) of appeal.

    (2) When determining the appeal on this basis, the Tribunal may confirm or set aside the decision (or any part of it) and may (i) remit the matter to the CMA, (ii) impose or revoke or vary the amount of a penalty, (iii) give such directions or take such other steps or make any other decision as the CMA could have made.

33. If it confirms the CMA's decision, the Tribunal may nevertheless set aside any finding of fact on which the decision was based.

(b) Approach

34. The Tribunal's approach to appeals of this kind was comprehensively considered in *BGL Holdings Ltd v. The Competition and Markets Authority*.[24] We adopt the approach

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out in full, but the substance of these statements were put to him in cross-examination, were not repudiated by him, and were (for that reason) relied upon by the Appellants (or some of them) as affecting the weight of Professor Valletti's evidence.

[24] [2022] CAT 36 (***BGL***) at [36]*ff*.

set out in *BGL*, and do not propose to repeat what was said at length in that case. However, we would stress the following points:

(1) The Tribunal is obliged to determine appeals (i) on the merits and (ii) by reference to the grounds of appeal set out in the notice of appeal.[25]

(2) Although the appeal is on the merits, and not a judicial review, where a decision involves an overall value judgement, based upon competing considerations in the context of a public policy decision, it might be difficult for the Tribunal to conclude that a decision of the CMA within the range of reasonable responses was not also right.[26]

(3) Any "on the merits" review is confined to a consideration of the points raised in the notice(s) of appeal. Appeals on the merits are not re-hearings, and the CMA's decision is to be reviewed through the prism of the specific errors alleged by the appellant(s) in the notice(s) of appeal.[27]

(4) In its decisions, the CMA is entitled to a "margin of appreciation",[28] but that margin of appreciation is always subject to the Tribunal's supervisory jurisdiction.[29] There is, inevitably, a certain tension between "margin of appreciation" and "supervisory jurisdiction", but the outcome is that the Tribunal should only interfere if it concludes that the decision is wrong in a material respect. The reference to "materiality" is important, and whether an error is material (or not) is a matter of judgement for the Tribunal.

(5) On an appeal, the legal burden of establishing any infringement falls on the CMA. The standard of proof is the ordinary, civil standard, of the balance of probabilities.[30] In this context, it is appropriate to mention the so-called (and non-existent) "higher" civil standard. This notion was explained in *Secretary of State for the Home Department v. Rehman*:[31]

> "I turn next to the Commission's views on the standard of proof. By way of preliminary I feel bound to say that I think that a "high civil balance of probabilities" is an unfortunate mixed metaphor. The civil standard of proof always means more likely than not. The only higher degree of probability required by the law is the criminal standard. But, as Lord Nicholls of Birkenhead explained in *Re H (Sexual Abuse: Standard of Proof) (Minors)*, [1996] AC 563, 586, some things are inherently more likely than others. It would need more cogent evidence to satisfy one that the creature seen walking in Regent's Park was more likely than not to have been a lioness than to be satisfied to

[25] *BGL* at [37].

[26] *BGL* at [38].

[27] *BGL* at [39].

[28] *BGL* at [46] to [49]

[29] *BGL* at [50]*ff*.

[30] *BGL* at [56] to [57].

[31] [2001] UKHL 47 at [55].

the same standard of probability that it was an Alsatian. In this basis, cogent evidence is generally required to satisfy a civil tribunal that a person has been fraudulent or behaved in some other reprehensible manner. But the question is always whether the tribunal thinks it more probable than not."

It will be necessary to revert to this need for cogent evidence when we come to consider the Cartel Infringements.

(6) Competition cases are *quasi*-criminal in nature. Given the nature and seriousness of such allegations, the presumption of innocence applies.[32] Again, this is a matter which we will need to consider with particular care when it comes to the Cartel Infringements.

C. THE RELEVANT PHARMACEUTICAL PRODUCTS

(1) Introduction

35. It is necessary to have a clear understanding of the various pharmaceutical products that are mentioned in this Judgment (Abuse of Dominance Infringements). This Section does no more than describe the various products. This Section does not consider: (i) how these products are regulated;[33] (ii) whether these products are or are not to be regarded as substitutes for market definition purposes;[34] (iii) who produced these products, and how they came to market.[35]

(2) Adrenal insufficiency

36. 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. If untreated, it is life-threatening. In almost all cases, it is a lifelong condition.[36]

37. Adrenal insufficiency can be either primary or secondary. Primary adrenal insufficiency occurs when the adrenal cortex (the outer region and the largest part of an adrenal gland), which produces cortisol (the hormone in question), has been destroyed.[37] Secondary adrenal insufficiency describes the situation where the adrenal glands are affected by a condition or disease in another part of the body. Such disruption means cortisol production by the adrenal glands is no longer controlled properly.[38]

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[32] *BGL* at [59] to [61].

[33] The regulatory framework is considered in Section D below.

[34] Market definition is considered in Section H below.

[35] This is considered in Section E below.

[36] Hydrocortisone Decision/3.117.

[37] Hydrocortisone Decision/3.117(a).

[38] Hydrocortisone Decision/3.117(b).

(3) Hydrocortisone

38. Hydrocortisone is a form of treatment for the replacement of cortisol in patients with primary or secondary adrenal insufficiency. Hydrocortisone is available in a number of different forms.

(a) Hydrocortisone "immediate release" tablets

39. Hydrocortisone tablets are a prescription only medicine used in primary and secondary care to treat adrenal insufficiency.[39] Hydrocortisone tablets are available in 10mg and 20mg strengths and are sold in packets of 30 tablets.[40] These tablets are "immediate release" drugs: the hydrocortisone contained in the tablets, once ingested by the patient, is rapidly absorbed into the bloodstream to deliver peak cortisol values in the blood approximately half-an-hour after administration.[41] We have referred to these medicinal products as "10mg immediate release hydrocortisone tablets" and "20mg immediate release hydrocortisone tablets".[42]

40. For those taking hydrocortisone tablets as a replacement therapy, the standard adult daily dose ranges between 15mg to 25mg. Higher doses may be needed when the patient is acutely unwell. Hydrocortisone tablets often need to be taken two or three times a day in order to secure sufficient blood cortisol levels throughout the day.[43]

41. A typical regime might be for a patient to take 10mg on waking, 5mg at lunchtime and 5mg in the late afternoon. The dosing regime aims to reflect the body's natural rhythm, with cortisol levels highest in the morning.[44] Patients often achieve such a dosing regime by splitting individual tablets into smaller doses. Thus, taking the typical regime just described, the patient would probably take a single 10mg tablet on waking, and split a second 10mg tablet for use at lunchtime and the late afternoon.[45]

42. Given that this is a typical regime, it is obvious that 10mg tablets are more commonly prescribed than 20mg tablets, simply because less splitting of tablets is required.[46] Of course, if higher doses of hydrocortisone are required, use of 20mg tablets might be indicated. The Hydrocortisone Decision records that 10mg tablets accounted for 96% of hydrocortisone tablets dispensed between 2012 and 2017.[47]

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[39] Hydrocortisone Decision/3.120.

[40] Hydrocortisone Decision/3.122.

[41] Hydrocortisone Decision/3.123.

[42] See [5(4)(ii)] and [11].

[43] Hydrocortisone Decision/3.124.

[44] Hydrocortisone Decision/3.124.

[45] Hydrocortisone Decision/3.124.

[46] Hydrocortisone Decision/3.125.

[47] Hydrocortisone Decision/3.125.

(b) Plenadren

43. Plenadren is a form of hydrocortisone, available in 5mg and 20mg strengths, and sold in bottles of 50 tablets.[48] It is a "modified release" tablet that is designed to mimic the body's normal steroid production and its natural daily steroid profile. It releases hydrocortisone over a longer period of time than the "immediate release" tablets described in paragraphs 39 to 42 above. It is therefore administered only once daily.[49] This medicinal product was branded, and we will refer to it by its branded name: **Plenadren**.

(c) Other forms of hydrocortisone

44. Hydrocortistab is an injectable form of hydrocortisone, and it would appear from the Hydrocortisone Decision that there are several such products available.[50] The Hydrocortisone Decision records that injectable hydrocortisone is used in preference to tablets only in exceptional cases:[51]

> "Injections are only used as cortisol replacement therapy 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- and post-major procedures, or where the patient is "nil by mouth"."

45. Soluble hydrocortisone tablets also exist. These are dissolved in water before being taken by a patient.[52] Such tablets are targeted at those patients who have a preference or need for a liquid form of hydrocortisone. That includes patients suffering from dysphagia (difficulty swallowing) or very young children.[53]

(4) Non-hydrocortisone treatments for adrenal insufficiency

46. The Hydrocortisone Decision records that hydrocortisone is the "first-line" treatment for the replacement of cortisol in patients with primary or secondary adrenal insufficiency. That is because hydrocortisone is the closest imitation of what the body normally produces; is absorbed into the body more quickly than other steroids; and is easily measured in the bloodstream, making monitoring easier.[54]

47. For these reasons, the Hydrocortisone Decision records that whilst other synthetic steroids exist which may be used for the treatment of adrenal insufficiency (e.g.

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[48] Hydrocortisone Decision/3.128.

[49] Hydrocortisone Decision/3.129.

[50] Hydrocortisone Decision/3.135.

[51] Hydrocortisone Decision/3.135.

[52] Hydrocortisone Decision/3.136.

[53] Hydrocortisone Decision/3.136.

[54] Hydrocortisone Decision/3.119.

prednisolone and dexamethasone), these drugs are only prescribed in exceptional circumstances, for example where a patient is intolerant or allergic to hydrocortisone.[55]

D. THE REGULATORY REGIME

(1) Introduction

48. It is necessary to consider the regulatory regime in the abstract first, before descending into specifics regarding the various pharmaceutical products considered in Section C above.

(2) Patented and generic medicaments

49. A medicament can either be patented or generic. A patented medicament benefits from the monopoly that is conferred upon inventions that are patented. Infringement of a patent can be enjoined (by way of injunction) or else give rise to a claim in damages or an account of profits. By contrast, a generic medicament is a product that may be produced and sold without infringing a patent and provided other requirements (in particular regulatory ones) are met. There is, thus, far greater potential for competition in the case of generic medicaments than in the case of patented medicaments.[56]

(3) Branded and unbranded medicaments

50. Branding refers to the attachment of a particular manufacturer's product specific brand to a product. A branded product will carry a product name unique to the holder of the applicable Marketing Authorisation, whilst an unbranded product will be sold under the World Health Organisation's International Nonproprietary Name.

51. Although the distinction between branded and unbranded will typically follow the patented/generic distinction considered above, it is perfectly possible for a generic to be branded: a so-called "branded generic".[57]

(4) The need for a Marketing Authorisation

52. The Hydrocortisone Decision records that in order to market and sell a pharmaceutical product, a company must obtain a Marketing Authorisation from the national competent authority, which in the United Kingdom is the Medicines and Healthcare products Regulatory Agency (the **MHRA**). The Marketing Authorisation will only be granted if the pharmaceutical product meets satisfactory standards of safety, quality and efficacy in treating the condition for which it is intended.[58] An applicant for a Marketing

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[55] Hydrocortisone Decision/3.137.

[56] Hydrocortisone Decision/3.42 and 3.79.

[57] Hydrocortisone Decision/3.76. This is relevant for purposes of some of the price regulations that we consider below: Hydrocortisone Decision/3.73*ff*.

[58] Hydrocortisone Decision/3.150.

Authorisation must provide certain material in relation to the product in question.[59] These must include the therapeutic indications.[60]

53. The Hydrocortisone Decision goes on to state that a Marketing Authorisation sets out the terms under which the marketing of a medicinal product is authorised within the United Kingdom. A Marketing Authorisation must contain a **Summary of the Product Characteristics** (sometimes referred to as an **SmPC**, a term we will try to avoid) and the terms of the labelling and packaging leaflet. The Summary of Product Characteristics is a document describing the properties and the officially approved conditions of use of a medicine. The Summary of Product Characteristics forms the basis of information for healthcare professionals on how to use the medicine safely and effectively. Amongst other clinical particulars, the Summary of Product Characteristics includes a list of **therapeutic indications** which define the target disease(s) or condition(s) for the medicine. The Summary of Product Characteristics also states the age groups for which the product is indicated.[61]

54. For reasons which we will come to, the therapeutic indications and the age groups for which a particular medicinal product might lawfully be marketed and sold assumed great importance in these appeals, and we received the evidence of Dr Newton on exactly this point. However, as Dr Newton accepted, she was not able to speak to the law underpinning Marketing Authorisations. She could only speak to the perceptions of risk that might exist – particularly amongst pharmacists – when dispensing a product for a therapeutic indication or age group not specified in the Summary of Product Characteristics. The law – as all accepted – is a matter for us and it is necessary for us to be clear as to exactly what the legal regime permits and does not permit:

    (1) There is no clear definition of a therapeutic indication in English law. The European Commission has defined a therapeutic indication as a form of words that perform the following function:[62]

        "The indication(s) should be stated clearly and concisely and should define the target disease or condition distinguishing between treatment (symptomatic, curative or modifying the evolution or progression of the disease), prevention (primary or secondary) and diagnostic indication. When appropriate, it should define the target population especially when restrictions to the patient populations apply.

        …

        Mandatory conditions of product usage not covered more appropriately in other parts of the SmPC may also be included when relevant, e.g. concomitant dietary measures, lifestyle changes, or other therapy.

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[59] Human Medicines Regulations 2012, SI 212/1916 (the **Human Medicines Regulations**), Regulation 50. These are then specified in Schedule 8.

[60] Human Medicines Regulations, Schedule 8, paragraph 27(a), as one of the "clinical particulars".

[61] Hydrocortisone Decision/3.151.

[62] *A Guideline on Summary of Product Characteristics (SmPC)* Rev 2 (September 2009) at [4.1].

It should be stated in which age groups the product is indicated, specifying the age limits, e.g. "X is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged x to y <years, months>>.

…"

A therapeutic indication is thus information concerning the use of a medicinal product.

(2) It is now possible to give some meaning to the terms **off-label** and **on-label**, which are also going to be significant in this Judgment (Abuse of Dominance Infringements). Off-label is principally defined as the use of a medicinal product for a therapeutic indication other than that set out in the Marketing Authorisation. Off-label use thus focusses on the patient actually taking the medicinal product. As we will describe later on in this Judgment, off-label use is not unlawful and is, in fact, sometimes encouraged as being in the patient's best interests. What is controlled – and at times rendered unlawful – is the facilitation of off-label use. Thus, as we shall see, the advertisement and sale of medicinal products for off-label use is controlled and generally prohibited. We are – for purposes of clarity – going to use the terms **off-label use** and **off-label facilitation** in the sense we have just described.

(3) **On-label use** refers to the use of a medicinal product that is in accordance with the therapeutic indication set out in the Marketing Authorisation. Unsurprisingly, **on-label facilitation** is lawful, although, as we shall see, tightly controlled.

55. The Hydrocortisone Decision adopts a somewhat wider and certainly more fluid definition:[63]

"Healthcare professionals may prescribe and/or dispense drugs to treat a condition that is not included in the therapeutic indications listed in the SmPC of the supplier's [Marketing Authorisation]. Situations where a licensed medicine is used outside the terms of its licenced indications are referred to as "off-label" use of medicines."

The Decision thus does not draw a hard-edged distinction between use and facilitation.

(5) Prescription and non-prescription medicinal products

56. Medicinal products – all of which will require a Marketing Authorisation – may be either **prescription** or **non-prescription** products. Non-prescription products are available for purchase "over-the-counter" without a prescription at a price that is not regulated.

[63] Hydrocortisone Decision at 3.226 (Ref only).

57. Prescription products are those prescribed to patients by their doctor or other healthcare professional, once they have been first assessed by a specialist.[64]

58. The distinction between prescription and non-prescription products is not, in all cases, watertight:

    (1) It is perfectly possible for a non-prescription product to be prescribed. Aspirin, for example, which is readily available over-the-counter without a prescription, can nevertheless be prescribed.

    (2) On the other hand, some products are only available on prescription.

59. For purposes of exposition, it is safer to differentiate between **prescription-only**, prescription and non-prescription products.

60. We refer to the **patient** as the actual consumer of any given pharmaceutical product. It is implicit in that definition that the patient is taking and using the product for medicinal purposes. The patient received remarkably little attention from anyone during the course of these appeals, a question of focus that we will be returning to.

61. The patient is, however, due to the regulatory regime, a far from normal consumer. The reason for this is that in the case of prescription-only products, the price paid by a patient for such a product is controlled, so that (generally speaking) the patient pays less than the actual price of the product. We fully appreciate that the term "actual price" in and of itself begs an enormous number of questions, to which we will come. For present purposes, it is important to note that:

    (1) Prescription products are "sold"[65] to patients at a price that is fixed. At the time of this Judgment (Abuse of Dominance Infringements), the price per product was £9.65, whatever the "actual price" of the product.

    (2) In the case of prescription products that are available on a non-prescription basis (like aspirin) the patient may well be advised to purchase the product without a prescription, because the "actual price" is lower than the prescription price. However, that possibility does not arise in the case of prescription-only products.

    (3) The prescription price is not the last word on the pricing: exemptions exist (where the patient pays nothing) and it is possible to pay for prescriptions on a three month or an annual basis (useful for those requiring repeat prescriptions).

62. Moving on from the patient, we turn to those persons involved in the supply of medicinal products.

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[64] Hydrocortisone Decision/3.215.

[65] Even this term is redolent with difficulty. Not only is the price fixed, but there are significant pre-conditions in relation to "purchase" (there must be a prescription) and significant pre-conditions in relation to "sale" (the pharmacist is – as we will see – obliged to provide the prescribed product).

(6) Persons involved in the supply of medicinal products

(a) Clinical commissioning groups

63. In England (the regime differs for Wales, Scotland and Northern Ireland), prescription medicines were funded by the NHS through **Clinical Commissioning Groups** or **CCG**s during the relevant period. For the purposes of this Judgment (Abuse of Dominance Infringements), we focus only on the regime in England, which is the only regime in relation to which we were addressed by the parties.[66]

64. The manner in which Clinical Commissioning Groups fund prescription medicines is as follows:

(1) Pharmacies purchase medicines from wholesalers and manufacturers. Pharmacies can be of varying sizes, ranging from the single unit high-street shop to chains like Boots. In some cases, pharmacies are vertically integrated with their own wholesaling arm.[67]

(2) The prices at which pharmacies buy prescription products are regulated in the manner considered in detail below.

(3) Pharmacies are reimbursed for each prescription that they fulfil by the patient's local Clinical Commissioning Group.[68] The amount of the reimbursement bears no necessary relationship to the amount paid by the pharmacy to obtain the medicinal product. The reimbursement "price"[69] is set by reference to a list of pharmaceutical products and their reimbursement levels are known as the **Drug Tariff** or **DT**.[70] The Drug Tariff is compiled by the Department of Health and Social Care.[71]

(4) The same reimbursement "price" is paid to a pharmacy irrespective of which supplier's product is dispensed or what price the pharmacy pays for the medicinal product.[72] Looking only at the profit on the marginal medicinal

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[66] The CMA considered that the differences between the various jurisdictions did not materially impact on the Hydrocortisone Decision (Hydrocortisone Decision/footnote 107 (Ref only)), and none of the Appellants disputed this.

[67] Hydrocortisone Decision/3.67.

[68] Hydrocortisone Decision/3.68.

[69] This is not a price in any meaningful sense.

[70] There is a different rate - the NHS Reimbursement Price – which is based on the Drug Tariff, but which reflects specific concessions negotiated and agreed. It is generally lower than the Drug Tariff, but not materially so. We will use the term Drug Tariff to refer indifferently to either the Drug Tariff or the NHS Reimbursement Price. The figures in Annex 3 under column (6) are the NHS Reimbursement Price (although the term "Drug Tariff" is nevertheless used).

[71] Hydrocortisone Decision/3.69(a).

[72] Hydrocortisone Decision/3.69(b).

product,[73] the pharmacy's profit can only be affected by the price paid for the medicinal product, rather than the price received by way of reimbursement. That is because there is no ability to negotiate or vary the reimbursement "price".

(5) The Decision does not explain exactly how this system works in practice:

(i) The Decision finds that once a prescription has been issued, the "system" – i.e. pharmacists – are obliged to dispense to the patient presumably at the prescription price. Thus, the Hydrocortisone Decision records:[74]

> "Once a particular medicine has been prescribed, pharmacies are bound to dispense it. Though pharmacies have a discretion over which product to dispense against an open prescription,[75] [Clinical Commissioning Groups] are bound to compensate pharmacies for whatever product they dispense, provided that the product dispensed is within the parameters of the prescription. [Clinical Commissioning Groups] do not negotiate the prices of hydrocortisone tablets with pharmaceutical suppliers or purchase the medicines directly from them. Moreover, [Clinical Commissioning Groups] have no formal powers enabling them to limit the price they pay for pharmaceutical products, nor are they able to influence the Drug Tariff price (i.e. the price they have to pay)."

(ii) This leaves unanswered the question of what the position is where the price to the pharmacy is higher than the reimbursement rate laid down in the Drug Tariff, which is at least a theoretical possibility, since the Drug Tariff is not (at least in formal terms) a price control over pharmaceutical manufacturers.

(iii) The Hydrocortisone Decision says little about how the Drug Tariff is computed, but it is clear (from the little that is said) that the Drug Tariff does not necessarily equate to the price charged by the manufacturer:[76]

> "The price of a drug within Category M was set using a weighted average from retrospective sales values (net of customer-specific discounts) and volume data supplied to the DHSC[77] by manufacturers (during the Infringements, under Scheme M (see further below)). These prices were then adjusted by a formula to ensure that pharmacy contractors retained the profit margin agreed as part of the funding of the community pharmacy contractual framework."

(iv) The Hydrocortisone Decision also says two inconsistent things. First, that the Drug Tariff "acts as a ceiling on the prices that suppliers can

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[73] I.e. considering only the cost of purchase and the revenue on sale, and disregarding other costs like staff and premises.

[74] Hydrocortisone Decision at 4.328 (Ref only).

[75] This is a term we will come to describe in due course.

[76] Hydrocortisone Decision at 3.178.

[77] The Department of Health and Social Care.

charge";[78] and, secondly, the Drug Tariff did not do so in a monopoly situation:[79]

> "…when there were no other suppliers the Drug Tariff price did not act as a ceiling on Auden's prices as it increased in line with those prices (there being no other suppliers to influence the Drug Tariff Price)."

(6) The position would therefore appear to be as follows, and we so find:

(i) The Drug Tariff acts as no real constraint at all. Rather it is competition in the market that acts as the constraint. It is perfectly possible – given the idiosyncratic price controls that operated – for there to be multiple comparable products, only one of which drives the Drug Tariff:[80]

> "During the Pre-Entry Period, the Drug Tariff did not impose any constraint on Auden. That is because the Drug Tariff price was based only on the prices of Auden's hydrocortisone tablets (via those set by its customers), since it was the only supplier in the market. That remained the case for the 20mg tablets during the Post-Entry Period because 20mg tablets remained within Category A, which meant that the Drug Tariff price was set based on wholesalers' and manufacturers' list prices…"

(ii) If this is right, then during the monopoly period (referred to in the Hydrocortisone Decision as the "Pre-Entry Period"), the Drug Tariff simply measured Auden's prices, and did not constrain them; and there was no constraint arising out of competition.[81]

(iii) During the period where there was some competition (referred to in the Hydrocortisone Decision as the "Post-Entry Period"), the Drug Tariff again was (or, at least, could be) informed by a single price (so, again, no constraint), but competition might act as a constraint (depending on all the circumstances).

(iv) In these circumstances, in the first scenario (monopoly) the Clinical Commissioning Groups would reimburse at monopoly prices, because these prices would inform the Drug Tariff. In the second scenario (Drug Tariff informed by one company ("*A*"), but that company is subject to competition from others ("*B*" and "*C*")) there would be some downward pressure on the Drug Tariff because of competition. Competition would

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[78] Hydrocortisone Decision at 4.280 (Ref only).

[79] Hydrocortisone Decision at 4.280 fn 1253 (Ref only). See also 4.278 fn 1448 (Ref only).

[80] Hydrocortisone Decision at 4.278 fn 1448.

[81] We note that this is accepted in Dr Bennett's second note, produced for the Tribunal, which states at footnote 8 – "[n]ote that if Auden wanted to increase its prices, it had to strike a balance between cutting into pharmacies' margins and risking delisting. If Auden was the only constituent of the DT, it could increase its prices further (without squeezing pharmacies margins) once its higher prices fed into the DT, thereby increasing the DT".

involve (amongst other things) price competition from and between *B* and *C* as against *A*. Thus, suppose:

A's price is £5, and that price informs the Drug Tariff.

B and *C* price at £3.50. Pharmacists will, other things being equal, purchase from *B* and *C*, but other things may not be equal, and demand is unlikely to be perfectly elastic. If it were perfectly elastic, *A* would have to price at £3.50 also, and the Drug Tariff would fall to this level.

But if price elasticity of demand was not 1 (or 100%), then *A* might profitably price at above £3.50, but lower than £5 – say £4.25. In due course, the Drug Tariff would fall to this level.

(v) Considering only the Drug Tariff, it is perfectly possible for a manufacturer's price (paid by the pharmacy) to exceed the Drug Tariff rate. In such circumstances, the pharmacy will be obliged to fund the difference itself,[82] because the pharmacy cannot refuse to supply the patient.

(7) We conclude that the statement in the Hydrocortisone Decision that the Drug Tariff "acts as a ceiling on the prices that suppliers can charge"[83] is either wrong or meaningless. In any event, we do not accept this finding as true in all circumstances.

65. Clinical Commissioning Groups have a role that goes significantly beyond merely reimbursing pharmacies. Again, the Hydrocortisone Decision says relatively little about this, but (from the little that is said) Clinical Commissioning Groups play an active role in informing or instructing doctors on what and how to prescribe by way of formularies and other direction to doctors:[84]

"Prescribing restrictions are imposed on GPs by [Clinical Commissioning Groups] which materially limit the use of Plenadren: Plenadren is not generally included in [Clinical Commissioning Group] formularies. By way of illustration, Plenadren was not included in [Clinical Commissioning Group] formularies of South Devon and Torbay CCG, Gloucestershire CCG and Coastal West Sussex CCG. Coastal West Sussex informed the CMA that it, along with several other groups representing 21 [Clinical Commissioning Groups] in England, does not include Plenadren and was also not aware of other [Clinical Commissioning Groups] that did include it. These three noted that the limited potential benefits of Plenadren are not significant enough to justify the considerable extra cost associated with prescribing Plenadren."

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[82] Although there are other means by which pharmacies can be paid, we do not discount the probability that such a deficit would be covered from public funds in some way. However, this is not an area that was explored in these appeals, or in the Hydrocortisone Decision, and it is not material for the purposes of this judgment.

[83] Hydrocortisone Decision at 4.280 (Ref only).

[84] Hydrocortisone Decision/3.133(c).

(b) Manufacturers and Contract Manufacturing Organisations

66. A company that holds a Marketing Authorisation may either manufacture the pharmaceutical product itself or it may contract with a third party to manufacture the product on its behalf. Such third parties are known as **Contract Manufacturing Organisations** or **CMO**s.

67. Whilst a Contract Manufacturing Organisation will have contractual liabilities to the holder of the Marketing Authorisation in relation to the manufacturing of the pharmaceutical product in question, it is the company procuring the production (i.e. the holder of the Marketing Authorisation) that is responsible for ensuring that the product is legally compliant.[85] Thus, if a Contract Manufacturing Organisation were to supply a company not holding an appropriate Marketing Authorisation, that company could not lawfully supply the product to the market.

68. The Hydrocortisone Decision notes that:[86]

> "There are different routes through which pharmaceuticals from manufacturers (or [Marketing Authorisation] holders) reach downstream customers and patients. For example, a manufacturer (or [Marketing Authorisation] holder) can sell its products directly to pharmacies, sometimes using a third-party logistics provider; or can sell to a wholesaler, which contracts with pharmacies directly. In the UK, most pharmaceutical products are distributed through wholesalers to pharmacies."

69. So that the market structure may be fully understood, there are companies (referred to as **pre-wholesalers**) which offer logistical services to manufacturers. These services tend to involve mainly the storage and transportation of pharmaceutical products from the manufacturer to wholesalers, hospitals and (in some cases) pharmacies. Pre-wholesaling services differ from wholesaling in that they are services provided to the manufacturers and do not concern the purchase and sale of pharmaceuticals.[87]

(c) Wholesalers

70. Wholesalers acquire pharmaceutical products from manufacturers and sell them on to pharmacies. Wholesalers tend to be classified either as "full-line" or "short-line". In the words of the Hydrocortisone Decision:

    (1) Full-line wholesalers "offer a full range of pharmaceutical product lines (over 12,000 product lines) and offer twice daily delivery to the majority of customers for products that are not typically kept in stock by pharmacies."[88]

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[85] Hydrocortisone Decision/3.205.

[86] Hydrocortisone Decision/3.207.

[87] Hydrocortisone Decision/3.208(a).

[88] Hydrocortisone Decision/3.208(b)(i).

(2) Short-line wholesalers "offer a smaller range of pharmaceutical product lines (around 3,000 lines) and typically operate on a next-day courier delivery basis. Typically, these are fast moving product lines and generics that sell in large quantities that do not necessarily require frequent deliveries to pharmacies".[89]

(d) "Customers"

71. We consider the label "customers" to be unhelpful and intend to avoid it so far as possible. However, this was a term used by both the CMA and the Appellants during the hearing, and to that extent its use is unavoidable.

72. The Hydrocortisone Decision says this:

> "3.212 At the end of the supply chain are retail pharmacies, dispensing doctors and hospitals which source hydrocortisone tablets either directly from a supplier or through a wholesaler. Retail pharmacies make up the largest customer group.
>
> 3.213 The purchase price paid by a pharmacy for hydrocortisone tablets is determined following negotiation between the pharmacy and the relevant supplier or wholesaler. Pharmacies then receive a payment for the prescriptions they fulfil from [Clinical Commissioning Groups]…[T]he amount that pharmacies receive is specified in the Drug Tariff.
>
> 3.214 In 2016/2017, there were 11,699 community pharmacies, of which 4,434 were independent, in the UK. The largest pharmacy groups were: Boots (a subsidiary of Alliance), Lloyds (a subsidy of AAH), Rowlands, Superdrug and Well Pharmacy (a subsidiary of Bestway). In 2015, these pharmacy groups together held around 44% of the retail pharmacy market. Boots was the largest single chain, with the highest market share."

73. The label "customers" is unhelpful because:

(1) It elides different roles, that are functionally distinct. There is, for example, a clear distinction between those who prescribe and those who supply pursuant to a prescription (i.e. dispense). Their roles are not alternative, but complementary; and the factors that inform their decisions in terms of what they prescribe and what they dispense are different. These differences need to be understood.

(2) It is wrong to say that either or both of the prescriber and dispenser are at the "end of the supply chain". Neither consumes the medicinal product they prescribe or dispense. It is the patient who does that; and it is the patient who is properly at the "end" of the supply chain.

74. Of course, we appreciate that this is far from a usual market. We have mentioned some price controls already; and will be coming to others. But on top of these factors that

[89] Hydrocortisone Decision/3.208(b)(ii).

render this market unusual, there is (amongst others) this additional unusual element, in that the "consumer function"[90] is effectively trifurcated:

(1) Normally, the **ultimate consumer** in a market – by which we mean the person who actually consumes, and does not buy a product simply to on-sell it (whether as part of or in order to make another product or not) – is a straightforward entity whose choices are relatively easy to understand. The ultimate consumer values a product to a certain level and – assuming means to pay – will be prepared to pay up to that value. This will inform the demand schedule for a product from ultimate consumers, and it is the demand of ultimate consumers that ultimately informs demand of what we will term **intermediate consumers**, those who buy a product as part of or in order to make another product.[91]

(2) In this instance, the choice of the ultimate consumer ("Do I buy product X at this price?") is far more complex and nuanced. The patient brings to the doctor a need (the patient's illness), which is translated by the doctor into a medical response (the treatment of the illness) using the doctor's clinical judgement. The outcome of that clinical judgement may result in a certain medicinal product being prescribed (and that is the case generally here: we are concerned with patients suffering from adrenal insufficiency, where the general medical response is to prescribe hydrocortisone in some form).

(3) That prescription – which can have different formulations – is then fulfilled by the pharmacy in a manner consistent with the prescription. The prescription may, however, give a degree of latitude to the pharmacy, which is something we will explore further.

(4) The patient takes what they are prescribed and has (apart from presenting to the doctor and choosing which pharmacy to go to) limited agency, unlike the ultimate consumer in the ordinary case.

75. Accordingly, instead of referring to "customers", we will refer to the following persons whose complex interaction collectively makes up the ultimate consumer:

(1) The **doctor**.

(2) The **pharmacy**.

(3) The **patient**.

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[90] By which we mean the process of judgement by which a consumer chooses to buy or not buy a given good or service.

[91] As to this, see *Optis Cellular Technology LLC v. Apple Retail UK Limited*, [2023] EWHC 1095 (Ch) at [419] to [423].

(e) Doctors

76. The Hydrocortisone Decision rightly notes that "[h]ealthcare professionals[92] select the most therapeutically appropriate and effective medicine to prescribe to a patient. Neither the patient nor the healthcare professional is sensitive to price since they do not pay for the product".[93]

77. The Hydrocortisone Decision describes the practice of prescribing in the following terms:

> "3.62 The clinical decision to prescribe a patient a medicine is typically taken by that patient's GP or specialist healthcare professional.[94]
>
> 3.63 A prescriber can choose how prescriptive they are when writing a prescription, which in turn has implications for the degree of choice that a dispenser (typically a pharmacy) has when fulfilling a prescription. A prescriber may choose to write:
>
> (a) a "generic" or "open" prescription for a medicine, which only specifies the active ingredient or specifies the active ingredient together with one or more of the medicine's forms, its strength and dose; or
>
> (b) a "closed" prescription for a medicine which specifies the particular brand, manufacturer or supplier.
>
> 3.64 Prescribers are generally encouraged to write open prescriptions using a medicine's generic name, e.g. "hydrocortisone tablets", regardless of whether a generic product is actually available, unless there are specific clinical reasons not to do so. For example, in cases where products are not interchangeable from a patient safety perspective, the Medicines and Healthcare Products Regulatory Agency (the MHRA) would generally require the use of a brand name (even for a generic product) so that product can be more easily distinguished.
>
> 3.65 During the second stage of the drug lifecycle (the market exclusivity period), even where prescriptions are open, in practice pharmacies have only one choice of product to dispense because there will be only one supplier of the drug.
>
> 3.66 However, during the third stage of the drug lifecycle, open prescriptions give pharmacies the option of dispensing any supplier's product because there can be multiple suppliers of the same drug."

78. Drawing on the foregoing, the position is as follows (and we so find):

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[92] We prefer the term "doctor" but appreciate that this is too narrow in terms of those that do the prescribing. Nevertheless, it is a more straightforward term. The term "prescriber", whilst functionally more accurate, loses the very important quality of clinical judgement that will inform a doctor's conduct.

[93] Hydrocortisone Decision/3.216(a).

[94] As we have seen (see [63] to [65]), Clinical Commissioning Groups can exert considerable influence over what doctors are able to prescribe. Clinical judgement is not the only factor in play.

(1) It is the doctor who determines what medicinal products ought to be prescribed for a given patient. It is the doctor's clinical judgement that is central here. The decision to prescribe on-label or off-label is that of the doctor. Generally speaking, it must be right to say that medicinal products should only be used in line with their Marketing Authorisation. (Otherwise, what is the point of all the regulation we have described?) However, there is here a tension between ensuring that medicinal products are used in line with the Marketing Authorisation and the doctor's clinical judgement. We will come to discuss the law in this area in greater detail below, but it seems to us that off-label prescription is appropriate where, in the clinical judgement of the doctor, prescribing a medicinal product for a therapeutic indication not stated in the Summary of Product Characteristics is nevertheless in the patient's interests. We do not consider that a doctor could appropriately prescribe off-label for other reasons (e.g. cost), save where the cheaper off-label option is clearly and distinctly no worse than the on-label option.

(2) The doctor will then issue a prescription. The prescription will not, typically, refer to the therapeutic indication at all, but only to the medicinal product that the doctor has selected. In other words, it will not be apparent, from the prescription itself, whether the doctor is prescribing on-label or off-label. As we have seen, the prescription will either specify a particular brand – a "closed" prescription – or reference the active ingredient – an "open" prescription. The prescription will also articulate more granular details: e.g. strength or dose.

(3) The patient's date of birth appears on every prescription,[95] next to the patient's name and address. It does not appear in the part of the prescription stating the medicinal product that the doctor has selected. Of course – and this matters a great deal in this case – where a pharmaceutical product is limited (e.g. because of something said in the Summary of Product Characteristics) to patients of a specific age,[96] and that fact is known to the pharmacist, then the statement of the patient's date of birth will make clear (in this specific circumstance) whether the doctor has prescribed off-label. Equally, the pharmacist will (quite understandably, whatever the legal position) be able to "second guess" an off-label open prescription, by selecting the product that is most age appropriate. We will return to the question of what a pharmacy's legal obligation is, but Dr Newton was, in her evidence, clear that in such a case, even where there was an open prescription, the pharmacy should dispense consistently with age.

(f) The pharmacy

79. The pharmacy is obliged to fulfil the prescription. In the usual case, we do not consider that the pharmacy can appropriately second-guess the doctor and either ignore limits on the prescription or impose limits of their own. In other words, where a "closed" prescription specifies a branded medicinal product, the pharmacist must dispense that

[95] See the evidence of Dr Newton (Transcript Day 5/p. 71): "…all prescriptions have the age of the patient on there straightaway, so I do not really need to know the indication, because I know if it is an adult or not…".

[96] See [53].

product. On the other hand, where a prescription is "open", the pharmacist has a discretion.

80. To take an example that is not hypothetical, but very much drawn from the facts of this case (although we consider the specific facts in greater detail below), let us suppose that there are two medicinal products – *A* and *B* – with the same active ingredient and for the same therapeutic indication, save that the Summary of Product Characteristics in the case of *A* specifies that "*A* is indicated in adults", whereas *B*'s Summary of Product Characteristics specifies that "*B* is indicated in children". Let us also suppose – again, to anticipate questions that arise in this case – that the Drug Tariff for *A* and *B* is the same (say, £10), but that the price to the pharmacy (i.e. what must be paid for the supply of the drug from the wholesaler) is £4 in the case of *A* but £7 in the case of *B*.

81. Where the doctor prescribes *A* or *B* in a closed prescription, the pharmacist will have no choice, but to prescribe that medicinal product. On the other hand, if the prescription is open in that it specifies the active ingredient common to both *A* and *B*, then the pharmacist has a choice. Assuming a legally unconstrained choice,[97] then, rationally, and assuming no issues about the supply of each medicinal product, the pharmacy will elect to supply *A*. That ought to be the case, even if the date of birth on the prescription indicates that the patient is a child. The pharmacist will be entitled, in such a case, to presume that the doctor has elected to go "off label".

82. That is very much what a rational pharmacy, with perfect legal knowledge, would do. But the law in this area – as we shall see – is by no means straightforward, and we consider that there would be a strong prudential motivation amongst pharmacists to dispense the age-appropriate product even if not legally obliged to do so. This was the evidence of Dr Newton, to which we will come.

(7) Specific regulatory controls and market perception

(a) Introduction

83. The law in this area broadly maps the regime described above. The reason we have separated a broad-brush description of the regime from this specific description is because the regime is extraordinarily complex and difficult to follow. Thus, for instance, the Human Medicines Regulations – referenced above and considered further below – run to over 1,000 pages in length. The regulations are remarkably specific and – inevitably – that level of detail entirely defeats the object of the specificity of these provisions (presumably legal certainty) by introducing legal uncertainty in having regulations that are in reality impenetrable.

84. This section, accordingly, sets out both the extent to which the regime supports and underpins the general description given above, and the extent to which legal uncertainties arise.

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[97] We come to the legal aspect in detail next, but the assumption we have articulated is, in our judgement, legally correct.

(b) Regulation

85. The overall objective of the regulation in this area is to ensure that whilst off-label use of medicinal products is permitted, it is tightly controlled. Thus:

(1) A person may not publish an advertisement for a medicinal product with a Marketing Authorisation unless the advertisement complies with the particulars listed in the Summary of the Product Characteristics.[98]

(2) Wholesale dealers in medicinal products that have a Marketing Authorisation or ought to have a Marketing Authorisation must be licensed and those licences contain conditions.[99] One of these conditions is not to sell or supply a medicinal product unless there is a Marketing Authorisation in force in relation to that product;[100] and only to sell or supply (or offer for sale or supply) that product in accordance with the Marketing Authorisation.[101]

(3) Essentially the same restriction applies to persons <u>not</u> wholesale dealers. A person may not sell or supply, or offer to sell or supply, an unauthorised medicinal product;[102] and where the medicinal product does have a Marketing Authorisation, no person may sell or supply, or offer to sell or supply, that medicinal product otherwise than in accordance with the terms of the Marketing Authorisation.[103]

86. The difficult question is how facilitation of off-label use is integrated into this regime. The position of the doctor is relatively straightforward, as the doctor prescribes, but does not sell. The position of the pharmacy is altogether more difficult because, quite naturally, in dispensing a medicinal product – and receiving some form of payment in return – the pharmacy might be said to be "selling" a medicinal product. If that is right, then the case described in [80] above, where the pharmacist provides *A* to a child on an "open" prescription is on the face of it fraught with legal risk.

87. The leading authority in this area is *Bayer plc v. NHS Darlington CCG*, where the first instance decision of Whipple J was substantially affirmed in the Court of Appeal.[104] We shall refer to these decisions as ***Bayer* (First Instance)** and ***Bayer* (CA)**. Although the case concerned rather different facts from the case we are here considering, the following appears to be the position in law:

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[98] Human Medicines Regulations, Regulation 280. It is an offence under Regulation 303 to act in breach of Regulation 280.

[99] Human Medicines Regulations, Regulation 42.

[100] Human Medicines Regulations, Regulation 43(5)(a).

[101] Human Medicines Regulations, Regulation 43(5)(b).

[102] Human Medicines Regulations, Regulation 46(1).

[103] Human Medicines Regulations, Regulation 46(2).

[104] *Bayer* (First Instance): [2018] EWHC 2465 (Admin); *Bayer* (CA): [2020] EWCA Civ 449.

(1) Whilst the Human Medicines Regulations use the phrase "sell or supply", the cognate European medicines legislation uses the term "place on the market" (see Bayer (CA) at [41]). English law therefore treats these terms as equivalent.[105]

(2) Both *Bayer* (First Instance) and *Bayer* (CA) found that the process of "placing on the market" came to an end at the point where a clinician (i.e. a doctor) prescribes the product in question for a particular patient. Any subsequent transfer of the product thus falls outside the process of "placing on the market" or "sale or supply".[106]

(3) In *Bayer* (First Instance), it was recognised that the reason for drawing the line here (in European law as well as English law) was to enable precisely the clinical freedom that we have described in paragraph 78(1) above.[107]

(4) In *Bayer* (CA), the Court of Appeal saw no difficulty "about reading the term "selling or supplying" in a manner that excludes supply pursuant to an individual prescription…".[108]

88. Accordingly, the law (as opposed to the market's understanding of the law) is as follows:

(1) Up to the point of prescription, off-label facilitation is unlawful.

(2) At the point of prescription, the doctor is entitled, in accordance with their clinical judgement, to prescribe off-label, and to that extent off-label facilitation is permitted.

(3) Thereafter, in that individual case (i.e. as regards that particular prescription) all steps involved in fulfilling it – even if they clearly involve off-label facilitation – are permitted. Thus, there is (as a matter of law) no legal risk to a pharmacy that elects to dispense *A* to a child on an "open" prescription.

(c) Market perception

89. We will consider the extent to which market perception of the regulation of off-label facilitation matters later on in this Judgment (Abuse of Dominance Infringements). For the present, we simply set out our findings in relation to the evidence we received. Although Dr Newton gave very detailed and clear evidence as to her view on the question of proper practice by a pharmacy when presented with an open prescription which could be fulfilled in an age-appropriate or age-inappropriate manner (because of

[105] This is certainly the position of the MHRA.

[106] *Bayer* (First Instance) at [118] to [119]; *Bayer* (CA) at [61], [82] and [118].

[107] *Bayer* (First Instance) at [127].

[108] *Bayer* (CA) at [162].

the way in which the date of birth is recorded on the prescription itself), we can set out the position quite shortly:

(1) Dr Newton made detailed reference to the Human Medicines Regulations and to the Association of the British Pharmaceutical Industry Code of Practice (the **ABPI Code**), which regulate the promotion of medicines, and in particular the prohibition on advertising a medicine outside the scope of its Marketing Authorisation.

(2) Dr Newton was careful to acknowledge that whilst she is an expert on market perception of the ABPI Code, and how the industry applies that code and the law that lies behind it, she was not a legal expert.[109]

(3) According to her evidence, it was not a breach of the ABPI Code for a company merely to know that their products were being used off-label. The prohibition would only apply in circumstances where the company promoted that use (which would include proactively highlighting bio-equivalence between an off-label alternative and a licensed drug),[110] or was aware that a wholesaler was promoting off-label use.[111] This difference was well understood in the industry.[112] We accept that evidence as being a true reflection of the general market perception and indeed as being in line with the law as we hold it to be.

(4) Turning then to the question of off-label prescriptions, Dr Newton referred to the MHRA Guidance on off-label prescriptions.[113] Her opinion as to the obligations on doctors when prescribing off-label was essentially common sense, and we accept her evidence. Doctors should not prescribe off-label unless: (i) it was in the best interests of the patient; (ii) such use would better serve the patient's needs than an appropriately licensed alternative; and (iii) the reason for the choice was recorded.[114]

(5) Dr Newton explained that in her view, when a doctor wrote an open prescription for hydrocortisone, that would not be off-label prescribing, given a licensed treatment was available.[115] The prescriber would not need to follow the MHRA Guidance in this situation, because a pharmacy would be expected to dispense in line with the patient's age where there was a choice between an age-appropriate and an age inappropriate product. Whilst we have every sympathy with Dr Newton's position – and consider that it may very well have represented the prevailing view amongst doctors – we do not consider it to be legally well-founded. The reason we have reached this conclusion is because: (i) our view of

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[109] Day 5/pp.32 to 34. In any event, as we have noted, the law is a matter for us.

[110] Day 5/p.43.

[111] Day 5/pp.44 to 46.

[112] Day 5/pp.46 to 47.

[113] *Off-label or unlicensed use of medicines: prescribers' responsibilities*, published 11 December 2014.

[114] Newton 1/17.

[115] Day 5/p.66.

the legal position is inconsistent with this stance; (ii) Dr Newton's approach places excessive weight on the presence of the patient's date of birth on the prescription, in a place which is not indicating that age is in any way significant to the product prescribed; and (iii) Dr Newton's approach results in therapeutic indications being inconsistently taken into account. Age can be informative – because (provided the pharmacist looks) age is apparent from the face of the prescription – but that is the only case.

(6) It seems to us that the burden of properly prescribing should fall on the doctor, and that if the doctor issues an open prescription that is the doctor's responsibility, and the doctor must "own" the outcome. We do not consider that it is generally appropriate for a pharmacy to second guess the doctor, and to presume that (by issuing an open prescription) the doctor is impliedly saying "please look at the date of birth of the patient, and give the appropriate product where there is a choice between age-appropriate and age-inappropriate products, but where there is only an age-inappropriate product, use that." We do not consider this to be the right implication to encourage. In this area, the doctor holds, and ought to hold, dominant sway.

(7) That being said, what matters is less the strict legal position than the perception of that position by the market. That is what determines market practice. Viewed in this way, we accept the general trend and direction of the evidence of Dr Newton, but not the ultimate extremity of Dr Newton's position. Thus:

(i) We consider that the implication of a doctor issuing an open prescription where there is a choice between two pharmaceutical products, both a proper response to the medicament prescribed, but one resulting in an on-label use, and the other in an off-label use, is that the on-label dispensing outcome would generally be perceived as preferrable.

(ii) We do not go so far as finding that the general perception in the market was that any other course was improper, and we consider that Dr Newton was too dogmatic in insisting that the on-label route was the course that a pharmacy must follow. That being said, we are quite prepared to accept that a risk-averse pharmacy might very well hold views like those of Dr Newton.

(8) Dr Newton's evidence was that when a pharmacy received an open prescription (which would not typically specify the patient's condition), a pharmacy would need to consider the MHRA Guidance before dispensing an off-label product. A pharmacy would have to record their reasons for off-label dispensation.[116] Although some pharmacists would know the relevant indication due to their case management system, not all would, and so they might need to call the prescriber for further details on the relevant indication for which the prescription was needed. In her view, the system was not designed to be "super easy" but designed

[116] Day 5/pp.82 to 83.

to ensure someone had carefully considered the MHRA Guidance.[117] In essence, Dr Newton's position was that a pharmacy should establish what condition an open prescription was intended to treat, and that failure to do so would be inconsistent with medicine usage and care quality. If pharmacists chose to dispense off-label on the basis of cost alone, this was not compliant with the MHRA Guidance, even in a case where the off-label product is bioequivalent and there were no patient safety concerns.[118]

(9) We consider that this goes too far, and we do not accept this evidence for the following reasons:

(i) It is tantamount to re-writing what we hold the law to be. As we have noted, there is nothing unlawful about the practice of off-label dispensing.

(ii) The implication of Dr Newton's evidence is that a large part of the pharmacy market was behaving in a manner well-short of best practice. We will come to describe this practice in due course, but it was clear from the evidence before us that a significant part of the market did not do what Dr Newton said they should have done. In light of our conclusion that there was nothing legally wrong in this course, we decline to make a finding of what is, in reality, unprofessional conduct.

(iii) There were other aspects of conduct not consistent with Dr Newton's view. Thus, the NHS could run tenders for hydrocortisone tablets where they awarded the contract to an off-label product on the grounds of price.[119]

(iv) If Dr Newton was right, then we consider the regime of open prescriptions would operate differently, with the decision and thinking of the doctor more clearly articulated on the face of the prescription.

90. We find that there was a sense within the body of pharmacies in the United Kingdom generally that, within the case of open prescriptions, the preferred course was to dispense the pharmaceutical product that was, on the face of the Marketing Authorisation and associated documentation, the product most appropriate for the patient. We do not say that a pharmacy could be criticised for taking another course, even if only because that other course produced a financial benefit to the pharmacy. But, and this (in a sentence) is what we derive from Dr Newton's evidence, forsaking that financial benefit on the grounds of regulatory prudence and good practice is, to put it no higher, understandable.

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[117] Day 5/pp.66 to 73.

[118] Newton 1/19; Day 5/pp.76 to 77 and 82.

[119] Day 5/p.81.

(8) "Orphan" drugs

91. An "orphan" drug is a pharmaceutical product indicated for the treatment of a rare disease or condition, "rare" in the sense that the patient population is sufficiently small to render it unviable for ordinary commercial pharmaceutical development. A prevalence of not more than five affected persons per 10,000 is generally regarded as the appropriate threshold for "orphan" status.[120]

92. In order to ensure that "orphan" conditions do not go untreated by pharmaceutical products that could be developed, but which are not developed for purely commercial reasons, incentives are created by law. Regulation (EC) No 141/2000 on orphan medicinal products entered into force on 28 April 2000 (the **Orphan Regulation**). The Orphan Regulation lays down a European Union procedure for designation of orphan medicines; defines incentives for the development and marketing of designated **Orphan Medicines**; and establishes the Committee for Orphan Medicinal Products.

93. The key constraint that matters for present purposes is that where a Marketing Authorisation in respect of an Orphan Medicine is granted, no subsequent application for a Marketing Authorisation shall be granted for the same therapeutic condition in respect of a similar medicinal product for a period of 10 years.[121]

(9) Price controls and price regulation

(a) Overview

94. The market is a highly regulated one, and the price controls and price regulation that apply are complex. For purposes of analysis, we include amongst these controls indirect controls on price, as well as direct controls. A direct control means exactly what it says: there is the ability – whether potential or actual – to control the price charged in the market by a supplier. An indirect control exists where a constraint on price arises not directly, but incidentally. The key example, in this case, is the Drug Tariff, considered above. This does not directly constrain a supplier at all: however, because a pharmacy is going to be very reluctant to pay more for a drug than the reimbursement price provided for in the Drug Tariff, some constraint does exist.[122] For present purposes, we are concerned only to identify and describe the various forms of regulation that existed at the material times.

95. We begin with the Drug Tariff; and then consider a series of price controls – including price controls capable of being deployed, but which were not in fact deployed.

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[120] The orphan drugs regime is described in Hydrocortisone Decision/3.152*ff*, and this description derives from those paragraphs.

[121] Hydrocortisone Decision/3.156.

[122] Although, as we have noted, there is no reason in law why the Drug Tariff reimbursement rate may not be lower than the price a pharmacy is obliged to pay for a drug.

(b) The Drug Tariff

96. The Drug Tariff is produced on a monthly basis "in arrears" by NHS Prescription Services and governs the reimbursement price that pharmacies can claim from the NHS when fulfilling prescriptions.[123] The reimbursement that pharmacies can claim is the Drug Tariff price subject to any price concessions agreed between the Department of Heath and Social Care and the Pharmaceutical Services Negotiating Committee.[124]

97. The Drug Tariff is calculated by reference to "virtual medicinal product packs", meaning products which are bioequivalent, and of the same strength and sold in the same pack sizes. However, and as was (at least at times) the case here, it may be that the "virtual medicinal product pack" comprises a universe of only one product, meaning that the Drug Tariff price is determined solely by that one product, albeit in arrears.

98. We considered the Drug Tariff at [64] above. As we have described, whilst the Drug Tariff is the primary mechanism for determining how dispensers – i.e. pharmacies – are reimbursed, for the reasons given in [64(6)] above, the Drug Tariff is an ineffective price control.

(c) Price controls

General

99. The price controls considered below are as follows:

    (1) The Secretary of State's general power to intervene in prices.

    (2) The "voluntary" schemes.

The Secretary of State's general power to intervene in prices

100. The Secretary of State has a general power to intervene in prices under the provisions of the National Health Service Act 2006 ("2006 Act"). Section 262(1) contains an apparently general power to "limit any price which may be charged by any manufacturer or supplier for the supply of any health service medicine". The only apparent limitation on this power is the requirement of "consultation with the industry body", a limitation contained within that section.

101. It was submitted to us that this apparently wide power was fettered or constrained or limited by other provisions, notably section 263 (concerned with the imposition of statutory schemes). In our view, this is a misreading of the relevant legislation. Section 262 is concerned with a specific price control, whilst section 263 is concerned with a

[123] Hydrocortisone Decision/3.174.

[124] Hydrocortisone Decision/3.174.

more general "scheme". Section 264 provides additional powers in relation to both, as the wording makes clear. Accordingly, we reject the CMA's contention in this regard.

102. The only limit to the power under section 262 – apart from the requirement of consultation and the general controls that would arise under the usual rules of judicial review – is contained in section 262(2), which provides (as from August 2017):

> "If at any time a health service medicine is covered by a voluntary scheme applying to its manufacturer or supplier, the powers conferred by this section may not be exercised at that time in relation to that manufacturer or supplier as regards that medicine."

The version in force prior to this provided to similar effect:

> "The powers conferred by this section are not exercisable at any time in relation to a manufacturer or supplier to whom at that time a voluntary scheme applies."

103. The general power to intervene thus cannot be exercised where there is a "voluntary" scheme in force and the supplier in question is a member of that scheme. However, the Secretary of State may take steps to eject the supplier from the "voluntary" scheme, and the supplier will then become subject to the Secretary of State's general power.

104. The Secretary of State's power has never been exercised under the 2006 Act. Indeed, even under the regime that preceded that contained in the 2006 Act, the parties before us were unable to point to any actual use of this power.[125]

Voluntary schemes

105. Voluntary schemes – which, nevertheless, have a high degree of bindingness when entered into (the "voluntary" refers to entry not to bindingness after entry) – are provided for in section 261 of the 2006 Act, in the sense that section 261 provides the means for the Secretary of State to eject a member of a voluntary scheme if certain conditions are met. That then opens the gateway to application of section 262, at least as regards future prices. (We doubt if there could be retrospective effect, but that is not a matter we need consider further.)

106. There are a number of voluntary schemes that are relevant, and which we briefly describe:

(1) The **Pharmaceutical Price Regulation Scheme** or **PPRS** was a voluntary agreement between the Department of Health and Social Care and the Association of the British Pharmaceutical Industry which applied to

[125] Mr Jowell, KC, noted in his submissions to us that this Tribunal's original judgment in *Flynn Pharma Ltd v. CMA*, [2018] CAT 11 recorded an informal intervention against Teva by the Department for Health for its phenytoin tablets, which led to a price reduction, in the context of Scheme M (Day 18/p.54). Mr Beighton gave evidence in those proceedings that Teva had a meeting with the Department for Health, who said that if Teva did not cooperate, they had the power to bring the price down (Day 11/p.72).

manufacturers and suppliers of branded medicines to the NHS (whether patented or not).[126]

(2) The **Category M Scheme** was a voluntary scheme between the Department of Health and Social Care and the British Generic Manufacturers Association, applying to those manufacturers and suppliers of generic medicines for use in the NHS who chose to join it.[127]

107. According to the Hydrocortisone Decision, whilst participation in the Category M Scheme was truly voluntary – in the sense that no other form of price control would be introduced if a supplier elected not to participate in the Category M Scheme – that was not so in the case of the Pharmaceutical Price Regulation Scheme. The Hydrocortisone Decision/3.77 states:

> "A company was able to choose not to become a member of the PPRS, and could be excluded by the Secretary of State. In such circumstances, a statutory pricing scheme would have applied to the company's branded products (but not to its non-branded generic drugs). See Section 3.D.I.d below."

Unfortunately, the Hydrocortisone Decision does not contain a Section 3.D.I.d, and it is not clear what this passage is referring to.[128] However, the regime that would apply in such circumstances was, from 1 April 2018, the Branded Health Service Medicines (Costs) Regulations 2018[129] and, prior to this, the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008 and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc) Regulations 2007.

E. A HISTORY AND DESCRIPTION OF THE "MARKET"

(1) Introduction

108. Having described the pharmaceutical products in issue (Section C above) and – in very general terms – the regulatory regime that applies (Section D above), we now set out (as neutrally as possible) the relevant factual background to the infringements found in the Hydrocortisone Decision. One of the unusual features of this case, which we have already touched upon, is how undertakings manufacturing and selling hydrocortisone medicinal products changed over time, and how the products entering and leaving the market also changed.

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[126] Hydrocortisone Decision/3.74 to 3.77. It was replaced in 2019 – but that is not material for present purposes.

[127] Hydrocortisone Decision/3.184 to 3.189.

[128] This may be a mis-reference to Section 3.E.I.d in the Hydrocortisone Decision, which begins at Hydrocortisone Decision/3.190. If so, then this section adds little to the description we have already provided.

[129] Hydrocortisone Decision at footnote 117.

109. Our description of the market[130] will not be chronological. It will be in accordance with the various Marketing Authorisations that – in this case – constitute the means of controlling the market in the manner that we have described. Thus, we consider the following Marketing Authorisations (which we abbreviate on occasion to **MA**) in the following order:

(1) The Merck, Sharpe & Dohme MA.

(2) The Plenadren MA (and the Orphan Medicine designation related to the Plenadren MA).

(3) Skinny Label MAs.

(4) The Waymade MA.

We explain these Marketing Authorisations in full in the following paragraphs.

(2) The Merck, Sharpe & Dohme MA

(a) Hydrocortisone "immediate release" tablets from 1955

110. Hydrocortisone "immediate release" tablets are a very old form of medicinal product. They were first sold in the United Kingdom in 1955,[131] and have long been out of patent.[132] For over 50 years, hydrocortisone immediate release tablets were sold by their originator, **Merck, Sharpe & Dohme** under the brand name Hydrocortone.[133]

111. As will be described, both the brand of Merck, Sharpe & Dohme's product (i.e. "Hydrocortone") and the Marketing Authorisation pursuant to which it was sold were on-sold a number of times. For the purposes of assessing the Hydrocortisone Decision, and for the purposes of this Judgment (Abuse of Dominance Infringements), it is important to keep a close eye on the reason why prices could lawfully be charged at all for these hydrocortisone immediate release tablets. That reason was the Marketing Authorisation, and we shall refer to it as the **Merck, Sharpe & Dohme MA**, although the rights to it transferred (directly or indirectly) many times over the years.[134]

112. The Merck, Sharpe & Dohme MA was granted on 23 February 1989.[135]

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[130] We should be clear that we are using the term in a non-technical sense. Market definition is a matter to which we will come in due course.

[131] Hydrocortisone Decision/3.101.

[132] Hydrocortisone Decision/3.101.

[133] Hydrocortisone Decision/3.102.

[134] Sale of medicinal products without a Marketing Authorisation is unlawful. The prices obtained for the medicinal products recorded as sold in Annex 3 are prices of products sold pursuant to a proper Marketing Authorisation. The existence of a Marketing Authorisation held by the vendor is a pre-condition to a lawful sale.

[135] Hydrocortisone Decision/3.204 (Table 3.4).

113. As branded products, the profits that Merck, Sharpe & Dohme made were regulated.[136] They were regulated under the PPRS Scheme (or a version of that scheme: we have no intention of setting out a comprehensive history of price regulation in this industry, and do not have the material to do so in any event).

114. It is at this point that we will begin to make extensive reference to Annex 3 to the Judgment (Abuse of Dominance Infringements), which we introduced in [5] above:

(1) Sales by Merck, Sharpe & Dohme under the Merck, Sharpe & Dohme MA are recorded between Period 1 and Period 3. The data – as can be seen from Annex 3 – exists only in annualised form. From Period 4 onwards, the data is available (and set out) on a monthly basis.

(2) As we have described, each row in Annex 3 that relates to a Period is colour-coded, where that coding relates to the Marketing Authorisation under which a particular medicinal product is sold. Thus, data regarding sales of 10mg immediate release hydrocortisone tablets under the Merck, Sharpe & Dohme MA is coded yellow. Similarly, data regarding sales of 20mg immediate release hydrocortisone tablets under the Merck, Sharpe & Dohme MA is coded green. In this way, Annex 3 differentiates between some of the various different medicinal products under consideration in this Judgment (Abuse of Dominance Infringements).[137]

(3) Each row in Annex 3 contains seven numbered columns ((1) to (7)). A number of these columns have already been described above,[138] but given the importance of this data some repetition is appropriate.

(4) Column (1) specifies the relevant date/date range/Period.

(5) Column (2) identifies the holder of the Marketing Authorisation for the data in that row. Thus, taking Period 1, we see data regarding sales of 10mg immediate release hydrocortisone tablets under the Merck, Sharpe & Dohme MA (coded yellow) and data regarding sales of 20mg immediate release hydrocortisone tablets under the Merck, Sharpe & Dohme MA (coded green). Beginning with Period 4, the holder of the Merck, Sharpe & Dohme MA changes to AM Pharma. The colour coding (which designates medicinal product sold under an MA) remains the same, but the holder of the MA (designated in Column (2)) changes.

(6) Column (3) specifies the "relevant parent or holding company or companies or persons". Often the actual holder of the Marketing Authorisation is itself a subsidiary of another company. The corporate structure of Merck, Sharpe & Dohme is (for the purposes of this Judgment (Abuse of Dominance Infringements)) nothing to the point, but structure does matter after Merck,

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[136] Hydrocortisone Decision/3.102.

[137] There are some medicinal products that feature in this Judgment for which we have no data. These medicinal products do not feature in Annex 3.

[138] See [5].

Sharpe & Dohme exit the story, having transferred their Marketing Authorisation to AM Pharma. Thus, to repeat what was said in sub-paragraph 5 above, Period 4 records under Column (2) that the Marketing Authorisation was held by AM Pharma, a company owned and controlled by Mr Amit Patel and Mrs Meeta Patel (as set out in Column (3)). That position changed in Period 59, when Mr Amit Patel and Mrs Meeta Patel interposed a holding company (Auden Mckenzie Holdings Ltd) between themselves and AM Pharma. The information in Column (3) matters for two, related, reasons. In the first place, the Marketing Authorisation was often transferred by the acquisition of the company holding it, not by actual transfer of the Marketing Authorisation itself. Thus, in Period 90, Auden Mckenzie Holdings Ltd, the parent of AM Pharma (holder of the Merck, Sharpe & Dohme MA), was acquired by Actavis plc. In acquiring Auden Mckenzie Holdings Ltd, Actavis plc also acquired AM Pharma and the MA, although the holder of the MA remained unchanged. In the second place, the CMA has looked beyond the holder of the MA for purposes of penalty. It is therefore extremely important to be clear about corporate structure.

(7) Column (4) states the price per pack at which any given medicinal product was sold for that Period and Column (7) states the quantities sold. It is to be noted that quantities sold varied significantly from period to period, as did the prices at which those units were sold. This data can be set out in graphical form, and the Hydrocortisone Decision makes appropriate and helpful use of graphical aids.[139] In this judgment we will – simply for purposes of ease of reference – primarily reference the data at Annex 3.[140] However, some visual aids are appropriate to show the general position:

(i) Annex 4A to this Judgment (Abuse of Dominance Infringements) sets out the volumes and prices sold for 10mg immediate release hydrocortisone tablets sold under the Merck, Sharpe and Dohme MA. Volume is represented by the dotted line, and price by the unbroken grey line. Time is plotted on the "x" axis, volume and price on the "y" axis (price on the left-hand side, volume on the right-hand side). As can be seen, volumes fluctuate considerably, but the average sales are broadly constant. The price line shows what was referred to in the hearing as the "Matterhorn": (i) a steep increase in prices up to around Period 21; (ii) a plateaux between around Periods 21 and 77; (iii) a further steep increase between Periods 77 and 113 (with a peak at around Period 97) followed by a steady, almost linear decline to an artificial cut-off at around Period 145.[141]

(ii) Scale, and generally the manner in which data is presented, can make a considerable difference.[142] Annex 4B also displays data regarding 10mg

[139] See, e.g. Figures 3.10, 3.11, 3.16, 3.22 and 4.12 of the Hydrocortisone Decision.

[140] It is easy to refer to data as at a Period in a table, rather less easy to identify unambiguously a point on a graph.

[141] Prices did decline further, but the CMA, for administrative reasons that we entirely appreciate, decided to limit the scope of its investigation to periods where the price was above a certain level.

[142] Another reason for preferring data in tabular form.

immediate release hydrocortisone tablets sold under the Merck, Sharpe and Dohme MA. The dotted line again represents volume and the unbroken black line price. Because scale is smaller, the "Matterhorn" is correspondingly flattened. This is because of the third metric illustrated, which is revenue (i.e. price multiplied by volume sold), which obviously requires a smaller scale. The "Matterhorn" appears, but is somewhat "spiky" because of the fluctuations in volumes.

(8) Considering the data as it appears in Annex 3 and as graphically represented in Annex 4, and confining ourselves, for the moment, to 10mg and 20mg immediate release hydrocortisone tablets sold under the Merck, Sharpe & Dohme MA (yellow and green in Annex 3), a number of points become apparent from the data:

(i) Apart from the time when Merck, Sharpe & Dohme were themselves selling hydrocortisone medicinal products (Periods 1 to 3), the data in Annex 3 is provided on a monthly basis i.e. each Period comprises one month.

(ii) Between Period 4 and Period 127, it can be seen that there are considerable fluctuations in price and in quantity sold. It will obviously be necessary to consider these in greater detail, as we will in due course, but it is important to understand that some fluctuations in quantity sold may simply be due to large orders being placed by wholesalers for their own needs at non-monthly intervals. Such fluctuations thus may very well not constitute a reaction to price change.[143] As a matter of basic prudence, it is better to look at trends rather than to seek to infer too much from month-on-month changes; and that is an approach we will adopt, as the CMA itself did.

(iii) Equally, whilst the price history is characterised by what can only be described as a steep ascent and an equally steep descent, there are what would appear to be at first sight oddities in prices where there is no particularly material increase or decrease in price, merely what might be said to be change for change's sake.[144] We anticipate that such changes are because these prices are average prices, and that where the composition of purchasers changed (as no doubt it will have done, month-by-month) so too will the average change, because the medicinal product in question was priced differentially according to purchaser. In short, we anticipate that the prices to purchasers remained fairly constant, and that the minor variations we are describing are due to an averaging effect across sales to different purchasers at different prices. Again, this emphasises the importance of reviewing trends, and not month-on-month changes.

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[143] For example, Periods 53, 64, 70, 73, 82 and 91.

[144] Thus, for instance, from Period 36 onwards, the price of 10mg "immediate release" hydrocortisone tablets (yellow in Annex 3) fluctuated around the £30 mark.

(9) Columns (5) and (6) concern price controls. Column (6) sets out the Drug Tariff price for the Period in question, whilst Column (5) indicates whether a direct price control regime operated. The figure in Column (6) – the Drug Tariff price – derives (as does all the data) from data provided by the CMA. The CMA in fact provided two sets of figures: the Drug Tariff Price and the **NHS Reimbursement Price**, which tended to be marginally lower than the Drug Tariff rate. This is because the latter includes a price concession agreed between the Department of Health and Social Care and the Pharmaceutical Services Negotiating Committee. The CMA, when providing the data, stated that the NHS Reimbursement Price "represents the true rate at which the pharmacies are reimbursed for the dispensing month for which the product is processed".[145] That is therefore the price used in Annex 3 (although, for simplicity, we refer to it as the "Drug Tariff").

115. Interspersed with data concerning Periods, are other events that are relevant to the chronology. These events are pure narrative, are cross-referenced back to the main part of the Judgment (Abuse of Dominance Infringements), and are coloured grey.[146]

116. Turning, then, from Annex 3 generally to the more specific, so far as the Periods in which Merck, Sharpe & Dohme were selling 10mg and 20mg immediate release hydrocortisone tablets (i.e. Periods 1 to 3), there is relatively little to say. Not only are these Periods of peripheral relevance to the Hydrocortisone Decision, there is little data available. What can be said is that:

(1) 10mg tablets were far more popular than 20mg tablets. That reflects what the Hydrocortisone Decision records,[147] and is generally true throughout the Periods recorded in Annex 3. Thus, in Periods 1 to 3, sales of 20mg tablets were less than 10% of the sales of 10mg tablets. Clearly, patients' dosing requirements rendered 10mg tablets more appropriate than 20mg tablets, and doctors prescribed accordingly.

(2) Given that 20mg hydrocortisone tablets will contain two times the dose of 10mg hydrocortisone tablets, it is interesting that in terms of volume of hydrocortisone supplied, 20mg tablets are far better value than 10mg tablets. Taking, simply, the prices in Periods 1 to 3, the position is as follows:

> 10mg tablets price at £0.70/pack, whereas 20mg tablets price at £1.07/pack. The price per mg is 0.178 pence in the case of 20mg packs, and 0.233 pence in the case of 10mg packs.[148]

If patients actually paid this price (and, of course, they would not – they would pay the prescription price, which would be the same as between the two tablet strengths), then this might be an indicator that not having to "split" tablets was

[145] Note 1 of Annex 1 of the data provided by the CMA to the CAT on 27 April 2023 and 15 May 2023.

[146] See also [5].

[147] See [42].

[148] I.e. in the case of 20mg, 107 / 30 / 20 = 0.178; and in the case of 10mg, 70 / 30 / 10 = 0.233.

something patients were prepared to pay a significant margin for. This is a feature of 10mg/20mg prices throughout the period considered in Annex 3.[149] The data shows that doctors considered it better for their patients to prescribe for them 10mg tablets, rather than 20mg tablets, but it is not possible to say anything more about the strength of that preference.

(b) Sale of the brand and Marketing Authorisation to AM Pharma

117. By 2007/2008 at the latest, Merck, Sharpe & Dohme were unable to make sufficient profit from the sale of Hydrocortone to persuade them to stay in the market.[150] On 21 April 2008,[151] Merck, Sharpe & Dohme sold both the brand (Hydrocortone) and the Merck, Sharpe & Dohme MA – i.e. 10mg and 20mg hydrocortisone "immediate release" tablets. The consideration received by Merck, Sharpe & Dohme was £200,000 (£190,000 for the Hydrocortone trademark, and £10,000 plus VAT for the Merck, Sharpe & Dohme MAs for 10mg and 20mg immediate release hydrocortisone tablets).[152]

118. The acquisition of the brand and the Marketing Authorisation was by **AM Pharma**. AM Pharma was a company focussed on the development, licensing and marketing of niche generic medicines and proprietary brands in the United Kingdom and across Europe.[153]

119. AM Pharma was, at this time, directly owned by Mr Amit Patel and Mrs Meeta Patel.[154] The ownership structure changed on 1 November 2012, when a holding company was interposed between Mr Amit Patel and Mrs Meeta Patel and AM Pharma. That company was **Auden McKenzie Holdings Ltd**.[155]

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[149] The division between 10mg immediate release hydrocortisone and 20mg immediate release hydrocortisone is illustrated in Annex 5 to this Judgment. We should make clear that this Annex presents the division between 10mg and 20mg sales in a simplified form, not differentiating between sales under different Marketing Authorisations.

[150] Information on this point is difficult to obtain due to the effluxion of time. But the sale of the brand and marketing authorisation at the rates we describe (which were low) is strongly suggestive that this was the case. In light of the price increases that subsequently occurred, this is remarkable. It is not a matter addressed in the Hydrocortisone Decision, but we did raise the point in the course of the hearing. In response, Ms Ford, KC (Day 11/pp.95, 97 to 99) suggested that the mechanism which enabled the price to be increased by AM Pharma was the debranding of the product, and that it was possible that Merck, Sharpe & Dohme could not or did not want to debrand because it was a member of the PPRS. Whilst this may explain the mechanism by way of which AM Pharma did what Merck, Sharpe & Dohme did not do, the question of why Merck, Sharpe & Dohme did not act differently still remains. We can take the matter no further and leave the point out of account. We do not consider it materially affects the outcome of this judgment.

[151] See between Period 3 and Period 4 of Annex 3.

[152] See Hydrocortisone Decision/3.338, and the documents there referenced.

[153] Hydrocortisone Decision/3.3 describes the nature of AM Pharma's business; Hydrocortisone Decision/3.103 describes the acquisition.

[154] Hydrocortisone Decision/3.4.

[155] The ownership structure is helpfully set out in diagrammatic form at Hydrocortisone Decision/Figure 3.1. In Annex 3, the change occurred between Period 58 and Period 59.

(c) AM Pharma's conduct after acquisition

120. On acquisition of the brand and the Marketing Authorisation, AM Pharma jettisoned the brand, removed the product from the Pharmaceutical Price Regulation Scheme, and sold the product as an unbranded, generic, product.[156] As such, the regulation which had applied to Hydrocortone (the Pharmaceutical Price Regulation Scheme) ceased to apply to the generic product formerly known as Hydrocortone.[157] No other form of price control mandatorily applied to the product; and AM Pharma did not enter any voluntary scheme.

121. The prices charged by AM Pharma were an increase over the prices charged by Merck, Sharpe & Dohme. Initially, the prices were £4.54 (for a 10mg packet) and £5.14 (for a 20mg packet). In the years following the acquisition, the price charged by AM Pharma for 10mg and 20mg immediate release hydrocortisone tablets increased, as can be seen from Annex 3 and (as regards the 10mg product) the graphs in Annex 4. Of perhaps greater significance, is that the revenue generated (i.e. price multiplied by volumes sold) also increased dramatically. In short, increased prices did not cause a material reduction in demand.[158]

122. In the period between the acquisition by AM Pharma of the brand and Marketing Authorisation to the sale, by Auden Mckenzie Holdings Ltd, of AM Pharma to **Actavis plc**, the following was the case:

(1) AM Pharma were the only supplier with Marketing Authorisations for 10mg and 20mg immediate release hydrocortisone tablets.

(2) There were either no, or no materially significant, alternative hydrocortisone medicinal products available for sale in the United Kingdom.

(3) The relationship between sales of 10mg hydrocortisone tablet and 20mg hydrocortisone tablets remained very much as it had been in Periods 1 to 3, in that sales of 10mg tablets predominated.

(4) The overall market demand for hydrocortisone appears to have been relatively stable. In other words, patient demand (intermediated by doctor prescriptions) did not significantly increase when viewed as an average.[159]

(5) There are two general (and related) consequences of this sort of market that one would expect to see – and which can be seen from the data in Annex 3:

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[156] Hydrocortisone Decision/3.103.

[157] Hydrocortisone Decision/3.103.

[158] By material, we mean that a fall in demand was not so great as to make the price increase not worthwhile in terms of revenue.

[159] There were, as we have described, "spikes" in some months, but which would appear to reflect a large order from a single wholesaler.

(i) First, price elasticity of demand is generally low in circumstances where there is an overall cap on demand. There is an overall cap on demand, because demand is based on patient need, clinically assessed by a doctor. If the price of the product in question falls, demand does not rise; and if the price rises, demand does not fall.

(ii) Secondly, in such circumstances, the supplier – if a monopoly – has every incentive to price as high as possible, because demand will not fall away on an increase in price, and demand will not increase on a price reduction.

(d) Sale of AM Pharma to Actavis plc in May 2015

123. **Actavis plc** is a global pharmaceutical company. On 29 May 2015 (Period 90), Actavis plc indirectly acquired the entire issued share capital of AM Pharma. As the Hydrocortisone Decision makes clear,[160] the acquisition was in fact of both AM Pharma, and the holding company of AM Pharma, Auden Mckenzie Holdings Ltd.

124. At about the time of this acquisition – in June 2015 – Actavis plc changed its name to **Allergan plc**.[161] We do not understand this change of name to have any other significance, but it does serve to add to the complexity of the narrative. We will use the name Actavis plc when describing events prior to June 2015 and the name Allergan plc when describing events thereafter. Where, in the 2015 period, it is not possible to identify which name would have been the applicable one, we will refer to **Allergan/Actavis plc**.

125. Shortly after the acquisition, AM Pharma's trading activities – including the business of selling hydrocortisone tablets – were transferred within the group to **Actavis UK Limited**.[162] Actavis UK Limited took over the business of supplying immediate release hydrocortisone tablets in the United Kingdom from 1 September 2015 (Period 93).[163, 164] AM Pharma and Auden Mckenzie thus cease their involvement and we need refer to them no more in this narrative.

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[160] See the diagram at Figure 3.1. In Annex 3, this occurred between Period 89 and Period 90.

[161] Hydrocortisone Decision/3.7.

[162] Hydrocortisone Decision/3.10

[163] I.e. Period 93 in Annex 3.

[164] Although the details of the acquisition probably do not matter, the CMA was assiduous in making inquiry. Thus, the shares in Auden Mckenzie Holdings Ltd were acquired by a subsidiary of the Allergan group, Chilcott UK Limited, pursuant to the terms of: (i) a Sale and Purchase Agreement dated 24 January 2015 between Mr Amit Patel and Mrs Meeta Patel, Actavis UK Holdings Limited and Actavis plc; and (ii) a Deed of Assignment dated 29 May 2015 between all of the parties with Chilcott UK Limited in addition.

The intra-group transfer of the business of Auden McKenzie to Actavis' existing UK generics business, Actavis UK Limited, was not effected by a formal written contractual arrangement.

(e) The Teva "acquisition"

126. In July 2015, Teva, a pharmaceutical company based in Israel, announced its intention to acquire Allergan plc's generics division.[165] The sale to Teva completed on 2 August 2016 (Period 104) and Teva became (through a chain of holding companies not material for present purposes) the indirect owner of Actavis UK Ltd (renamed **Accord UK Ltd** at Period 123).[166]

127. Allergan plc's generics division was, in terms of the geographic scope of its business, worldwide. In order to secure merger control clearance for the purchase of Allergan plc's generics division from the European Commission, Teva was required to divest itself of the United Kingdom part of the business it was acquiring through merger.[167]

128. For this reason, from 10 March 2016 (Period 99), Actavis UK Ltd was held separate under commitments given to the European Commission, pending divestment to a third party purchaser.[168] This **Hold Separate Regime** originally applied to Allergan plc's holding of Actavis UK Ltd and then – when Teva acquired Actavis UK Ltd – to Teva's holding of Actavis UK Ltd. The date on which Teva acquired Actavis UK Ltd, and the date on which Teva became subject to the Hold Separate Regime, was 2 August 2016 (Period 104).[169]

(f) Acquisition by Intas

129. Intas Pharmaceuticals Limited ("Intas") is a privately-owned pharmaceutical company based in Ahmedabad, India.[170] On 9 January 2017 (Period 109), Intas (through a chain of holding companies not material for present purposes) acquired – amongst other companies and shareholdings – the shares in Actavis UK Ltd.[171]

(g) The Teva-Allergan-Intas agreement in January 2018

130. In January 2018, Teva and Allergan plc entered into an agreement, which is described in the Hydrocortisone Decision as follows:[172]

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[165] Hydrocortisone Decision/3.13.

[166] The Hydrocortisone Decision/3.14 states that Teva also acquired AM Pharma. That is not, in our judgement, relevant to either the Hydrocortisone Decision or this Judgment. That was also the conclusion of the CMA: see Hydrocortisone Decision/3.17.

[167] Hydrocortisone Decision/3.14.

[168] Hydrocortisone Decision/3.15.

[169] Hydrocortisone Decision/3.15. The relevant periods in Annex 3 are between Period 98 and Period 99 and between Period 103 and Period 104.

[170] Hydrocortisone Decision/3.18.

[171] Hydrocortisone Decision/3.19.

[172] Hydrocortisone Decision at 3.16.

"In January 2018, Teva and Allergan entered into a settlement agreement and mutual releases for which Allergan made a one-time payment of US$703 million to Teva to settle the working capital adjustments under a Master Purchase Agreement dated 26 July 2015. In the context of this settlement agreement, Teva indemnified Allergan against losses arising from the CMA's investigation into hydrocortisone tablets. Teva also indemnified the acquirer of Accord-UK, Intas…against any losses in relation to anti-competitive conduct Accord-UK had been involved in up to the date of that acquisition. Teva therefore effectively bears contractual liability for the Infringements attributed to the Auden/Actavis undertaking up to January 2017."

(h) Change of name of Actavis UK Ltd

131. On 5 March 2018 (Period 123), Actavis UK Ltd was renamed **Accord-UK Ltd**. Again, we do not understand this change of name to have any other significance. We will use the name Actavis UK Ltd when describing events prior to 5 March 2018 and the name Accord-UK Ltd when describing events thereafter. Where it is not possible to identify which name would have been the applicable one, we will refer to **Actavis UK/Accord-UK Ltd**.

(3) The Plenadren MA

(a) The nature of Plenadren

132. We have described the nature of Plenadren.[173] This was a branded product.[174] As such, it fell to be controlled in accordance with the regime applicable to branded products described above. The Hydrocortisone Decision recognises this.[175] However, the Hydrocortisone Decision says very little about the actual effect of these controls on the price of Plenadren.

133. In contrast to the 10mg and 20mg tablets under the Merck, Sharpe & Dohme MA, Plenadren is a "modified release" tablet, not an "immediate release" tablet.

(b) Plenadren's status as an Orphan Medicine; and the Plenadren MA

134. Plenadren is an Orphan Medicine and received its Marketing Authorisation from the European Medicines Agency.

135. We draw from the Hydrocortisone Decision:

"3.158 On 22 May 2006, the European Commission granted an orphan designation to DuoCort AB for modified release hydrocortisone tablets (5mg and 20mg) in respect of the therapeutic indication "for the treatment of adrenal insufficiency". Since a pre-existing

[173] See [43].

[174] Hydrocortisone Decision/3.128

[175] Hydrocortisone Decision/5.417 fn 1858 (dealing with the question of whether Plenadren could be regarded as a comparable for market definition purposes).

treatment for the condition (immediate release hydrocortisone tablets) existed,[176] DuoCort was required to demonstrate that Plenadren would be "of significant benefit" to patients suffering from adrenal insufficiency – i.e., that it offered "a clinically relevant advantage or a major contribution to patient care" as compared to immediate release hydrocortisone tablets. This "clinically relevant advantage" was the modified release formulation, which mimics more closely the natural level of cortisol in the body over the course of a day than immediate release tablets.

3.159 The orphan designation was subsequently transferred to DuoCort Pharma AB in November 2008 and to Viropharma SPRL in February 2012. In November 2013, Shire plc acquired ViroPharma Inc and its group of companies, including the Plenadren portfolio. In February 2016, ViroPharma SPRL changes its name to Shire Services BVBA. In January 2019, Takeda Pharmaceutical Company Ltd acquired Shire plc (including Plenadren).

3.160 On 3 November 2011, the EMA[177] granted a centralised European MA for Plenadren (5mg and 20mg) in respect of the therapeutic indication "for treatment of adrenal insufficiency in adults".

3.161 The grant of Plenadren's MA and the orphan designation granted to modified release hydrocortisone tablets triggered a 10-year period within which no **new** MAs would granted and no extensions of existing MAs would be accepted for the therapeutic indication "adrenal insufficiency in adults" in respect of a "similar medicinal product"."

136. Plenadren came onto the market commencing in Period 73 and thereafter. The **Plenadren MA** was granted somewhat earlier in November 2011 (between Periods 46 and 47).

(c) Implications and relevance of Plenadren

137. The prices charged for Plenadren are, in one sense, not material to the Judgment or to the Hydrocortisone Decision because the prices for Plenadren were never under consideration by the CMA as being excessive. For that reason, no doubt, pricing information for Plenadren does not feature very much in the Hydrocortisone Decision.

138. However, given the nature of the appeal on the part of the Auden/Actavis Appellants in particular, Plenadren cannot be dismissed so easily. A central part of the attack on the Hydrocortisone Decision by the Auden/Actavis Appellants was that Plenadren was a substitute for "immediate release" hydrocortisone tablets, and that its pricing – at a level above that for "immediate release" hydrocortisone tablets – was a significant fact that needed to be taken into account. Without in any way pre-determining this question, we consider that the point – having been raised – has to be dealt with. Accordingly, whilst the nature of the undertakings selling Plenadren under the Plenadren MA are not material to this Judgment (Abuse of Dominance Infringements), the prices at which Plenadren was sold is a matter that needs to be borne in mind.

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[176] No doubt amongst other EU productions, this would have included supplies under the Merck, Sharpe & Dohme MA.

[177] I.e. the European Medicines Agency.

139. Accordingly, Annex 3 contains (colour-coded orange) pricing data concerning Plenadren over time. Annex 3 shows that the price of Plenadren was consistently well-above that of 10mg or 20mg immediate release hydrocortisone tablets, by a multiple of several times the price of the immediate release alternative. Annex 3 shows no particular shift away from immediate release hydrocortisone tablets to Plenadren, and this supports the conclusions in the Hydrocortisone Decision that (i) Clinical Commissioning Groups were doing their best to ensure that Plenadren was not prescribed by doctors and (ii) that as a result Plenadren was not prescribed unless a clear clinical need was established justifying Plenadren over-and-above an "immediate release" alternative.[178]

140. Plenadren is significant for a second reason, in addition to its possible (and argued for) status as a substitute for "immediate release" hydrocortisone tablet.[179] That second reason arises out of Plenadren's status as an Orphan Medicine. As to this:

(1) Plenadren's status as an Orphan Medicine did not affect the ability to sell 10mg or 20mg "immediate release" hydrocortisone tablets under the Merck, Sharpe & Dohme MA. That is because the Merck, Sharpe & Dohme MA pre-dated Plenadren's designation as an Orphan Medicine.

(2) Plenadren's designation as an Orphan Medicine did, however, have a material effect on all future Marketing Authorisations that might be sought in the ten year period from 3 November 2011 (the date of the Plenadren MA). That is because any similar medicinal product – such as immediate release hydrocortisone tablets – would not be granted a Marketing Authorisation (whether by original grant or extension) where the therapeutic indication specified was adrenal insufficiency in adults. The effect of Plenadren's designation as an Orphan Medicine thus meant that such later Marketing Authorisations would be therapeutically indicated for children but not for adults. They are – because of this (artificially) reduced list of therapeutic indications – referred to as **Skinny Label Marketing Authorisations** or **Skinny Label MAs**. Those Marketing Authorisations unaffected by Plenadren are (for obvious reasons) referred to as **Full Label Marketing Authorisations** or **Full Label MAs**.

(3) As will be described, a number of Marketing Authorisations were granted in respect of immediate release hydrocortisone tablets subsequent to the Plenadren MA. For the reasons we have given, none of these Marketing Authorisations identified adrenal insufficiency in adults as a therapeutic indication, because of Plenadren's Orphan Medicine status. In consequence, any "open" prescription for adrenal insufficiency would – if dispensed to an adult (but not a child) – by definition be "off-label".

141. Self-evidently, this must be a relevant factor for our consideration, and a great deal of evidence and submission was devoted to the point. Indeed, this is why the evidence of

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[178] Hydrocortisone Decision/3.130, 3.131, 3.133, 4.52.

[179] We stress that at this point of the Judgment we are simply seeking to establish the relevant facts. The fact that we do so is to enable us to evaluate the arguments, not pre-determine them.

Dr Newton, which we have described, is so important. Our analysis again comes later in this Judgment (Abuse of Dominance Infringements). For the present, we set out (in the next section) the Marketing Authorisations that were granted in respect of 10mg and 20mg immediate release hydrocortisone tablets after the Plenadren MA. Because all of these Marketing Authorisations could not extend to adrenal insufficiency in adults, they were referred to in both the Hydrocortisone Decision and before us as Skinny Label MAs, a term we have adopted, in contrast to the Merck, Sharpe & Dohme MA, which was (in this regard) a Full Label MA.

(4) Skinny Label Marketing Authorisations

(a) Type of Marketing Authorisations granted

142. Skinny Label MAs were granted both in respect of 10mg "immediate release" hydrocortisone and in respect of 20mg "immediate release" hydrocortisone.

(b) 10mg Skinny Label MAs

143. The Hydrocortisone Decision records that the following Marketing Authorisations were granted (also setting out the date supply commenced):[180]

Company	Date Skinny Label MA granted	Date of commencement of supply
Alissa Healthcare	25 Nov 2014	Oct 2015
Bristol Laboratories	12 Jan 2016	Mar 2016
Resolution Chemicals	1 Mar 2016	Mar 2016
AMCo (Aesica)	27 Sep 2012	May 2016
Teva	29 Nov 2016	Feb 2017
AMCo (Focus)	10 Oct 2016	Oct 2017
Genesis Pharmaceuticals	1 Jun 2017	Nov 2017
Renata	14 Aug 2017	Feb 2019

(c) 20mg Skinny Label MAs

144. The Hydrocortisone Decision records that the following Marketing Authorisations were granted (also setting out the date supply commenced):[181]

[180] Hydrocortisone Decision/3.204 (Table 3.4).

[181] Hydrocortisone Decision/3.204 (Table 3.5).

Company	Date Skinny Label MA granted	Date of commencement of supply
Bristol Laboratories	12 Jan 2016	Mar 2016
Resolution Chemicals	1 Mar 2016	Mar 2016
Teva	29 Nov 2016	Feb 2017
AMCo (Focus)	10 Oct 2016	Aug 2017
Genesis Pharmaceuticals	1 Jun 2017	Nov 2017
Renata	14 Aug 2017	Feb 2019

(d) Annex 3

145. For reasons which are obvious, the prices charged over time by these undertakings are relevant. They are set out in Annex 3 to this Judgment (Abuse of Dominance Infringements) (coloured blue).

(5) The Waymade MA

146. The **Waymade MA** was only in respect of 20mg "immediate release" hydrocortisone tablets. The Marketing Authorisation was granted on 11 May 1987.[182] Given this date was well before the Plenadren MA, the Marketing Authorisation was a Full Label MA.

147. Although the Waymade MA dates from 1987, supply by Waymade to pharmacies did not commence until much later, and under circumstances that need to be specifically described. Those circumstances are considered in detail below. The present confines itself to the bare facts, which involve an agreement between Waymade and Auden which the Hydrocortisone Decision describes as the 20mg Agreement, a term which we adopt.

148. According to the Hydrocortisone Decision, the 20mg Agreement existed between Waymade and all holders of the Merck, Sharpe & Dohme MA commencing with AM Pharma and including all subsequent holders of that MA until 30 April 2015.[183] The Hydrocortisone Decision characterises the 20mg Agreement in somewhat trenchant terms, which we will come to. In this Section, we simply set out, as neutrally as we can, the transactions that resulted from the 20mg Agreement, rather than considering the terms of the 20mg Agreement itself:

[182] Hydrocortisone Decision/3.204 (Table 3.5)

[183] Hydrocortisone Decision/1.4 (c).

(1) The 20mg Agreement was made on 11 July 2011 between Waymade and AM Pharma. The 20mg Agreement continued – with variations – until 30 April 2015.[184]

(2) From 11 July 2011 AM Pharma supplied per month 1,000 packs of 20mg "immediate release" hydrocortisone tablets to Waymade at £4.50/pack.[185]

(3) Of these 1,000 packs:

(i) 200 packs would be supplied to Waymade for sale on its own behalf. These sales are included in Annex 3, coloured red. (Given these were the less popular 20mg doses, Waymade could not always sell all 200 packs.) The 20mg Agreement ended in April 2015, according to the CMA, and after this point in time, Waymade stopped supplying the market pursuant to these arrangements, but commenced its own supply (as described in Hydrocortisone Decision/3.395) thereafter.

(ii) A set rate of packs (initially 800) would be bought back by AM Pharma at a market rate, initially £34.50. These "sales" are not included in Annex 3 because the sale of these packs will already be included in the AM Pharma figures. However, it is appropriate – at this point – to identify the cash-flow to Waymade as a result of this arrangement:

(1) Date or date period	(2) Quantity of product sold to Waymade by Auden and then bought-back by Auden	(3) Price paid by Waymade to Auden (per pack)	(4) Price paid by Auden to Waymade (per pack)	(5) Per pack difference between (3) and (4)
Jul 2011 to Mar 2013	800/month	£4.50	£34.50	£30.00
Apr 2013 to Sep 2013	928/month	£4.50	£42.00	£37.50
Oct 2013 to Nov 2013	928/month	£4.50	£51.00	£46.50
Dec 2013 to Mar 2014	982/month	£4.50	£51.00	£46.50
Apr 2014 to May 2014	982/month	£4.50	£59.77	£55.27
Jun 2014 to Oct 2014	982/month	£4.50	£60.50	£56.00
Nov 2014	982/month	£4.50	£62.50	£58.00

[184] Hydrocortisone Decision/3.375(a).

[185] Hydrocortisone Decision/3.370(a).

Dec 2014 to Apr 2015	982/month	£4.50	£71.50	£67.00

(iii) The profit per pack is obviously substantial. The table below shows profit per pack, profit per month on the basis of the quantities supplied and then an annualised figure:

(1) Date or date period	(2) Quantity of product sold to Waymade by Auden and then bought-back by Auden	(3) Profit per pack	(4) Profit per month (i.e. Column (2) x Column (3))	(5) Annualised profit (i.e. Column (4) x 12)
Jul 2011 to Mar 2013	800/month	£30.00	£24,000	£288,000
Apr 2013 to Sep 2013	928/month	£37.50	£34,800	£417,600
Oct 2013 to Nov 2013	928/month	£46.50	£43,152	£517,824
Dec 2013 to Mar 2014	982/month	£46.50	£45,663	£547,956
Apr 2014 to May 2014	982/month	£55.27	£54,272	£651,264
Jun 2014 to Oct 2014	982/month	£56.00	£52,992	£635,904
Nov 2014	982/month	£58.00	£56,956	£683,472
Dec 2014 to Apr 2015	982/month	£67.00	£65,794	£789,528

(6) The 10mg Agreement

149. The Hydrocortisone Decision concludes that an agreement was reached – initially between AM Pharma and Waymade and then between AM Pharma and AMCo – regarding 10mg "immediate release" hydrocortisone tablets. This agreement – the 10mg Agreement – was controversial before us and (as with the 20mg Agreement) we set out only the transactions that occurred pursuant to the 10mg Agreement. Although they arise principally for consideration in the Judgment (Cartel Infringements) we should record – if only for the purposes of the chronology in Annex 3 – that the 10mg Agreement was orally concluded with Waymade; thereafter with AMCo; and was given documentary form in the shape of a **First Written Agreement** and a **Second Written Agreement**. We do not need to expand upon these for the purposes of this Judgment (Abuse of Dominance Infringements).

150. The 10mg Agreement was concluded in October 2012.[186] According to this agreement, AM Pharma supplied, first to Waymade and then to AMCo 10mg "immediate release"

[186] Hydrocortisone Decision/6.11.

hydrocortisone tablets at a discount. The discount does not matter at this stage, nor do the precise terms of the agreement, which are in any event contentious and which we consider when we come to the Cartel Infringements. For present purposes, it is simply necessary to identify the volumes of product and prices at which that product was released into the market by Waymade or AMCo. These sales are recorded in Annex 3 coloured white on dark red.

F. ABUSE OF A DOMINANT POSITION CONTRARY TO THE CHAPTER II PROHIBITION

(1) The Chapter II prohibition

151. The Chapter II prohibition is contained in section 18 of the Competition Act 1998. It provides that "any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the United Kingdom".[187]

152. The question of whether an undertaking or undertakings have abused a dominant position requires the following steps to be considered and resolved:

(1) The market must be defined, and a finding of dominance must be made. In most cases, these jurisdictional questions are at least straightforward to test for. The market tends to be defined by reference to what is known as the hypothetical monopolist test, usually using what is known as a "SSNIP", although there is no need to use this test, and other tests are used for market definition. In this case, these jurisdictional questions of dominance in a market were highly controversial, and we will need to disentangle a number of different approaches that were put forward as to how this particular market must be analysed.

(2) We should explain – although it ought to be obvious – why we call these "jurisdictional" questions. The reason is that there can only be an abuse of a dominant position where a dominant position is found to exist. In other words, conduct permitted in or by a non-dominant undertaking, may be abusive conduct in or by a dominant one.

(3) Not only was the method by which the market was to be defined, and dominance identified, methodologically controversial, so too was the question as to whether dominance can be lost whilst an abuse is (or may be) on-going, and if so how. This is a question that is sufficiently fundamental as to require a degree of preliminary explanation now:

(i) Considering only, at this stage, the prices at which hydrocortisone supplied pursuant to the Merck, Sharpe & Dohme MA was sold, it is quite clear that these prices resembled what we called a "mountain". At times, the metaphor was stretched further, or rendered more specific, and

[187] Quoting from section 18(1). Article 102 TFEU requires an effect on trade "between Member States" and refers to the "internal market", but these differences are not material for present purposes.

"Matterhorn" became a name that was used during the trial also. Recognising that metaphor in legal analysis can be as dangerous as it is helpful, the point was as follows.

(ii) In this case, the high prices for 10mg and 20mg immediate release hydrocortisone tablets were bookended by low prices. This can be seen graphically from Annexes 4A to this Judgment (Abuse of Dominance Infringements), and is clear from Annex 3. This bookending of high prices by low – resulting in the "Matterhorn" – is unusual. Normally, a pharmaceutical product is initially sold at a high price. That is because it will, if a new product, be patented and will benefit from the monopoly conferred by patents on inventions. As the Hydrocortisone Decision describes, the development of medicinal products occurs in stages, beginning with patent protection and a monopoly, moving towards the entry of (first) one and then several "generic" competitors. The price that a competitive market would produce, in these circumstances, would look something like a cliff edge, with the edge softened by the extent to which the owner of the expired patented product and the single generic competitor could contrive to keep prices high. The Hydrocortisone Decision contains a helpful graph at Figure 3.3,[188] which sets out the stages in the commercialisation of a pharmaceutical product. The graph shows the price that would be expected in such a case as the blue line, which remains constant until the end of patent protection, when the cliff edge sets in. In this case, instead of a cliff edge, there is a mountain of ascending prices, reaching a peak, with then, on the other side of the peak, a decline in price resulting in reversion to "low prices".

(iii) It would be wrong – in that it would anticipate the outcome – to describe the prices in the valleys or plateaus[189] either side of the mountain as "competitive" prices. That would lead to the implication that the prices in-between are not competitive – which is precisely the question before us on this appeal. But we can say that the "mountain" of higher prices is bookended by lower prices, and that that is a phenomenon worthy of note and requiring of explanation.

(iv) The mountain, as we have noted, has upward and downward slopes. Those Appellants who sold "immediate release" hydrocortisone through the Merck, Sharpe & Dohme MA when the price was coming down – albeit still on the mountain – contended that there was no dominance at this stage. (They further contended that even if there was dominance, there was no abuse: this is an argument we will come to.)

[188] Hydrocortisone Decision/3.43.

[189] The terminology rather depends on one's optimism about markets.

Accordingly, it is going to be necessary to ascertain which undertakings were responsible for which parts of the "mountain".[190]

(4) It is also worth stressing that although this "mountain" is unusual in terms of pharmacological markets, it is by no means unusual *per se*. One example – which we referred to generally during the trial, was what was termed the **Face Mask Example**, drawing on what happened to the price of face masks during the COVID-19 pandemic. We stress that this was used as an example of a "mountain" that might be capable of justification. There is no empirical analysis behind the Face Mask Example (to that extent, the facts are assumed or hypothetical), and we rely upon it simply as a useful thought experiment or warning that things are not always what they seem. The example is as follows:

(i) Prior to the suggestion made during the course of the COVID-19 pandemic that face masks might assist in dealing with the virus, demand for face masks was low; and the prices correspondingly low. The capacity for producing additional face masks was limited in the short-run, although the market was contestable to those who chose to make the investment to enter.

(ii) When demand for face masks increased, supply could not immediately keep up. Prices rose, thus rendering the creation of new supply attractive to suppliers making other products.

(iii) Diversion of manufacturing capacity to make face masks took time. As a result (during this time) existing suppliers of face masks made monopoly profits. When supply increased to meet demand, prices fell.

(5) The prices in this scenario would look like our "mountain". An automatic assumption of abuse of dominance based solely on high prices would, however, be misconceived:

(i) The defensibility of the monopoly profits earned by the market incumbent(s) rests on an assumption of a contestable market – that is a market which does not have any improper barriers to entry. It is one thing for it to take time and investment for a rival manufacturer to gear up to produce more face masks. The high prices are precisely the encouragement that rival manufacturers not in the market need in order to be to induced enter it.

(ii) High prices in these circumstances, whilst not to be welcomed,[191] are the means by which the market creates greater capacity. Avoiding high

[190] It is for this reason that the CMA's definition in Hydrocortisone Decision/1.3 is not fit for purpose. The "umbrella" label "Auden/Actavis" cannot differentiate between these different periods of infringement, because all of the actors are thrown together into a single undertaking spanning what are, in fact, very different temporal segments.

[191] Consumers do not like high prices, and rightly so.

prices – by, for instance, rationing supply and controlling demand[192] – may serve to control prices, but at some considerable disadvantage: (i) the incentive to increase supply is lost; (ii) rationing involves the immediate assessment of need by reference to values that may be controversial; (iii) and "black" markets (that is to say unlawful markets) are generated by legal regimes that are inefficient in the sense that they cannot be controlled in practice.[193]

(iii) Of course, where a market is not properly contestable, such that there are barriers over-and-above the time and money it takes simply to enter the market, then the monopoly profits of the market incumbents are improperly maintained, and an abuse of dominance becomes more likely to exist.[194]

(6) The fact that increases and decreases in price over time cannot, of themselves, justify a conclusion of an abuse of a dominant position serves to underline the importance of analytical integrity. An entity that is not colluding (i.e. not infringing the Chapter I prohibition) and not dominant (i.e. not capable of infringing the Chapter II prohibition) will not have the market power to be abusive. Clearly, it is critical that markets be reliably defined so that conclusions as to dominance are rational and justifiable. In an ideal world, the assessment of dominance will be intuitive, and be readily defensible to the intelligent layperson.[195]

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[192] Cf the CMA's *Update on the work of the CMA's Taskforce*, published on 3 July 2020. This update stated:

"The price consumers are prepared to pay for essential goods is less likely to be a reflection of their preferences, and more likely to be a reflection of their income. There is a risk that anxious wealthier consumers buy-up all the stock at the hiked prices while others, who may need products such as hand sanitiser even more, are faced with empty shelves. The result is not a socially optimal allocation of the product, but simply an inability of the less well-off to acquire it. In such circumstances, quantity rationing (i.e. restrictions on the number of the same item a consumer can purchase), rather than rationing on the basis of ability to pay, is likely to lead to better outcomes."

Such a position is only economically defensible if the market is not properly contestable. Of course, our example is hypothetical, whereas the CMA was considering the actual market before it.

[193] See, for instance, the problems caused by prohibition in the United States from 1920. There is no question of moralising here: it is simply that an inefficient legal regime (whereby that which is prohibited in law cannot easily be stopped as a matter of practice) generates "false" incentives. Demand is not controlled, but is met by illegal supply at a premium price which factors in the costs of law-breaking. See, for example, Behr, *Prohibition: The 13 years that changed America*, 1st ed (1997), ch 12; McGirr, *The War on Alcohol: Prohibition and the Rise of the American State*, 1st ed (2016).

[194] See, for example, Kianzad in *Concurrences* (Feb 2021), *Excessive Pricing During the COVID-19 Crisis in the EU: An Empirical Inquiry*:

"As a departing point of analysis of competition law dynamics in times of pandemic, a surge in demand combined with shortages in supply invariably causes the prices to rise, sometimes dramatically so. Nevertheless, due to pandemic specific conditions (lockdown nullifying mobility and choice of consumers, the necessity of face masks, hand sanitizers and disinfectants due to public orders and overall measures to combat the pandemic), the legal "fairness" rules ought to inform the analysis to a greater extent, as opposed to normal times, where competitive market forces are presumed (at least in theory) to act as price arbiters."

[195] Whilst, unsurprisingly, this Tribunal places considerable weight on economic analysis and values greatly the input of economists, competition law is too important to be left to the expert. It is vital – if only for compliance

(7) Related to this is the question of abuse. Whilst it is well-recognised that excessive prices can constitute an abuse of a dominant position, this is an area of abusive conduct that competition courts the world over have rightly treated with considerable caution. The reason is that price is the outcome not of any kind of central and predictable process (as it might be in a "command" economy), but because of the interplay between supply and demand in markets. Why should the face mask sell so far above cost? There is a natural explanation: fear of infection from COVID-19, and a sense (that might or might not be right) that a face mask enables its wearer to avoid infection.[196] But there are other, altogether less rational markets. Why, for example, do some purchasers acquire a more expensive iPhone when there are materially cheaper handsets with a similar functionality at least so far as connectivity is concerned?[197] Whilst it undoubtedly may be the case that the cost of producing the iPhone is more than that of rivals, we would be surprised if the cost difference fully informed the difference in price. Rather, there is something in the value attributed to a product that drives (at least in part) its price.

(2) The dangers of backward reasoning

153. Particularly where the abuse alleged is one of excessive pricing, there is great danger in reasoning backwards from a perceived excessive – and so potentially abusive – price. The backwards reasoning goes like this:

(1) Only a dominant undertaking can raise price so as to constitute an abuse of a dominant position. If the undertaking were not dominant, competition would ensure a "proper price".

(2) Therefore, if the price is abusive, the undertaking is dominant.

(3) If the undertaking is dominant, then the market must be defined consistently with that finding of dominance.

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reasons – that it be readily comprehensible. See *BGL* at [114(8)]: "It is important that market definition not be over-analytical or over-dependent on expert evidence. It is necessary that the law be predictable to those persons who are subject to it, so that their behaviour can conform without the need for regulatory intervention. It may be that a market is sufficiently technical to require technical expert evidence as regards the product and its uses, but (as a general proposition) we do not consider that this Tribunal will always be assisted by solely expert economic evidence on questions of substitutability. It is incumbent on the parties to consider and establish the probative value of expert economic evidence on this issue. Although we appreciate that market definition is, from time-to-time, referred to as a science, we consider such a description to unduly accentuate the technical aspects of what ought to be a common sense exercise of judgement, informed substantially by an understanding of the thinking of the persons in the market in question."

[196] Some say that face masks are better at avoiding spread of infection to others than in protecting the wearer. It may be that this altruistic motive informed demand, but we rather doubt it. We suspect that it was a desire (whether well-founded or not) to avoid infection that drove demand. The point about a market economy, however, is that it avoids the need to resolve such questions and the need to justify demand. In the market economy, demand does not have to be justified: it is the trigger by which supply to the market is encouraged and the demand (be it rational or irrational) fulfilled.

[197] See *Optis Cellular Technology LLC v. Apple Retail UK Ltd*, [2023] EWHC 1095 (Ch) at [34(iii)].

154. Particularly in difficult cases, it is important to keep the processes of (i) market definition, (ii) dominance and (iii) abuse as distinct analytical stages. Take an allegedly wantonly or obviously abusive monopoly, where it appears that the monopolist is charging abusive monopoly rents because (i) the monopolist has the market power and (ii) it pays the monopolist to exercise that power because high margins on low sales are what brings in more revenue than smaller margins on higher sales. In such a simple case, it is tempting to reason from outcome, as follows: (i) the price is abusively high (the outcome), (ii) therefore there is dominance (because the monopolist could not abuse market power without dominance) and (iii) therefore the market has got to be defined as excluding what might otherwise be regarded as substitutes to the monopolist's product, so as to achieve the dominance in the market to render an abuse of dominance possible.

155. The problem with this sort of reasoning is that whilst the conclusion (an abuse of a dominant position) may be right, the reasoning assumes that which needs to be tested for. For that reason, this approach is to be deprecated as creating an avoidable risk of wrong outcomes. The fact is that there are many explanations for high prices that are consistent with competitive behaviour and inconsistent with a finding of infringement of the Chapter II prohibition. For example:

(1) An undertaking may have a statutory monopoly (e.g. a patent) which enables it to charge a premium, because competitors can be excluded. Such a premium is by no means necessarily an abuse of a dominant position. Yet the existence of an intellectual property right may well create a dominant position. The point is that there is no necessary connection between dominance and abuse.

(2) Circumstances may render a price temporarily very high. The Face Mask Example (assuming a contestable market) is a case in point. A dramatic spike in demand enables high prices to be charged, but only whilst other suppliers gear up to enter the market themselves in order to take advantage of the high prices, and thereby bring them down through the provision of additional supply to meet excess demand. There may be natural barriers to entry that make it costly in terms of money and time to enter (the market may be difficult to contest) but that does not render either the conclusion of an abusive price or the conclusion of a dominant position inevitable.

(3) Our approach and the structure of the next sections of this Judgment (Abuse of Dominance Infringements)

156. An infringement of the Chapter II prohibition can only arise where there is an abuse by an undertaking of a dominant position, in circumstances where the undertaking's dominance can only be assessed where the market (in which the undertaking operates) has been defined. Infringements are, therefore, assessed in terms of:

(1) Market definition.

(2) Dominance of the undertaking within that market.

(3) Abuse, by that undertaking, of its dominant position.

157. The next sections of this Judgment (Abuse of Dominance Infringements) deal with these three topics in this order. Thus, Section H considers market definition; Section I considers dominance; and Section J considers abuse of dominance.

158. Before, however, we turn to these three topics, it is necessary to "parse the Matterhorn" and to ascertain precisely how the CMA allocated responsibility (and penalty) amongst the Appellants. It is important to do this now because the CMA has made findings of infringement of the Chapter II prohibition against actors (the Appellants) who came into the market in sequence, one after the other. Their responsibility for the "mountain" must therefore be considered in the context of their sequential roles. It is, therefore, this topic that we turn to next, in Section G.

G. "PARSING THE MATTERHORN": FACTUAL RESPONSIBILITY AND FINDINGS OF SEQUENTIAL LIABILITY BY THE CMA

(1) Introduction

159. As we have noted,[198] the Hydrocortisone Decision finds that various of the Appellants committed Abuse of Dominance Infringements. The purpose of this Section is to set out with precision and by reference to Annex 3 precisely which undertakings were found to have committed Abuse of Dominance Infringements and for what periods.

160. Before setting out the findings that were made in the Hydrocortisone Decision, it is necessary to set out the theory of liability pursuant to which firms are found to infringe competition law, and how they can in law be penalised. Self-evidently, there is a close connection between infringement and penalty, although the connection is in no way an automatic one. It is, as we will see, perfectly possible for a firm to infringe competition law and yet not be liable to be punished.

(2) Theories of liability and punishment

(a) The undertaking as the "unit of account"

161. The Chapter II prohibition – like the Chapter I prohibition – imposes a duty on undertakings not to infringe these prohibitions. Thus, the Chapter I prohibition (and its TFEU equivalent, Article 101 TFEU) prohibits certain "…agreements between undertakings, decisions by associations of undertakings or concerted practices…",[199] whilst the Chapter II prohibition (and its TFEU equivalent, Article 102 TFEU) prohibits "…any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position…".[200]

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[198] See [9] .

[199] To quote from section 2(1) of the Competition Act 1998. Emphasis added.

[200] To quote from section 18 of the Competition Act 1998. Emphasis added.

(b) The meaning of "undertaking"

162. In Case C-41/80, *Höfner and Elser v. Macroton GmbH*,[201] the CJEU stated that "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". "Economic" activity is broadly conceived as "any activity consisting in offering goods and services on a given market".[202]

163. As was noted by the Tribunal in *Sainsbury's Supermarkets Ltd v. Mastercard Inc*,[203] "[a]n undertaking therefore designates an economic unit, rather than an entity characterised by having legal personality." In *Hydrotherm Gerätebau GmbH v. Compact de Dott Ing Mario Andreoli & C Sas* (Case C-170/83), [1984] ECR 2999 at [11], the Court of Justice stated that "[i]n competition law, the term "undertaking" must be understood as designating an economic unit for the purpose of the subject-matter of the agreement in question, even if in law that economic unit consists of several persons, natural or legal"."

164. The Tribunal went on to say this in *Sainsbury's*:

> "357. Because the focus of EU law is on the economic, rather than the legal, nature of an entity, a number of individual legal bodies can be treated as a single undertaking for the purposes of competition law.
>
> 358. Thus, a single undertaking may comprise a parent company and its subsidiary, provided that the relationship between them is such that they form a single economic entity. Equally, an employee (obviously a natural person in his or her own right) will typically be part of the undertaking that employs him or her. Similarly, an independent contractor and the person engaging that contractor can be a single undertaking. In *Marlines SA v. Commission of the European Communities* (Case T-56/99), [2003] ECR II-5225, a cartel case, the Court of First Instance (now the General Court) had to consider whether a manager of certain vessels was a part of the same economic unit as the owners of those vessels. The Court concluded that he was, and stated at [60]:
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> > "It is clear from case-law that, where an agent works for his principal, he can in principle be regarded as an auxiliary organ forming an integral part of the latter's undertaking bound to carry out the principal's instructions and thus, like a commercial employee, forms an economic unit with this undertaking (*Suiker Unie and others v. Commission*, cited above, [539]."
>
> 359. The basic definition of an undertaking – set out in [352] to [355] above – is uncontroversial. The concept is neutral as regards legal personality, and does not seek to define itself by reference to the legal persons that might comprise it."

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[201] EU:C:1991:161 at [21].

[202] Case C-180/98, etc, *Pavlov*, EU:C:2000:428 at [75].

[203] [2016] CAT 11 (***Sainsbury's***) at [356]. The discussion of what constitutes an undertaking at [351] to [360] generally is helpful and one that we adopt.

165. Thus, when considering what legal entities may have infringed competition law, an economic approach must be taken. The undertaking is defined by reference to the economic unit and economic functionality. To move, for a moment, from the abstract to the concrete, and to refer to Annex 3, Column (2) in that Annex lists in each case the holder of the relevant Marketing Authorisation. Where an infringement involves the sale of medicinal products at an abusively excessive price in breach of the Chapter II prohibition, it is clear that the starting point for defining the undertaking must be this entity, for the Marketing Authorisation is central to the ability to sell the medicinal product. Without a Marketing Authorisation, the medicinal product cannot lawfully be sold; and (as we have seen) what is pharmacologically the same product can be differentiated by a Marketing Authorisation.[204]

166. But the meaning of undertaking can extend further, including in particular to the persons described in Column (3) of Annex 3. It is important that we are very clear: Annex 3 does not purport to define what was and what was not an "undertaking" in any given case. Column (3) simply sets out the persons – natural and legal – who held or owned the holder of the Marketing Authorisation described in Column (2). The approach, in other words, is legal, not economic. We are describing corporate structures, not undertakings. The mere fact that persons are part of the same legal or corporate structure does not mean that they are part of the same undertaking. However, it is important to identify the legal structures, in order to work out which entities form part of the undertaking, and which do not.

(c) The "functional approach" to undertakings

167. As Whish and Bailey note,[205] the same legal entity may be acting as an undertaking when it carries on one activity but not when it is carrying on another. A "functional approach" must be adopted when determining whether an entity, when engaged in a particular activity, is doing so as an undertaking for the purpose of the competition rules.

(d) Translation from undertaking to "legal" person

168. As was noted in *Sainsbury's*, "[t]he problem with the economic basis for the meaning of an "undertaking" is that at some point it must be translated into legal terms: at some point, it will be necessary to be clear as to which legal persons form a part of the undertaking and which do not. This point has been clearly expressed both by the EU courts and the English courts".[206]

169. This translation process is precisely what we were referring to at paragraph 165 above. It will be necessary, in order to ascertain which legal persons are guilty of primary infringement of the (in this case) Chapter II prohibitions; and that turns on reading across the economic unit concept of the undertaking onto the corporate legal structure that pertains in any given case, remembering always that it is perfectly possible for a

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[204] As in the case of immediate release hydrocortisone tablets sold under a Skinny Label MA, in contrast to the same product sold under a "full label" MA.

[205] Whish and Bailey, *Competition Law*, 10th ed (2021) at 86. Cited with approval in *Sainsbury's* at [360].

[206] *Sainsbury's* at [363(1)].

corporate structure to embrace many natural and legal persons, many of whom may not be a part of the undertaking and so not guilty of any infringement by that undertaking.

(e) "Secondary" liability

170. It is, thus, entirely possible for a person, part of the legal corporate structure of a group not to be part of an infringing undertaking, and so not liable for that infringement of competition law.

171. Any law-based analysis of liability for legal infringements may have a form of secondary liability. This is characteristic of English law. Where an employee, acting within the scope of their employment,[207] does a tortious act and injures a third party, not only will the employee be liable in tort to the third party, but so too will the employee's employer, according to the doctrine of vicarious liability. More widely, the law of agency can render a principal liable for the acts (including wrongful acts) of their agents, and agents' knowledge and/or acts can be attributed to the principal.

172. It is, however, unnecessary to consider the English common law in this area. The relevant law is English law as derived from EU law and retained as the law of the United Kingdom post the UK's departure from the EU. The principle is that it is the undertaking that is liable.[208] The concept of an undertaking serves to create a link between a subsidiary and a parent company such that – even if the parent had nothing to do with the specifics of an infringement committed by the subsidiary – the parent is nevertheless part of the same undertaking provided only that the parent could and did in fact exercise decisive influence over the subsidiary with the result that the latter did not enjoy "real autonomy" in determining its commercial policy on the market.[209]

There is great danger in using the language of vicarious liability and agency when considering this form of liability. Thus, the Allergan Written Closing Submissions tended to refer to the imputation of a subsidiary's conduct to its parent.[210] We do not consider the language of imputation to be helpful, because it is redolent of precisely those doctrines of agency and vicarious liability that do not apply in this case.

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[207] We have no intention of even summarising the law of vicarious liability. We appreciate that the scope of the doctrine has significantly developed in recent years: but, as we describe, we are not here concerned with vicarious liability under English law.

[208] To the exclusion of national law processes of attribution: Case C-724/17, *Vantaan kaupunki v. Skanska Industrial Solutions Oy*, EU:C:2019:204.

[209] Whish and Bailey, 96. See also Advocate General Warner in Joined Cases 6 and 7/73, *ICI and Commercial Solvents Corporation v Commission,* EU:C:1974:5: "That argument is that, **in order for the parent and subsidiary to be treated as a single undertaking**, "there must be (a) power of direction of the parent company over the subsidiary and also (b) the actual exercise of the parent's control to such an extent that the subsidiary does not determine its behaviour on the market in an autonomous manner, but essentially carries out the instructions given to it by the parent company. "The yardstick", it is said, "is the complete absence in a subsidiary of the power to determine its own market behaviour. The possibility of control by the parent is not sufficient; what is needed is the actual exercise of such control to the extent that the subsidiary loses market autonomy" (emphasis added).

[210] See, for example, at [77.1] and [77.3].

173. The point is made with clarity in *Tesco Stores Ltd v. Office of Fair Trading*.[211] In particular:

> "60. Attribution of a mental state to a corporate entity depends on the interpretation of the legal rule that calls for the question of attribution to be decided (*Meridian Global Funds Management Asia Limited v. Securities Commission*, [1995] 2 AC 500, at 507, per Lord Hoffmann). The relevant legal rule in this case is the Chapter I prohibition. Hence, the state of mind to be attributed to an undertaking should be determined as a matter of UK and, by virtue of section 60(2) of the 1998 Act, EU competition law. Common law concepts of ostensible authority and/or vicarious liability are therefore not relevant (see Case No. 1122/1/1/09 *AH Willis & Sons Limited v OFT* [2011] CAT 13, paragraphs 23-26).
>
> 61. An "*undertaking*" is not defined in the 1998 Act, nor in the TFEU, but its meaning has been clarified by the jurisprudence of the EU Courts. It is well-established that an undertaking does not correspond to the commonly understood notion of a legal person under, for example, English commercial law. It is much wider and can include several corporate entities, so long as they are acting as a single economic unit and the corporate entities within this unit do not act independently on the market (*Willis*, paragraphs 27-30 and the case law cited there).
>
> 62. In *Suiker Unie*, the Court of Justice stated, at [539], that employees form part of the same undertaking, or "*economic unit*", with their employer. Employees are "*auxiliary organs forming an integral part of the principal's undertaking*" ([542]). It was on this basis that the Court of Justice attributed the employees' collusive activities to their respective employers in the sugar industry. Since an undertaking comprising a body corporate can only act through the individuals employed by it, the acts or conduct of an undertaking are inevitably performed by those individuals. It follows that any act by any employee could, potentially, lead to an infringement attributable to their corporate employer, with whom they comprise the same undertaking.
>
> 63. It appears to have been common ground that Tesco was the undertaking responsible for the acts of (at least) Mr Scouler, Mr Hirst and Mrs Oldershaw, which were found by the OFT to comprise the Infringements during the course of 2002 and 2003. It was not suggested by Tesco that any of these individuals acted without authority or disobeyed instructions given to them."

174. It will be necessary to consider the **Decisive Influence Test**, by which a parent may become part of the same undertaking as its subsidiary, in greater detail when we come to consider the various entities involved in the Abuse of Dominance Infringements. For the present, however, we would only observe that the concept of the undertaking in essence elides the English law notions of primary and secondary liability.

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[211] [2012] CAT 31 (***Tesco***) at [60]*ff.*

(f) Power to impose penalties

175. Section 36 of the Competition Act 1998 states (so far as presently material):

> "(1) On making a decision that an agreement has infringed the Chapter I prohibition, the CMA may require an undertaking which is a party to the agreement to pay the CMA a penalty in respect of the infringement.
>
> (2) On making a decision that conduct has infringed the Chapter II prohibition, the CMA may require the undertaking concerned to pay the CMA a penalty in respect of the infringement.
>
> (3) The CMA may impose a penalty on an undertaking under subsection (1) or (2) only if the CMA is satisfied that the infringement has been committed intentionally or negligently by the undertaking.
>
> …"

176. Two points are significant: first, exposure to a penalty is again by reference to the undertaking; and secondly, the power to impose a penalty requires that the CMA be satisfied that the infringement was committed "intentionally or negligently by the undertaking".[212] State of mind of the undertaking is therefore a jurisdictional requirement to the CMA's ability to penalise infringements.

(g) Conclusions

177. Drawing together the threads, the position is as follows:

(1) Knowledge and state of mind can be relevant to infringements of competition law, even though the Chapter I and Chapter II prohibitions are "strict liability". This is particularly clear when the jurisdiction to penalise for infringements under section 36 of the Competition Act 1998 is considered, but (as Lord Carlile, QC noted in *Tesco*) there are other reasons why state of mind can matter.[213]

(2) Attribution of a mental state (including knowledge) to an entity depends on the interpretation of the legal rule that calls for the question of attribution to be decided. Here, we are concerned with infringements of the Chapter I and Chapter II prohibitions: the entity whose state of mind (where that is material) must be ascertained is that of the undertaking, which is (as we have described) understood as an economic unit and not a concept based upon corporate legal structure.

(3) All kinds of actors – employees, independent contractors, corporations – can form part of the same undertaking. Whether a parent company, not otherwise

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[212] Emphasis added.

[213] See *Tesco* at [64]*ff*.

involved in the economic activity of its subsidiary, is part of the same undertaking depends upon the Decisive Influence Test, a test it will be necessary to come back to.

(4) What is clear, however, is that the knowledge and state(s) of mind of all actors part of the undertaking are the undertaking's knowledge and state of mind without more. Common law concepts of ostensible authority and/or vicarious liability are simply not relevant and should be avoided. Equally, the language of attribution – to the extent that it evokes these common law concepts – is to be avoided.

(3) The CMA's findings in regard to Abuse of Dominance Infringements

178. The CMA made a number of findings as regards the Abuse of Dominance Infringements. The Hydrocortisone Decision makes broad-brush findings in this regard, finding that:

(1) There was an Abuse of Dominance Infringement in respect of 10mg immediate release hydrocortisone tablets sold under the Merck, Sharpe & Dohme MA from 1 October 2008 (Period 10 in Annex 3) to 31 July 2018 (Period 127 in Annex 3).[214]

(2) There was an Abuse of Dominance Infringement in respect of 20mg "immediate release" hydrocortisone tablets sold under the Merck, Sharpe & Dohme MA from 1 October 2008 (Period 10 in Annex 3) to 8 January 2017 (Period 108 in Annex 3).[215]

A fine of £155.2 million was imposed in respect of these infringements.[216] We accept that the manner in which the CMA attributed penalties to different entities did take into account the shifting nature of the undertaking(s) in this case and we will come to penalty in due course. For the present, our concern is that, when considering whether there was even an Abuse of Dominance Infringement, the Hydrocortisone Decision adopts far too broad a brush.

179. We consider that the "Matterhorn" must be analysed or broken down into a number of distinct phases, reflecting the economic ownership and control of the Merck, Sharpe & Dohme MA over time, and for the Abuse of Dominance Infringements to be considered in respect of each distinct phase. For the present, we confine ourselves to identifying the various phases in this case:

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[214] Hydrocortisone Decision/1.4(a) (Ref only). The decision uses the umbrella "Auden/Actavis" definition, which we have criticised and which fails to differentiate between the differently shaped undertaking over time. Annex 3 shows the shifting changes in ownership of both the entity holding the Marketing Authorisation for 10mg and 20mg immediate release hydrocortisone tablets and of the parent companies of those entities. These are differences that go not merely to penalty (where we accept the CMA considered these questions) but also to infringement (where the CMA did not).

[215] Hydrocortisone Decision/1.4(b) (Ref only).

[216] Hydrocortisone Decision/1.73(a) (Ref only).

(1) *Phase 1.* This phase begins with Period 10, when AM Pharma, Mr Amit Patel and Mrs Meeta Patel owned and controlled the Merck, Sharpe & Dohme MA and ends with Period 89, when Mr Amit Patel and Mrs Meeta Patel sold their business to Actavis plc. As we have described, from Period 59 Auden McKenzie Holdings Ltd was interposed between AM Pharma and Mr Amit Patel and Mrs Meeta Patel, but we do not consider this to be material to the analysis. We refer to this phase as the **Patel Phase (Phase 1)**, because Mr Amit Patel and Mrs Meeta Patel were the ultimate holders and owners of the relevant corporate entities during this period.

(2) *Phase 2.* Phase 2 begins at Period 90, when Actavis plc's ownership of AM Pharma and Auden Mckenzie Ltd began. There are several changes in corporate ownership and name which are recorded in Annex 3, but which are in fact not material (because they were "internal" only). Phase 2 ends with the commencement of the Hold Separate Regime (Period 98), for (as we will describe) it was contended that the Hold Separate Regime significantly affected the liability for competition law infringements of Allergan plc. This is not a matter that we resolve at this point, but (self-evidently) we need to be in a position to be able to evaluate and resolve the point. We refer to this, second, phase as the **Actavis Phase (Phase 2)**.

(3) *Phase 3.* This phase concerns the period when Allergan plc (which indirectly owned and controlled the Merck, Sharpe & Dohme MA) was subject to the Hold Separate Regime. This phase begins at Period 99 and ends at Period 103. We refer to this, third, phase as the **Hold Separate Regime Part I (Phase 3)**.

(4) *Phase 4.* This phase – the **Hold Separate Regime Part II (Phase 4)** – begins with Period 104 (when Teva acquired Actavis UK Ltd, but subject to the Hold Separate Regime) and ends with Period 108 (when Intas acquired Actavis UK Ltd and the Hold Separate Regime ended).

(5) *Phase 5.* This phase – which only concerns excessive pricing in connection with 10mg hydrocortisone tablets[217] – begins with Intas' acquisition of Actavis UK Ltd (Period 109) and ends on 31 July 2018 (Period 127).[218] We refer to this phase as the **Intas Phase (Phase 5)**.

180. These phases essentially map on to the phases that the CMA used to assess penalty.[219] Whilst, of course, the phases are relevant to penalty, we also consider that they are relevant to the anterior questions of infringement. The five phases that we have

[217] There is no infringement finding in respect of 20mg hydrocortisone tablets after 8 January 2017: see Hydrocortisone Decision/1.4(b) (Ref only) and [192] below.

[218] The CMA made no finding of infringement after this date: Hydrocortisone Decision/1.4(a) and above.

[219] See Hydrocortisone Decision/1.74 and Sections 9 and 10 of the Hydrocortisone Decision. Thus: (i) Phase 1 (September 2008 to May 2015) = CMA Period A1/B1 (October 2008 to May 2015); (ii) Phase 2 (June 2015 to February 2016) = CMA Period A2/B2 (May 2015 to August 2016); (iii) Phase 3 (March 2016 to July 2016) = CMA Period A2/B2 (May 2015 to August 2016); (iv) Phase 4 (August 2016 to December 2016) = CMA Period A3/B3 (August 2016 to Jan 2017); (v) Phase 5 (January 2017 to July 2018) = CMA Period A4 (January 2017 to July 2018).

identified are graphically represented in Annex 4C to the Judgment (Abuse of Dominance Infringements).[220]

181. Although we do not (yet) hold that the CMA made a material error in the manner in which it parsed the period of prices that the Hydrocortisone Decision finds to have been abusive, we are uneasy about the undifferentiated approach to infringement adopted by the Hydrocortisone Decision. We will come to questions of market definition, dominance and abuse in due course, but will use the five phases we have defined, and which reflect the arguments both as to liability and penalty advanced by the Appellants in these appeals, as a cross-check on the CMA's approach. We now proceed to consider the question of Market Definition.

H. MARKET DEFINITION

(1) Introduction

182. The CMA's market definition came under attack from a number of Appellants. In order to understand those criticisms, it is necessary first to state how the CMA defined the market in this case. This we do in Section H(3) below. In Section H(4) we set out, and consider, the criticisms of the CMA's approach. These criticisms operated on two levels:

(1) First, it was contended that the general approach of the CMA to market definition was either wrong or incoherent.

(2) Secondly, and relatedly, it was said that even if the CMA's approach to market definition was soundly based, the outcome (in terms of how the CMA had actually defined the market) was in any event wrong.

183. These points need to be considered together, and not separately. If the CMA's general approach to market definition was wrong or incoherent, then it is unlikely that the final outcome of that process – the way the market was actually defined – would be defensible. On the other hand, if the final outcome of the process results in a market definition that works, in the sense of providing a consistent and rationally defensible test for substitutability, then we are unlikely to consider that the CMA's general approach was wrong. This is because market definition is a tool to aid in analysis, not some approach that can, by reference to axiom or theory, automatically be said to be "right" or "wrong". For this reason, we begin by considering the function of market definition generally, and what a test for market definition is supposed to achieve (Section H(2) below).

[220] This Annex, using the data from Annex 3, respectively shows the price (only) for 10mg (the first graph) and 20mg (the second graph) immediate release hydrocortisone tablets, differentiating between the phases we have defined.

(2) Market definition: purpose and objective

184. Market definition is a means for the assessment of constraints on market power. It therefore acts as both an important analytical tool and as a control against competition law overreach.[221] Focussing on the Chapter II prohibition, this requires consideration of whether an undertaking has a dominant position. A dominant position exists within a market. Clearly, how that market is defined matters, because that definition will likely affect a finding of dominance. Market definition plays a key role in the analysis of dominance and in limiting the jurisdictional ambit of competition law intervention. Unless an undertaking is dominant in a particular market, there can be no abuse of a dominant position.[222]

185. Market definition – or rather the process by which a market is defined, and the analytical tools that are used – is context sensitive, and varies according to <u>why</u> the market is being defined.[223] Here, we are concerned to define the market in order to see whether the Chapter II jurisdiction is triggered. The process in this case is rather more straightforward than would be the case with market definition where the Chapter I prohibition is or may be engaged.[224] Much of what was said in *BGL* about approach (in, e.g. [114]) was very specific to infringements of the Chapter I prohibition. Here we are concerned with the Chapter II prohibition. We would emphasise the following:

(1) Market definition needs to be outcome neutral.[225] Accordingly, when considering what products fall within and what products fall outside the market, it is important that subjective considerations be discarded, and that a demonstrably objective approach be adopted. Ideally, such an approach will also be intuitive and readily comprehensible to the layperson.

(2) Substitutability lies at the heart of market definition. When defining whether an undertaking is or is not dominant, one must begin with what it is that the undertaking is selling:

(i) Let us suppose a hypothetical case where it is said that Undertaking *A*, which sells only one product, Product *X*, is dominant in the market. If Undertaking *A* is only one of many sellers of Product *X*, and holds only a 10% share of supply, a finding of dominance in the market is unlikely, and the need to identify substitutes for Product *X* is unlikely even to arise (as a matter of practicality).

(ii) Let us suppose, however, that Undertaking *A* actually holds a 95% share of supply for Product *X*. A finding of dominance in the market may, but should not automatically, follow in this case. Whether a finding of

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[221] *BGL* at [108].

[222] *BGL* at [109].

[223] *BGL* at [110].

[224] *BGL* at [111]*ff*.

[225] *BGL* at [114(1)].

dominance is soundly based will turn on the existence of substitutes for Product *X*. Are Products *Y* and *Z* substitutes for Product *X*? If they are, then it may well be that Undertaking *A* is not dominant, because the market in question extends beyond Product *X*.

(iii) Suppose (different) Products *Y* and *Z* are perfect substitutes for Product *X*, such that in terms of the market for Products *X*, *Y* and *Z*, Undertaking *A* only holds a 10% share of this market so defined. A finding of dominance is unlikely to follow, even though (defining the market purely by reference to Product *X*) a finding of dominance was on the cards.

(3) This explains the importance of what competition lawyers call the **focal product**, in contradiction to and in contrast with substitutes for the focal product:

(i) It is perfectly possible for multiple different undertakings to sell the focal product. Undertakings *A*, *B* and *C* may all sell Product *X*, and – in an ordinarily competitive market – one would expect each undertaking to act as a constraint on the others' market power. If Undertaking *A* were to increase its price for Product *X*, but Undertakings *B* and *C* were not to, then demand would flow to Undertakings *B* and *C* such that Undertaking *A*'s price increase would be economically damaging. Undertaking *A* would lose so much demand as to make the price increase not worthwhile.

(ii) If that were not the outcome, then something worthy of investigation is going on. Competition law is concerned with the cases where: (i) Undertaking *A* lacks competition in regard to the focal product (there are, on this hypothesis, no Undertakings *B* and *C*); and (ii) whilst Undertakings *A*, *B* and *C* may well all be selling the focal product, there is a concern that they are acting collusively. In both such cases, it is necessary to look beyond the focal product, and to the substitutes for the focal product, in order fully to understand what (if any) market constraints exist.

(iii) Market definition is obviously concerned with identifying the focal product; but it is also – and perhaps more so – concerned with identifying substitutes for the focal product. The reason for this was explained in *BGL*, when considering the Chapter I prohibition (i.e. cartelist behaviour).[226] But the same point applies here. The point is that if there are substitutes for the focal product, such that an increase in the focal product's price generally (i.e. by Undertakings *A*, *B* and *C*) is not economically worthwhile (because demand will flow to Product *Y*, a substitute for Product *X*), then the market needs to be defined accordingly. Hence the need to assume a hypothetical monopolist, so as to capture competition from products that are not the focal product. Thus, even where Undertakings *A*, *B* and *C* are all selling the focal product and

[226] *BGL* at [89].

are all ostensibly in competition with one another, it is nevertheless often appropriate to ask what the case would be if there was only one undertaking selling the focal product (the hypothetical monopolist). Would "monopoly rents" accrue to that monopolist, or would that monopolist nevertheless be acting within a competitive market, subject to competitive constraints?[227]

(4) As a matter of good practice, the focal product ought to be defined as conservatively i.e. as narrowly as possible. Suppose a need to investigate whether there is dominance in the market for pay-TV for live football matches. Many sports will be televised for pay-TV, and it would be plausible (to those who are not football fans) to say that the focal product is not pay-TV for live football matches, but pay-TV for all live sports – rugby, tennis, lacrosse, etc. Defining the focal product in this way results in an assumption that an increase in the price of pay-TV for live football matches will not be economically worthwhile, because demand will immediately shift to the viewing of other sports. That may very well be the case,[228] but it needs to be tested for. In this (hypothetical) case, an appropriate approach might be to:

(i) Define the focal product narrowly, to include all pay-TV for live football matches, if that is the way products are sold. The prudent competition lawyer would probably differentiate between the male and female versions of the game, if the focal product(s) can be differentiated in this way.

(ii) Hypothesise an increase in price across all providers of pay-TV for live football matches and consider what is likely to occur in this case. If there is no change in demand, then clearly other live sports will not be a substitute. If – on the other hand – all football fans immediately decide to forsake watching football, and migrate to other sports, then the other sports will be proper substitutes for the focal product.

This is, in many respects, an obvious example: but the underlying point is worth making nonetheless. If one tests the focal product narrowly, then if that definition proves to be too narrow, no harm is done: the substitutes will be captured, not as focal products, but as substitutes for the focal product. On the other hand, if too wide a definition of the focal product is adopted, one runs the risk of "baking in" an erroneous assumption, and thereby adopting an incorrect definition of the market by including within the market definition products that should not be so included. In this example, defining the focal product as all pay-TV for live sports would lose the distinction between fans of different sports

[227] The point is that an assumption of a hypothetical monopolist does not automatically result in a conclusion of dominance. If that were the case, the test would not be pointful. The point of the test is to ascertain whether – even if there is a hypothetical monopoly over the focal product – the hypothetical monopolist is nevertheless constrained by competition.

[228] We suspect that the viewers of sport – those with an interest, and whose interest informs demand – would disagree. That is the importance of asking questions: the attitudes and preferences of those who matter (the consumers) are ascertained.

only being prepared to pay in relation to those sports in which they are interested. We apologise for labouring this point but – as will be seen – it is of significance in the present case, and the question of focal product is one that we will be returning to.

(5) The tests for abuse of dominance and market definition are very different. The role that market definition plays is that of "gatekeeper" to the Chapter II jurisdiction. Unless a dominant market position can be established, the question of abuse of a dominant position simply does not arise.

(6) Judgement, when defining a market, is therefore critical.[229] That is particularly so where the question of substitutability is in issue.[230] As was said in *BGL*, when considering the relevant product market, it is important to bear in mind precisely what it is that is being bought and sold, and why.[231] As we shall see, that is a question of peculiar difficulty in the present case, because of the manner in which demand for pharmaceutical products is articulated.[232]

(7) A second, key, issue that we raise now, so that we can return to it in detail later on, is how one tests for substitutability. The usual test is by way of price and by way of the **SSNIP test** or **Hypothetical Monopolist Test**. This was explained in *BGL* in the context of the CMA's decision regarding a Chapter I infringement, but the principles are the same:[233]

"(1) In order to define the market in this case, the CMA "uses the conceptual framework known as the hypothetical monopolist test to carry out its assessment of the relevant market. This test seeks to establish the smallest product group and geographical area such that a hypothetical monopolist controlling that product group in that area could profitably sustain 'supra competitive prices'." We shall refer to this as the Hypothetical Monopolist Test.

(2) As the Decision notes:

"The assessment starts by considering a hypothetical monopolist of the focal product operating in a focal area (i.e. an area under investigation in which the focal product is sold). Then the question is whether it would be profitable for the hypothetical monopolist to sustain a "Small but Significant Non-transitory Increase in Price" (SSNIP) above competitive levels. If the answer to this question is "yes" then the relevant market is defined: the product and area under the hypothetical monopolist's control is (usually) the relevant market".

(3) The Decision then goes on to state:

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[229] *BGL* at [114(9)].

[230] *BGL* at [114(7)].

[231] *BGL* at [114](5)].

[232] See [74] above.

[233] *BGL* at [88].

> "If the answer to the question is "no", the scope of the products/geographic area under consideration is expanded and then the question is considered again based on the expanded set of products/geographic area. This is repeated until it is possible for the hypothetical monopolist to sustain profitably a SSNIP and therefore the relevant market is defined."
>
> And also:
>
> "The relevant product market is defined primarily by considering the degree of demand-side substitution. In practice, the question the CMA considers in relation to demand side substitution is whether the customers of the focal product would switch to alternatives in response to a 5% - 10% price increase such that a hypothetical monopolist of the focal product would find such a price increase unprofitable and therefore the product consumers switch to should be considered to be part of the market in which the focal product competes. The CMA will only factor in supply-side substitution if it is reasonably likely to take place, and already has an impact by constraining the supplier of the product in question."

Thus, the Hypothetical Monopolist Test eliminates competition between different sellers of the focal product, enabling focus to be transferred to the constraints – if any – that arise out of the existence of genuine substitutes for the focal product. We have explained why this is important.

186. It is also important to stress that neither the Hypothetical Monopolist Test nor the SSNIP involve any findings of fact in the traditional sense. They are explicitly counter-factual in nature; and are intended to enable understanding as to how a market in any given case operates. They are tools or tests for analysing markets. How useful they are as tools depends on the market that is being analysed, and there is no substitute for understanding the true operation of the market under analysis. To put the point more concretely, and to root it in this particular case, the factual considerations in Sections C (the relevant pharmaceutical products), D (the regulatory regime) and E (the history and description of the "market") are fundamental and fundamentally anterior to the exercise of market definition. Unless one has a true understanding of what is actually going on, market definition is liable to fail. To this extent, market definition is rooted in the facts, even though (as a test in and of itself) it is counter-factual in nature.

187. In this case, for various reasons which we will articulate, no party (whether the CMA or the Appellants) contended for a "vanilla" application of the Hypothetical Monopolist Test or applied the Hypothetical Monopolist Test in a standard fashion. In this, they were entirely right, for reasons we will come to. But it is obvious that atypical tests are deserving of greater scrutiny than the normal tests of market definition and substitutability; and one of the key questions to ask in this regard is why an atypical approach has been adopted. This brings us to the two questions we articulated in [182] above, namely (i) the CMA's market definition in this case and (ii) the criticisms that can be made of that approach.

(3) The CMA's market definition

188. The Hydrocortisone Decision states:[234]

> "The CMA has concluded that the relevant markets are the supply of hydrocortisone tablets (including both full and skinny label tablets) in the UK. The evidence demonstrates that there were separate 10mg and 20mg hydrocortisone tablet markets following the entry of competing suppliers and also suggests that there was a combined market for 10mg and 20mg strengths prior to the entry of competing suppliers. The CMA has concluded that Auden/Actavis was dominant in those markets throughout the [Abuse of Dominance Infringements]. However, the CMA's conclusion that Auden/Actavis was dominant prior to the entry of competing suppliers holds regardless of whether there was a single combined market for both tablet strengths or separate markets for each tablet strength."

189. Thus, the Hydrocortisone Decision defines a market with a geographic scope that was UK-wide,[235] but which divided temporally according to product type. The UK-wide (geographic) market definition is uncontroversial, and we will not have to mention it again in this Judgment (Abuse of Dominance Infringements). The temporal division is far more controversial. According to the substance of the CMA's analysis, it was occasioned by the entry of other immediate release hydrocortisone tablets. Although the CMA appear to suggest that this temporal division was occasioned only by Waymade's sale of full label 20mg tablets, and not by the entry onto the market of products sold under the Skinny Label MAs for 10mg and 20mg hydrocortisone, the effect of the various new entrants cannot be isolated easily one from the other. But it is obvious that the entry of skinny label products was hugely significant. We do not understand the Hydrocortisone Decision to deny this. Referring – as we will throughout this part of our Judgment – to the data in Annex 3, these skinny label products are shaded blue in Annex 3, and the market was supplied with these products beginning with Period 94 (October 2015), when Alissa Healthcare sold 5,530 packs of 10mg Skinny Label MA immediate release hydrocortisone into the market. Thereafter, other suppliers joined the market, and supply (or purchase) of both 10mg and 20mg Skinny Label MA product increased.

190. The Hydrocortisone Decision treats this as a "watershed" moment in terms of market definition, differentiating between the **Pre-Entry Period** and the **Post-Entry Period**. Thus, the Hydrocortisone Decision records:[236]

> "The CMA has assessed whether Auden Actavis held a dominant position by reference to two periods:
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> a. from the beginning of the Unfair Pricing Abuses on 1 October 2008 until the end of June 2015, when Auden was the only supplier of 10mg and 20mg hydrocortisone tablets in the UK (the "Pre-Entry Period"); and

[234] Hydrocortisone Decision at 4.5 (Ref only).

[235] Hydrocortisone Decision/4.170.

[236] Hydrocortisone Decision/4.227 (Ref only).

b. from the first independent competitor's entry in July 2015 until the end of the Unfair Pricing Abuses (the "Post-Entry Period"):

i. in relation to 10mg hydrocortisone tablets, on 31 July 2018; and

ii. in relation to 20mg hydrocortisone tablets, on 8 January 2017."

191. As the Hydrocortisone Decision notes, the start and end points for the period of the Unfair Pricing Abuses are arbitrary cut-offs, where the CMA "has exercised its discretion to determine its administrative priorities and has not prioritised the periods before 1 October 2008 and after 31 July 2018 as part of the 10mg Unfair Pricing Abuse and before 1 October 2008 and after 8 January 2017 as part of the 20mg Unfair Pricing Abuse". The CMA is, of course, entirely within its rights to take such an approach and we will not stray outside those confines when considering the infringements found by the CMA in the Hydrocortisone Decision and the consequent penalties.

192. However, there are two points that we would make in addition:

(1) When considering what was going on in the market, we consider that it is appropriate to look outside these periods in order to understand what was going on during the periods where the CMA found Abuse of Dominance Infringements. Annex 3 has a slightly broader temporal range accordingly. We should make clear, in case it is not already clear, that the entirety of Annex 3 constitutes findings of fact by the CMA arising out of the Hydrocortisone Decision. The content of Annex 3 constitutes findings by the CMA which we have repackaged but not otherwise changed, and which we affirm.

(2) The only temporal distinction made by the CMA is in relation to the Pre-Entry Period and the Post-Entry Period. Whilst we certainly accept the relevance of this distinction, we consider that the shifting ownership and control of the Merck, Sharpe & Dohme MA (as set out in the five phrases described at [179]) cannot be disregarded without doing serious injustice to the contentions advanced by the Appellants. In short – and as we have mentioned a number of times[237] – the use of the umbrella definition of "Auden/Actavis" as the sole undertaking involved in these infringements is too broad to reflect the market position as it changed over time.

193. Returning to the CMA's market definition, the Pre-Entry Period is thus brought to an end by the entry of suppliers of Skinny Label MA 10mg immediate release hydrocortisone tablets in October 2015.[238] The Hydrocortisone Decision does not separately identify the later entry of suppliers of Skinny Label MA 20mg immediate

[237] See [4] and [5(4)(vi)].

[238] Not, we consider, July 2015, as stated in the Hydrocortisone Decision. The relevant date must be the date of supply into the market, not the date of grant of Marketing Authorisation. Alissa Healthcare entered the market – so far as 10mg "skinny label" was concerned – in October 2015 (Period 94).

release hydrocortisone tablets in March 2016.[239] We do not, at this stage, make any criticism of the CMA's adoption of a single "watershed" date, but only note that the Hydrocortisone Decision focuses only upon a single temporally relevant event, namely first entry of Skinny Label 10mg immediate release hydrocortisone tablets.

194. It is also worth noting that this market definition does not include within the market definition other types of hydrocortisone supply. Annex 3 records in addition to (i) 10mg "full label" hydrocortisone tablets by AM Pharma (yellow in Annex 3), (ii) 20mg "full label" hydrocortisone tablets by AM Pharma (green in Annex 3) and (iii) "skinny label" supply (blue in Annex 3), the following other supplies:

(1) Plenadren (orange in Annex 3).

(2) Supplies via the 20mg Agreement (red in Annex 3).

(3) Supplies via the 10mg Agreement (white on dark red in Annex 3).

At this stage, we do no more than note this absence from the CMA's market definition. The exclusion of Plenadren was specifically considered by the CMA;[240] the supplies pursuant to the 10mg and 20mg Agreements were not, doubtless because these supplies ultimately emanated from AM Pharma in each case.[241]

195. What is interesting, and unusual, about the market definition used in the Hydrocortisone Decision is that the entry of Skinny Label MA hydrocortisone products does not result in a mere expansion of the product market definition but in a combined expansion (Skinny Label MA products are "in") and contraction (20mg "full label" hydrocortisone immediate release tablets are "out"). The Hydrocortisone Decision in substance concludes that:

(1) The supply of 10mg and 20mg "immediate release" hydrocortisone tablets prior to the entry of competing ("skinny label") suppliers were part of the same product market; but

(2) The supply of 10mg "immediate release" hydrocortisone tablets (including both full and skinny label tablets) after the entry of competing suppliers subsisted in a different product market to the supply of 20mg "immediate release" hydrocortisone tablets (including both full and skinny label tablets) after the entry of competing suppliers.[242]

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[239] This was when Bristol Laboratories and Resolution Chemicals entered the market with both 10mg and 20mg "skinny label" products (Period 99).

[240] Hydrocortisone Decision/4.85 (Ref only).

[241] There are other products – not specifically recorded in Annex 3 – which also need to be taken into account. We have not forgotten these and will consider them in due course. We are not (at this stage) identifying every omission from the product market definition used in the Hydrocortisone Decision.

[242] Hydrocortisone Decision/4.5.

(4) Criticisms of the CMA's market definition in the grounds of appeal

(a) Our approach to criticisms made in the grounds of appeal

196. Before we turn to these, it is appropriate that we remind ourselves of the approach that should be taken where a judgemental decision of the CMA is under review (even on an "on the merits" appeal). As the Tribunal has held in other decisions,[243] the CMA is entitled to a significant margin of appreciation when deciding how to define a market. To put the same point another way, if there are various ways – all reasonable and proper – of defining a market, and the CMA has selected one of these, its decision should not be challenged successfully simply because an appellant is contending for a different approach. We do not consider that the CMA can or should be second-guessed in this way. It is only where the CMA has clearly and distinctly "got it wrong" – in that it has adopted a methodology that is outside the range of methodologies reasonably capable of defining the market in question – that we consider a ground of appeal should succeed.

(b) The criticisms made: our approach

197. As we have described,[244] the CMA's approach was the subject of attack on <u>two</u> levels:

(1) The correctness of its general approach (as a matter of principle); and

(2) The granular correctness of its actual market definition.

We consider the latter aspect to be more important, reflecting the fact that a market definition is practical tool intended to enable an outcome neutral analysis of a market. Accordingly, we begin with the specific criticisms made of the CMA's actual market definition in the <u>Hydrocortisone Decision</u>, as we have described it in Section H(3) above.

(c) Granular correctness of the CMA's market definition

(i) <u>Introduction</u>

198. The market definition used by the CMA throws up a number of oddities or matters of concern which would – we consider – puzzle the interested layperson. Given the need

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[243] See, for example, *BGL* at [105]: "As we have described, this is an appeal "on the merits", where the question of market definition is squarely raised in the Notice, but where it must be recognised that market definition involves a significant degree of judgement and where (we consider) the CMA is entitled to an ample margin of appreciation before this Tribunal can or should interfere. This is simply to emphasise that we must be satisfied that the CMA has erred in a material respect before we can say that its definition of the market was "wrong""; also *BGL* at [121]: "…We have made clear that we agree neither with the CMA's market definition in this case, nor with the process by which it was derived. We are conscious, however, that in conducting an investigation, the CMA is entitled to a significant margin of appreciation; and that whilst the Tribunal has an "on the merits" jurisdiction in this case, the CMA's assessment, particularly if it turns on questions of judgement, ought only to be departed from where there has been a material error. We do not consider that it is open to us to allow Ground 1 of the appeal simply because of the disagreements that we have articulated unless such an error exists."

[244] See [182].

for comprehensibility and legal certainty, such oddities or matters of concern are indicators (no more) that something has gone wrong. We set them out below and then consider them in detail in the paragraphs that follow. The matters of concern are as follows:

(1) *Approach to the "focal product".* We have stressed the importance of identifying an appropriate narrow focal product, hypothesising a monopolist selling only that product, and using that approach to ascertain whether the hypothetical monopolist's monopoly in that regard actually confers market power, or whether the existence of substitutes renders the hypothetical monopolist's power more apparent than real.

(2) *The treatment of Plenadren in the Hydrocortisone Decision.* As we have described,[245] Plenadren is excluded as a substitute product from the CMA's market definition. This exclusion was criticised, and is difficult to explain.

(3) *The nature of the relationship between 10mg and 20mg immediate release hydrocortisone tablets*. These products are (apart from dose) exactly the same. The manner in which the Hydrocortisone Decision analyses their substitutability is unclear on the face of the decision.

(4) The inter-relationship between reimbursement rates (the Drug Tariff) and prices charged to pharmacies. Generally speaking, the effect of price change is a key consideration in market definition. It is the basis for the SSNIP. In this case, changes to price do not have the effects that might be expected in another market, and the question arises as to how the CMA's market definition deals with this issue.

(5) A logical inconsistency in the CMA's temporal market definition. As we have described,[246] the CMA's definition of the market changes on the entry of "skinny label" products. That change is difficult to understand and justify.

We turn to consider each of these matters in turn below.

(ii) The approach to the "focal product"

The definition of focal product in the Hydrocortisone Decision

199. The focal product is, in cases of abuse of dominance, the product that is said to be dominant in the market. Although it might appear to be a straightforward matter to identify the focal product, that is not necessarily the case, and it is important to be precise as to what is being done, and why. When considering the relevant product market – and therefore the focal product within that market – it is important to bear in mind what is being bought and sold, and why.[247] The purpose of defining a relevant

[245] See [194].

[246] See [195].

[247] *BGL* at [114(5)].

product market is to identify the products or services which are sufficiently close substitutes to the focal product so as to exercise a competitive constraint on the price of the product or service under consideration.[248] The test is one of interchangeability or substitutability, and that is something which is assessed not merely by reference to the objective characteristics of the products or services at issue, but also:

(1) Why a given good or service is being bought.[249]

(2) More widely, the competitive conditions and the nature of supply and demand in the market.[250]

200. The Hydrocortisone Decision defined the focal product as follows:[251]

"The focal products for the purposes of this Decision are 10mg and 20mg full label hydrocortisone tablets. This is because Auden/Actavis supplied only full label hydrocortisone tablets throughout the Infringements."

201. There are a number of difficulties with this definition of focal product.[252]

Two, not one, focal products

202. The Hydrocortisone Decision is in fact concerned with two Abuse of Dominance Infringements – one in relation to 10mg immediate release hydrocortisone tablets and the other in relation to 20mg immediate release hydrocortisone tablets. There is an immediate problem in labelling both a focal product without being clear as to whether it is being assumed, without more, that they are substitutes. It is a necessary implication that anything falling within the term focal product is necessarily a very close substitute for any other thing falling within that term.

203. In this case, an important question that needs at least to be considered in terms of focal product is how – if one has two focal products – their possible interrelationship in the market is to be tested for. As we have noted,[253] the question of substitutability – even between these products – is not straightforward.

204. Of course, it might be said that this point is immaterial, since at all times "Auden/Actavis" (to use a term we dislike) sold both 10mg and 20mg immediate release hydrocortisone tablets. We do not accept that characterisation of this difficulty. When assessing market power, it is necessary to understand (i) what is the focal product and (ii) what are substitutes for a focal product irrespective of who controls supply. If it is the case that there is one focal product (say 10mg immediate release hydrocortisone

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[248] *BGL* at [114(5)].

[249] *BGL* at [114(6)]

[250] *BGL* at [114(5)].

[251] Hydrocortisone Decision/4.39 (Ref only).

[252] Although the term "focal products" is used, they are not properly differentiated one from the other.

[253] See [186].

tablets), it is relevant to understand whether another product (here 20mg immediate release hydrocortisone tablets) is or is not a substitute. The fact that one undertaking may sell both goes to the question of dominance, not market definition. The Hydrocortisone Decision does not grapple very well with the substitutability of 10mg and 20mg immediate release hydrocortisone tablets.

A failure to recognise the significance of Marketing Authorisations as a defining characteristic of the focal product and substitutes for the focal product

205. As Annex 3 makes clear, products in this market are differentiated not merely by their pharmaceutical characteristics but by the fact that (in order lawfully to be sold) they must be sold under a Marketing Authorisation. What is more, Marketing Authorisations do not treat what are pharmacologically the same products in the same way. As we have seen, the distinction between "full label" and "skinny label" products exists not because of any difference between the products *per se* (they are pharmacologically identical) but because of the effect of Plenadren's recognition as an Orphan Medicine under the Orphan Regulation.[254]

206. To revert to the definition of focal product in the Hydrocortisone Decision set out in paragraph 200 above, the failure to define product by reference to Marketing Authorisation is both patent and fatal to the CMA's approach:

(1) Adopting a definition of the focal product that was "Marketing Authorisation blind", then involves eliding all 10mg immediate release hydrocortisone tablets including "skinny label" products, for the only way of differentiating between the products is by reference to the Marketing Authorisation. Abandoning the Marketing Authorisation as a definitional element of the focal product inevitably means abandoning the distinction between full label and skinny label since that difference only arises because of the Marketing Authorisation.

(2) Relatedly, the Marketing Authorisation under which a product is sold is an intrinsic part of that medicinal product. We have described – at some length[255] – the regulatory arrangements that ensure that the supply of medicinal products to the market is controlled – and rightly so. The Marketing Authorisation is central to these arrangements. In particular:

(i) The Marketing Authorisation ensures that a medicinal product comes to market under the responsibility of a defined entity, which controls that product.

(ii) Although a Marketing Authorisation is transferable, it is personal to a particular holder, which is the only entity able to supply the product pursuant to that Marketing Authorisation.

[254] See [91]*ff.*

[255] See Section D.

(iii) Competition is introduced by way of multiple Marketing Authorisations for what is – pharmacologically speaking – the same product. This is the way "generic" pharmaceutical companies operate. Once a medicinal product comes "off-patent" then provided a competitor has a Marketing Authorisation for that product, there can be competition.

(3) Annex 3 – as can be seen from its heading – identifies six products which might (or might not) be said to be substitutes and which might (or might not) fall within the meaning of focal product. These products include:

(i) 10mg "immediate release" hydrocortisone tablets sold under the Merck, Sharpe & Dohme MA. This, of course, is one of the products in respect of which the Hydrocortisone Decision found an abuse of a dominant position, although it must be stressed that no allegation was ever even considered against Merck, Sharpe & Dohme itself.

(ii) 20mg "immediate release" hydrocortisone tablets sold under the Merck, Sharpe & Dohme MA. Again, this is one of the products in respect of which the Hydrocortisone Decision found an abuse of a dominant position.

(4) These products were supplied to the market not only by AM Pharma and its successors in title to the Merck, Sharpe & Dohme MA, but also pursuant to the 10mg and 20mg Agreements (using the same Marketing Authorisation).[256]

(5) We say nothing, at this stage, about the nature of these agreements as agreements potentially infringing the Chapter I prohibition. We would want to leave the question of these agreements entirely out of account for present purposes, but that cannot completely be done. The market was supplied via these agreements, and that supply is tracked in Annex 3 under the headings: (i) Waymade's supply to the market of 20mg "immediate release" hydrocortisone under the 20mg Agreement; and (ii) supply of 10mg "immediate release" hydrocortisone under the 10mg Agreement. The CMA's definition fails to consider these alternative supplies of the same product.

(6) A similar question arises in relation to Skinny Label MA 10mg and 20mg immediate release hydrocortisone. Clearly, these products fall outside the definition of focal product in the Hydrocortisone Decision, because that definition refers to "full label hydrocortisone tablets". But that is to overlook the critical fact that that the Skinny Label MA products comprise the same medical

[256] In other words, it is wrong to say that only "Auden/Actavis" supplied 10mg and 20mg full label hydrocortisone tablets throughout the Infringements. There were other supplies to the market, under the same Marketing Authorisation, but not by "Auden/Actavis". The market was supplied by others pursuant to the 10mg and 20mg Agreements. Of course, we appreciate that serious questions arise in respect of both of these Agreements: but they cannot – even if infringing of the Chapter I prohibition (as the CMA has found) – for that reason be excluded from the definition of the market. Our approach, to be clear, is to consider the Cartel Infringements separately from the Abuse of Dominance Infringements, and not to presume that the Cartel Infringements are made out when considering the Abuse of Dominance Infringements.

formulation, and that the differentiation between "full label" and "skinny label" arises only because of the different Marketing Authorisations under which these products are sold. This is a critical fact because it goes to the question of substitutability.

207. The focal product as defined in the Hydrocortisone Decision/4.39 (Ref only) and as set out in paragraph 200 above is dangerously unnuanced. Is the focal product defined by reference to the Marketing Authorisation under which it is permissibly supplied? Or is the focal product the identical pharmaceutical product, irrespective of the Marketing Authorisation under which it was supplied? The answer to this question is obviously critical to an understanding of substitutability and so market definition. Indeed, because of its specificity, it could be said that the Marketing Authorisation is the only relevant product characteristic of the medicinal products under consideration in the Hydrocortisone Decision.[257] This can be demonstrated as follows:

(1) If what is relevant is the pharmacological composition of the product, absent the Marketing Authorisation under which such products are sold, then all 10mg immediate release hydrocortisone tablets are the same product, including "skinny label".

(2) If, on the other hand, the terms of the Marketing Authorisation are relevant, then by virtue of those terms alone immediate product differentiation arises, even though the product may (pharmacologically) be the same. The distinction between "full label" and "skinny label" products arises only because of the Marketing Authorisation.

A failure to have proper regard to temporal aspects

208. There is a temporal aspect to this entire inquiry. Annex 3 begins with Period 1 (May 2005) and ends with Period 127 (July 2018), a term of more than 12 years, Obviously, things changed over this time. The question arises as to how one assesses the focal product and substitutes to the focal product over an extended time frame.

209. The CMA was clearly alive to this point, as is seen from the change in market definition elicited by the entry of "skinny label" hydrocortisone products. This pre-supposes:

(1) That "skinny label" hydrocortisone is a different product to the focal product.

(2) That it is so different to 20mg immediate release hydrocortisone tablets as to require the market to be defined anew such that one of the two focal products now resides in a different market, but was sufficiently similar to 10mg hydrocortisone as to subsist in the same market previously.

[257] That is because the terms of the Marketing Authorisation will define everything else: (i) dose (e.g. 10mg or 20mg); (ii) immediate release or delayed release; (iii) tablet or other form of delivery; and (iv) therapeutic indications (e.g. "full label" or "skinny label").

210. At least the significance of "skinny label" entry has been raised, even if not answered. But what is the position as regards Marketing Authorisations extant before AM Pharma began supplying the market. As Annex 3 shows, Waymade had a Marketing Authorisation in respect of 20mg "immediate release" hydrocortisone in May 1987. The Plenadren MA was granted in November 2011. These are developments in the market that at least need to be considered.

(iii) The treatment of Plenadren in the Hydrocortisone Decision

211. As we have noted, the CMA excluded Plenadren from its definition of the market. We do not say (at this stage) that the CMA's approach is wrong, merely that it appears odd that a medicinal product that was intended to treat exactly the same condition as that in fact treated by 10mg immediate release hydrocortisone tablets (if we assume that to be the focal product) was excluded from the market definition. Clearly, that exclusion needs to be closely justified, if the CMA's market definition is to withstand proper scrutiny:

(1) Plenadren is difficult to exclude as a substitute on clinical grounds – although the Hydrocortisone Decision does rely on such grounds. The fact is that "modified" release for exactly the same active ingredient as is used in "immediate release" hydrocortisone makes it difficult to see Plenadren as a product that is to be excluded as a substitute for the focal product.

(2) It may be that doctors did regard Plenadren as a non-substitute on clinical grounds. However, we find no data to support that conclusion in the Hydrocortisone Decision. What the Hydrocortisone Decision does record is that doctors were inhibited from prescribing Plenadren on grounds of price or cost.[258] If money becomes a factor in clinical choice, as clearly it was, then the CMA is not excluding Plenadren from the market definition because it is not a substitute, but because it is too expensive a substitute. One can see an argument for eliminating Plenadren on the grounds of price. As Annex 3 shows, Plenadren was, by any metric, very expensive.[259] The Drug Tariff rate for Plenadren was £242.50 for a 5mg pack and £400.00 for a 20mg pack, and the prices paid by pharmacies to the wholesalers were £30 to £50 less than this. By contrast, the average Drug Tariff for hydrocortisone sold under the Merck, Sharpe & Dohme MA was £46 (10mg) and £60 (20mg).

(3) But this makes the basis for the exclusion of Plenadren from the market definition harder, and not easier. True it is, Plenadren was very expensive. But to the buyer, if the buyer is the pharmacy, price was not a significant factor. In terms of the margin to the purchaser (the pharmacy), that margin was generally greater than was the case with "immediate release" hydrocortisone tablets. Pharmacies would – had the choice lain with them – have been keen to dispense Plenadren.

[258] See [139].

[259] See Periods 74 and thereafter in Annex 3.

(iv) The nature of the relationship between 10mg and 20mg immediate release hydrocortisone tablets

212. Priced on a "per mg" basis, it is clear that 20mg tablets are far better value than 10mg tablets. This is clear simply from the prices for packets of tablets, where 20mg is only marginally more expensive than 10mg. This is true both for "full label" and "skinny label" immediate release hydrocortisone tablets. Using the data in Annex 3, we know:

(1) That in the period May 2005 and July 2018, the average price on a "per mg" basis for "immediate release" hydrocortisone tablets was around £1.56 for 20mg tablets and around £3.34 for 10mg tablets.

(2) The average price for all "immediate release" tablets (whichever Marketing Authorisation they were sold under) was £0.68 (20mg) and £1.48 (10mg).

213. The following questions – indicating unexplored complexities – arise:

(1) Why, if price is a relevant factor in choice between products, is there not a shift in demand from 10mg hydrocortisone tablets to 20mg hydrocortisone tablets? The products are exactly the same, except in terms of the quantity of hydrocortisone contained in each tablet. If price mattered, one would expect more 20mg tablets to be purchased, with more splitting of tablets occurring so that the correct dosage could be administered to the patient.

(2) But price clearly does not matter in this context, because 20mg remained persistently cheaper (by the metric of price per mg of hydrocortisone) and yet demand for it did not rise.[260]

(3) The explanation for this oddity is straightforward, once the true operation of the market is understood. It is, in dosing terms, better to prescribe 10mg than 20mg, because less splitting of tablets needs to occur, which is both a trouble and liable to result (through "bad splitting") in over- or under-dosing.[261]

(4) A doctor will, therefore, quite rightly, prescribe the former, not the latter, all other things being equal. And all other things are equal, for the doctor is not exposed to the price differential between the two products. Nor does it matter (much) to the patient, who either pays nothing at all or pays a prescription rate, which does not differentiate between products.[262]

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[260] See Annex 5.

[261] See [41] to [42] above, where we explain that this was the only difference between 10mg and 20mg tablets of "immediate release" hydrocortisone tablets, whether "full label" or "skinny label".

[262] There would be a marginal price difference in favour of 20mg "immediate release" hydrocortisone tablets because – although the prescription price per packet would be the same – a 20mg packet would last the patient for longer. That price advantage would be eroded by the fact that patients needing hydrocortisone would need repeat prescriptions (whether on 10mg or 20mg "immediate release" hydrocortisone) and would doubtless pay for their medicine by way of an annual certificate.

(5) Differentiated pricing would matter to the pharmacy, to the extent that the margin between the price paid by the pharmacy and the reimbursement rate (represented by the Drug Tariff) was affected. The pharmacy would – given free choice – select the product offering the biggest margin. But, importantly, this is a choice that the pharmacy does not have. The prescription will specify the name of the product, form, strength and dosage instructions.

(6) In an unregulated market, where the patient had a choice between 10mg immediate release hydrocortisone tablets (which did not have to be split to achieve the correct dosage) and the equivalent 20mg tablets (which would have to be split),[263] but where the former was 10% more expensive to the patient than the latter, one would soon get a sense of how much patients would value not having to split their tablets. But that reaction can in no way be discerned from the data in Annex 3 and does not feature in the consideration in the Hydrocortisone Decision.

(7) This makes the question of substitutability between 10mg and 20mg extraordinarily difficult to determine. In a market where price makes a difference, one would expect 10mg immediate release hydrocortisone tablets to be substitutes for 20mg immediate release hydrocortisone tablets (and *vice versa*), but such data as exists (i.e. Annex 3) in no way supports that conclusion. That is because the regime through which these products are "bought" and "sold"[264] is not responsive or reactive to price or price change in this regard.

(v) The inter-relationship between reimbursement rates (the Drug Tariff) and prices charged to pharmacies.

214. We have described the operation of the Drug Tariff earlier in this Judgment (Abuse of Dominance Infringements).[265] The following points emerge in terms of the broader effect of the Drug Tariff on prices charged by the suppliers of these pharmaceutical products:

(1) The Drug Tariff generally sits above the price of the pharmaceuticals that are subject to that tariff. It acts as a price control to this extent only: namely, pharmacies will be highly reluctant to order products which exceed the Drug Tariff. Generally speaking, the price of a pharmaceutical product will be below the Drug Tariff.

(2) That is not, however, inevitably the case. When Merck, Sharpe & Dohme were supplying 10mg and 20mg "immediate release" hydrocortisone tablets to the

[263] This is something of a simplifying assumption: the evidence before us was that even 10mg tablets would require splitting, only less often.

[264] We qualify these terms because buying and selling pharmaceutical products is in no way like the sale and purchase of ordinary commodities.

[265] See [96]*ff.*

market, they appear to have priced at the Drug Tariff rate.[266] On the marginal sale, a pharmacy would not lose out (but neither would the pharmacy make a profit); taking into account common costs,[267] the pharmacy would make a loss. However, since pharmacies are obliged to dispense in response to a prescription that has been presented, and since pharmacies will be dispensing many prescription products where the margin will be better, this is unlikely to be a systemic problem.[268]

(3) It is clear from the early days of AM Pharma's involvement, that AM Pharma sold hydrocortisone tablets at a rate above the Drug Tariff reimbursement rate. In other words, pharmacies would, for these periods, make a marginal loss.[269] Clearly, AM Pharma was able to price as it wished, and was not constrained by the Drug Tariff.[270] What Annex 3 shows is that in due course the Drug Tariff followed the price change up. AM Pharma could set its own price, and the Drug Tariff would in due course follow.

(4) It is, at this stage that we should make clear a number of more general points regarding the operation of the Drug Tariff and the figures in Annex 3:

(i) First, the prices charged to pharmacies and recorded as a monthly price are average prices. Each pharmacy, or group of pharmacies, would negotiate an individual price with their suppliers, and doubtless the more economically powerful pharmacies would achieve the lower prices. The difference between the price charged[271] and the Drug Tariff reimbursement rate[272] is therefore also an average rate, and would doubtless be lower for small pharmacies, and higher for large groups of pharmacies.[273]

(ii) Secondly, although we have correlated the monthly average price and monthly Drug Tariff rate in Annex 3, it may be that the Drug Tariff reimbursement rate followed in arrears. We were not addressed on the precise mechanics as to how pharmacies were in fact reimbursed, and we

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[266] Annex 3, Periods 1, 2 and 3. We stress that the CMA qualified the information it provided for these periods, by noting that there was an informational gap that was filled by using the NHS Reimbursement Price. Accordingly, the Drug Tariff rate used in Annex 3 may not be the right rate and may be too high.

[267] I.e. the costs of sale going beyond the marginal cost of acquiring the product itself.

[268] Merck, Sharpe & Dohme were subject to the PPRS price control, as Annex 3 demonstrates. Quite why Merck, Sharpe & Dohme could not de-brand and price as AM Pharma immediately did was never explained to us, and the fact that Merck, Sharpe & Dohme forwent an opportunity to price higher that AM Pharma took full advantage of does not seem to us to be a material fact.

[269] Annex 3, Periods 4 to 8. We do not know – and it does not matter – whether these losses were borne by the pharmacies or whether they were reimbursed by their Clinical Commissioning Group.

[270] Nor, it would appear, by competition: but that is to anticipate.

[271] Set out in Column (4) of Annex 3.

[272] Set out in Column (6) of Annex 3.

[273] We heard no specific evidence on this point, but is a finding that we make, to the extent not expressly found in the Hydrocortisone Decision.

consider that the parties were right to spare us this detail. The general point articulated in Annex 3 holds good, even if there was a mismatch between a pharmacy's monthly expenditure on pharmaceutical products and the pharmacy's precise method of reimbursement.

(iii) Thirdly, the Drug Tariff is not, as the CMA pointed out,[274] intended to operate as a control in relation to the price of specific drugs.[275] Rather, according to the CMA, it seeks to control the general price level of pharmaceutical products, and it may be that (when viewed in the round) general price levels are more effectively controlled. That is consistent with the existence of various margin controls over the profits made by pharmacies generally, which we were referred to *en passant*, but never addressed specifically.[276] That is because we are here concerned with the extent to which the Drug Tariff operated as a constraint on specific prices charged for the various products set out in Annex 3.

(iv) Fourthly, although there was some debate, and a good deal of econometric analysis by Dr Bennett (responded to by the CMA) regarding the correlation between prices charged for hydrocortisone products and the Drug Tariff, the relationship is straightforwardly to be seen from the data in Annex 3:

(a) As we have noted,[277] the Drug Tariff generally sits at above the prices charged by the suppliers of pharmaceutical products. That is not always the case,[278] but unless there were (in general terms)

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[274] A note on the Drug Tariff ("The CMA's Note on the Constraints Arising From the Drug Tariff") handed up during the hearing by the CMA explained this at [15]: "When calculating the Drug Tariff Price, the DHSC also takes into account pricing trends, meaning that increasing drug prices will also be reflected in an increase in the Drug Tariff Price and vice versa. Importantly, the DHSC has itself recognised the risk that the Drug Tariff may unintentionally become a pure regulatory constraint (rather than a reflection of competition in the market). To guard against that, the DHSC uses additional adjustments (in a form of alpha and gamma coefficients) when setting the new Drug Tariff Price which are 'intended to ensure that the Tariff reimbursement price reflects market price movements (instead of the market being influenced by the Tariff)', i.e. the Drug Tariff mechanism is aimed at reflecting the level of price competition in the market rather than seeking to determine the price at which medicines are sold".

[275] That comes as something of a relief, for if that was the intention, the Drug Tariff falls remarkably short of this intention. Why there is no specific control of drug prices generally, absent a competitive market, is a question which we do not need to answer.

[276] This refers to the "clawback" provision which regulates a pharmacy's profit overall. It was mentioned in passing in the Hydrocortisone Decision (fns 108 and 239, and paragraph 3.175). Clawback refers to a discount applied by the NHS to reflect that pharmacies can buy some medicines cheaper than the Drug Tariff price. According to a note produced by the Advanz Appellants, Allergan Appellants, Cinven Appellants and Auden/Actavis Appellants handed up during the hearing ("Note on the Questions Raised by the Tribunal on the Drug Tariff and Pricing in the Pharmaceutical Sector"), the clawback from pharmacies is a fixed deduction percentage from the amount pharmacies receive from the Drug Tariff, which is applied for most drugs (some are exempt). The clawback percentage applied is the same percentage of the Drug Tariff price regardless of the medicine being dispensed. It is applied on a sliding scale depending on the size of the pharmacy and it is applied regardless of the profitability of the pharmacy – it looks only to the size, assessed by the value of reimbursed prescriptions dispensed per month.

[277] In [214(1)].

[278] See Periods 1 to 8 of Annex 3.

sufficient margin for the pharmacy, the system would likely not be sustainable. Pharmacies would cease to trade.

(b) However, the Drug Tariff seeks to operate as a general constraint on the prices charged for drugs generally, and not as a specific constraint limiting either the amounts charged for a particular product or the margin of the pharmacy. That is generally the case with the data in Annex 3, where it is clear that constraints other than the Drug Tariff operated on prices, and that the margins of pharmacies were (where prices were high) also extremely large.

(c) Generally speaking, where there was an absence of competition, the Drug Tariff followed prices up, and it was only with the entry of competition that the Drug Tariff followed prices down.[279] This can be seen with the onset of competition from "skinny label" 10mg and 20mg hydrocortisone commencing in Period 94. We appreciate that the nature of this competition is by no means straightforward (in that some pharmacies eschewed "skinny label" in favour of higher priced "full label"), but even so the effects of competition are clearly discernible.

In conclusion, although the Appellants suggested that the Drug Tariff acted as a constraint on supplier price, we reject that contention as impossible to reconcile on the data. The Drug Tariff followed price, not *vice versa*. But, at least in these markets at these times, it followed at a higher distance, floating well above the price actually charged to pharmacies.

(5) All this shows is that price as a determinant of quantity bought (and so as a test for substitutability) is not a reliable metric in this market, and that a market definition approach that is based on price would need careful consideration and justification.[280] Take Period 25: 10mg "immediate release" hydrocortisone sold to the pharmacy at £28.55/pack. That might, or may not, be an excessive price. But, to the pharmacy, the price was immaterial, because the reimbursement rate was £39.95, a return of £11.40 per pack. Given during this period (one month) 70,574 packs were sold, pharmacies received £804,544 after paying for the product. We doubt very much whether a SSNIP would be an effective test for demand elasticity. If, in Period 25, the price to the pharmacy had gone up by 10%, of course the pharmacy would have received less not in terms of reimbursement in that period, but in terms of margin. We doubt if that SSNIP would have been sufficient to cause a shift in demand to other products, but even if there had been such an inclination, we doubt whether it could have been acted upon. In Period 25, the pharmacies might theoretically have shifted to 20mg "immediate release" hydrocortisone: but, had they been able to do so, they would have done so without a SSNIP, because the margin was even higher in

[279] See the graph at Annex 6.

[280] Which, to be clear, it does not receive in the Hydrocortisone Decision. As we have noted, Plenadren appears to be excluded on the basis of its price.

that case.[281] Applying a SSNIP to the reimbursement rate (i.e. the Drug Tariff) would – self-evidently – be entirely pointless, as the "buyer" would receive more and not less for every purchase.

(vi) A logical inconsistency in the CMA's temporal market definition

215. There is an inconsistency between the CMA's "before" and "after" positions as regards its market definition:

(1) The CMA has concluded that before independent entry of "skinny label" 10mg and 20mg hydrocortisone tablets, "full label" 10mg and 20mg hydrocortisone tablets were in the same market (i.e. the Pre-Entry Period). In other words, one was a substitute for the other and *vice versa*. We have identified the difficulties in that conclusion,[282] and this conclusion is not borne out by the data in Annex 3.

(2) Nevertheless, given that the products are identical in all but dosage, the conclusion is a defensible one, and we certainly do not wish to suggest otherwise. This is a point we will be returning to: but for the moment we take the CMA's conclusion at face value.

(3) On this basis, 10mg and 20mg "immediate release" hydrocortisone tablets are substitutes. That being the CMA's conclusion, how can the entry of 10mg "skinny label" products (in Period 94, the Post-Entry Period) affect the status of "full label" 20mg immediate release hydrocortisone tablets as a substitute product for "full label" 10mg immediate release hydrocortisone tablets (and *vice versa*). The "skinny label" product is either a rival to both or neither, since the two products are themselves substitutes. This logical inconsistency is not explained.

(vii) Conclusion

216. We conclude that there are serious difficulties in the market definition adopted by the CMA, in that the definition of the market adopted by the CMA fails to produce the sort of consistent and straightforward answers to questions of substitutability that a test for market definition must deliver. Without repeating ourselves, and by way of example only, the following questions cannot straightforwardly be answered by reference to the Hydrocortisone Decision:

(1) *On what basis can it be said that Plenadren is or is not a substitute for 10mg or 20mg immediate release hydrocortisone tablets?* The Hydrocortisone Decision excludes Plenadren as a substitute product, but it is difficult to understand the basis for this. It cannot be on grounds of clinical substitutability, because the products are functionally very similar. The reason for the exclusion must be price – but it is difficult to understand the rationale for excluding a product as a

[281] The reason why the pharmacy would have stuck with 10mg is explained in [89] to [90] above.

[282] See [213].

substitute on this basis, unless one is rigorously applying a SSNIP (which the Hydrocortisone Decision does not purport to do).

(2) *On what basis is price a relevant factor to market definition in this case?* The problem – which we will come to address – is that there is no reliable market price to deploy within the SSNIP. Neither the patient nor the doctor is exposed to price differences (the doctor does not pay; and the patient either does not pay or else pays the prescription rate which does not differentiate between medicinal products and bears no relationship to market price). The pharmacies are exposed to price differentials, but in a very unusual way:

(i) First, they are limited in what they can dispense (and therefore buy as stock) because they must fulfil prescriptions according to their terms. If a prescription does not specify Plenadren, then Plenadren cannot be dispensed.

(ii) Secondly, their margin is determined by the Drug Tariff, which provides a return to the pharmacies that has little to do with market price. As we have already indicated, Plenadren would have been the pharmacies' medicinal product of choice, given the difference between the high price of Plenadren and the even higher Drug Tariff rate. Given free choice, a pharmacy would rather dispense Plenadren than 10mg immediate release hydrocortisone tablets.

(3) *Are 20mg immediate release hydrocortisone tablets a substitute for 10mg immediate release hydrocortisone tablets?* The difficulty is that they appear on their face to be paradigm substitute products: exactly the same product, differing only as to dose. Yet the evidence in Annex 3 and Annex 5 is that these products were not substitutes. By reference to what criteria is this question to be resolved?

(4) *What is the difference between 10mg immediate release hydrocortisone tablets sold under a Skinny Label MA and the same product sold under a Full Label MA?* The difference is only the Marketing Authorisation itself. To what extent, then, must products in this case be differentiated by reference to Marketing Authorisations?[283]

All of the above matters give rise to extraordinarily difficult questions of substitutability and so to market definition. Those questions are insufficiently answered by the market definition propounded by the CMA. For this reason, we consider that the market definition in the Hydrocortisone Decision cannot be defended and is wrong in the several material respects that we have articulated. We consider, later on in this Judgment (Abuse of Dominance Infringements), whether the question of market definition must

[283] Generally speaking, one Marketing Authorisation will be much like another. If one were defining a market for headache tablets, it is very unlikely that one would differentiate between the different Marketing Authorisations pursuant to which aspirin came to market, because the indications for treatment would likely be the same. But if there was a material difference in therapeutic indications for which the products could be sold, then that would make a difference. That – in this case – is the effect that Plenadren has had on hydrocortisone tablets coming onto the market after Plenadren's designation as an orphan drug.

be remitted to the CMA, for it to decide again, or whether we are able to undertake our own market definition, based upon the wealth of factual material contained in the Hydrocortisone Decision.

217. We cannot say whether the deficiencies that we have identified will be material to the ultimate outcome of the Abuse of Dominance Infringements. That is because market definition is a tool intended to assist in determining that very outcome. But to seek to answer questions of dominance by reference to a test for market definition that is flawed would itself be a mistake, because it runs the risk of obtaining an incorrect answer to a critical jurisdictional question, namely whether an undertaking is dominant in a market or not. For this reason, if (as we consider it to be) the market definition in the Hydrocortisone Decision is materially flawed, then the market definition must be re-visited.

218. We next turn to consider the basis on which the CMA derived its market definition, the criticisms that were made of this, and the alternative approaches that were articulated by (some of) the Appellants. It is important that we do this not because this affects our conclusion as to the CMA's market definition, but because these matters will inform our thinking as to whether it is possible for us to undertake our own market definition.

(d) General approaches to market definition in "atypical" markets

(i) Introduction

219. We have identified a number of "usual" methodologies that are used to define markets,[284] and we have noted that neither the CMA nor any of the Appellants have contended that such methodologies are appropriate in the present case. The fact is that the market in which 10mg and 20mg immediate release hydrocortisone tablets were sold under the Merck, Sharpe & Dohme MA is not susceptible of "traditional" analysis. The difficulties that we have identified with the market definition as articulated by the CMA testifies to the importance of understanding these difficulties, and articulating a methodology that can deal with them so as to craft an approach to market definition that will enable market power (i.e. dominance and abuse of dominance) to be analysed sufficiently so as to reach a robust conclusion in relation to the Abuse of Dominance Infringements.

220. Accordingly, we consider first how the CMA got to the place that it did – in short, its methodological approach. We thereafter consider alternative approaches that were articulated by (some of) the Appellants.

(ii) The CMA's methodological approach

221. The Hydrocortisone Decision lists a number of factors that the CMA has taken into account and which are obviously relevant to be taken into account. Thus:

[284] See [185(7)].

(1) The Hydrocortisone Decision describes the "qualitative" evidence that it has taken into account.[285] This includes consideration of the therapeutic substitutability of the various hydrocortisone products in the market. This was an approach strongly contended for by the Auden/Actavis Appellants, and which we will consider further below.

(2) However, the Hydrocortisone Decision does not nail its colours to the "therapeutic substitutability" mast. The decision articulates the view that "it is not sufficient to state that products have similar characteristics and are generally prescribed to treat the same conditions".[286] The Hydrocortisone Decision thus has resort to a range of "quantitative" evidence regarding demand-side substitutability,[287] including "actual consumption patterns".[288]

222. The concern when considering the Hydrocortisone Decision is that it is unclear how this wealth of data (carefully set out and on the face of it relevant to the question of market definition) has actually been applied to derive a market definition. We are driven to the conclusion that whilst the Hydrocortisone Decision has listed a multitude of potentially relevant factors, it has nowhere articulated a coherent approach to the evaluation of these factors in order to derive a plausible market definition. As to this:

(1) As we have noted, once a focal product has been defined, the next step in the process involves seeking to work out the substitutes that exist for a focal product. Although there is a "standard" approach to assessing substitutability, that is in no way set in stone. The SSNIP is well regarded as a test, but it is significant that no-one before us contended for a "vanilla" SSNIP – and we doubt, given the issues we have identified, whether a conventional SSNIP could ever be applied.

(2) In the Hydrocortisone Decision, the CMA rejected the SSNIP test. We have no issue with this. However, some lip service was given to the use of a SSNIP,[289] and there are passages in the decision where the CMA suggests that a SSNIP is indeed being applied. Hydrocortisone Decision/4.63 states:

> "In this case, the CMA does not need to hypothesise that there is a single supplier (monopolist) of the focal product as Auden/Actavis was the only supplier of full label hydrocortisone tablets in the UK during the infringements up until the independent entry of other hydrocortisone tablet suppliers from July 2015…"

Not only is this inaccurate (supplies to the market were made via the 10mg and 20mg Agreements, as we have described),[290] but also there is an assumption

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[285] Hydrocortisone Decision/4.41*ff* (Ref only).

[286] Hydrocortisone Decision/4.57 (Ref only).

[287] Hydrocortisone Decision/4.60*ff* (Ref only).

[288] Hydrocortisone Decision/4.61 (Ref only).

[289] Hydrocortisone Decision/4.59*ff* (Ref only).

[290] See above at [4].

(which may be right, but needs to be justified) that the focal product is that which "Auden/Actavis" sold. If that product was 10mg immediate release hydrocortisone tablets, irrespective of the Marketing Authorisation under which it was sold, there will have been multiple other suppliers or potential suppliers of that product. If that product was the product sold under the Marketing Authorisation, then there should at least have been consideration of the extent to which similar products sold under different Marketing Authorisations were substitutes. The whole point of a SSNIP is to assess the market power of (generally speaking) a supplier.[291] That supplier may or may not be a monopolist in regard to a particular product. That is nothing to the point. The point of the SSNIP is to see whether there are substitutes for the product the seller (who may or may not be a monopolist) sells. If there is clear substitutability, then the seller's status as a monopolist is entirely irrelevant.[292] It is important not be beguiled into considering that simply because a "monopoly" exists, a state of dominance exists also. What the CMA is doing here is jumping straight to an assessment of dominance, without actually appreciating that it is necessary, first, to define the market.[293]

(3) The CMA did not conduct a traditional SSNIP test, and concluded this was not necessary in light of Auden/Actavis being the sole supplier of the focal product up until independent entry in 2015. We consider that the conclusion is a defensible one, whilst the reasoning getting to the conclusion is not. Instead of applying a traditional SSNIP, the CMA assessed, as an empirical matter, the extent of switching away from hydrocortisone tablets in the face of the actual price increases implemented by "Auden/Actavis".

(4) As is clear from Annex 3, and the graphs in Annex 4, "Auden/Actavis" were able to profitably implement price increases without experiencing a discernible impact on volumes, including price increases of 200% and 171% for 10mg and 20mg tablets respectively between 2008 and 2015.[294] Prices of hydrocortisone tablets only started to decrease with the entry by other suppliers of those tablets – not other potential medicines.[295] Further, when prices did begin to fall, there was no change to existing volume trends in dispensing 10mg and 20mg tablets i.e. other treatments were not switching to the now cheaper focal tablet product.[296]

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[291] SSNIPs can, of course, work on both the demand and supply side of the market.

[292] The position is clearest in the context of patents. There are, literally, thousands of patents which claim inventions (and so a monopoly running for around 20 years), which confer no market power whatsoever, because they are simply not useful or easily side-stepped by producers in the market.

[293] In short, this paragraph shows precisely the "backwards" reasoning we cautioned against in [153] to [155] above.

[294] Hydrocortisone Decision/4.64.

[295] Hydrocortisone Decision/4.66.

[296] Hydrocortisone Decision/4.72.

(5) We entirely accept that this is what the data shows, but this is the "backwards" reasoning we warned against above.[297] Of course, the prices for 10mg and 20mg immediate release hydrocortisone tablets sold under the Merck, Sharpe & Dohme MA increased dramatically, before subsiding equally dramatically. That is the "mountain" we are seeking to explain. Unless the prices giving rise to the mountain are, *ipso facto*, an abuse of dominance, it is difficult to understand how prices can be relevant at the market definition stage.

(6) It is for this reason that we substantially reject the analysis of Professor Valletti. Professor Valletti used pricing and volume data from 2008 until 2015 to evidence Auden/Actavis' ability to implement "substantial" price rises without losing volume. He argued this demonstrated that Auden/Actavis faced no competition constraints and were acting as a monopolist. He rejected the suggestion that other therapeutically similar drugs were in the same market, because, despite potential substitutability from a therapeutic perspective, they did not exert a sufficient competitive constraint (because prices continued to rise. Following entry of skinny label tablets, and price decline, there was no increase in volume of hydrocortisone tablets, indicating the market remained the same after independent entry. Full and skinny label tablets were, in his view, clearly in the same market, as the result of the entry of skinny label products was price and volume decreases – namely, full label hydrocortisone tablets started to face a competitive constraint.

(7) As regards other factors, apart from price, the CMA articulated the test that it was proposing to apply in the following terms:[298]

> "The CMA has, in its analysis, taken account of the entire economic context, having considered both qualitative and quantitative evidence in the round before forming a judgement as to the relevant market. The CMA does not agree that clinical substitutability is of decisive importance when defining the relevant market. Rather, it is substitutability in practice (i.e. how prescribers actually choose between and prescribed different medicines and how pharmacies dispensed different medicines, consistent with the CAT's finding in *Phenytoin* that "What matters, for this competition analysis, is what pharmacists actually did"), that shows the degree of competitive constraint from potential substitutes. While clinical substitutability plays a role, it is not sufficient for including a product within the relevant market."

(8) The CMA thus rejected an approach based (solely) on clinical substitutability. The CMA's approach appears to have been that clinical substitutability was not of decisive importance in market definition (although it played a role). The CMA preferred a test of "substitutability in practice", which would seem to be a reference back to the price-based analysis considered above.

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[297] See [153] to [155].

[298] Hydrocortisone Decision/4.76 (Ref only). Emphasis added.

223. We conclude that it is difficult to articulate the methodology adopted by the CMA in the Hydrocortisone Decision. That explains the difficulty we have in satisfactorily answering the questions we have posed in [216] above.

(iii) The approach of the Appellants

224. We turn to consider the approaches to market definition contended for by the Appellants. The reason we consider the Appellants' own approaches (having rejected that of the CMA) is because we will obviously have regard to what the Appellants contended when seeking to frame our own approach market definition (assuming that to be a process we are able to undertake at all).

The Auden/Actavis Appellants

225. The Auden/Actavis Appellants proposed a market definition for products based on "therapeutic substitutability". They contended that where products had similar objective characteristics and catered for similar groups of patients, there would be no particular difficulty in finding that such products fell within the same market.

226. Two particular characteristics of the pharmaceutical sector militated in favour of such an approach to market definition:

(1) The Anatomic Therapeutic Chemical (**ATC)** classification classifies medicines according to their functional interchangeability. Medicines classed at ATC Level 3 are generally used as a starting point in market definition in pharmaceutical cases because they are so similar at that Level.[299]

(2) The role of price is attenuated in the pharmaceutical sector, and was not a good guide to substitutability. In the case of medicinal products, doctors acted as the main determinant of demand, and they were primarily guided by the therapeutic appropriateness of medicines rather than their price.

227. The Auden/Actavis Appellants characterised the CMA's approach as focusing unduly on price throughout the market definition exercise, to the exclusion of clinical substitutability. For this reason, the Auden/Actavis Appellants criticised the CMA for excluding products from the market definition which were therapeutically substitutable, including Plenadren and other corticosteroids such as Prednisolone. They submitted that the CMA's exclusion of Plenadren from the market was illogical, particularly in the context of an alleged excessive pricing case.

228. The approach of the Auden/Actavis Appellants was thus firmly based on clinical equivalence and substitutability. The approach articulated by the Auden/Actavis Appellants is radical, although not without some precedent.[300] It entirely jettisons the notion of consumer choice and the concept of price as the means whereby consumer

[299] It is unnecessary for us to consider the details any further. We are, at this point, considering approaches to market definition, not the application of those approaches to the facts of the present case.

[300] See the references in the Auden/Actavis NoA/38*ff*.

choice is articulated and assessed. Instead, it substitutes a purely functional approach to the question of substitutability: Is the medicinal product in question functionally the same or functionally different from other medicinal products?

229. Applying this test to the facts of the present case appears to provide a beguilingly easy solution to the problem of substitutability:

(1) It is very hard to resist the conclusion that 10mg and 20mg immediate release full label hydrocortisone tablets are substitutes for one another. They are exactly the same product, differing only in their strength. Strength does not preclude anyone suffering from adrenal insufficiency from using either form of medicament. It is simply a question of splitting tablets or taking multiple tablets in order to achieve the correct dosage. The effect is the same.

(2) It is similarly very hard to resist the conclusion that full label and skinny label immediate release hydrocortisone tablets are functionally equivalent. That is because – pharmacologically speaking – they are the same. Of course, the therapeutic indications for which they can be used are different – more extensive in the former than in the latter – due to the effects of the Plenadren Orphan Regulation. Usually, a difference in therapeutic indication arises because of a functional difference: but that is not the case here. For the reasons we have given, skinny label is a regulatory consequence of the Orphan Medicines regime.

(3) Plenadren is – to an extent – functionally different. Although it, too, is a medicinal product intended to treat adrenal insufficiency, it does not operate in an "immediate release" fashion, but is a "modified release" tablet. That is a material difference. Yet does it make the medicinal product so functionally different as not to be a substitute?

230. The problem with the approach is that it can only answer questions of substitutability by reference to the doctor's standpoint. It may very well be the case that this is the best solution to defining the market in this case, but it is important to understand that the approach removes all forms of patient preference from consideration. As to this:

(1) It might very well be said in answer to this point that this is an advantage, and not a disadvantage, of the therapeutic substitutability approach. A premium is placed on an expert evaluation of clinical need and if two different products are therapeutically equivalent then (on the basis of this test) they will be substitutes.

(2) However, patients, as well as doctors, can be expected to have due regard to their own health issues (indeed, for patients perhaps more so, given that it is their health that is in issue), and there is some merit in attributing weight to the patient's non-therapeutic preferences. By way of example, there are available therapeutically similar products for the treatment of adrenal insufficiency some of which are delivered in tablet form and some of which are injectable. A doctor may be indifferent as to treatment form, whereas the patient may have very definite views as to what they prefer, such that these (therapeutically equivalent) treatments would not be substitutes so far as the patient is concerned.

(3) Similarly, it may be quite difficult to evaluate the substitutability of "immediate release" and "modified release" treatments. Ms Ford, KC, for the Auden/Actavis Appellants, contended that there was no material difference, functionally speaking, between "immediate release" and "modified release" hydrocortisone. The trouble with this assertion is that it rapidly degenerates into a "is/isn't" debate that is impossible to resolve by use of the "functional" test. Ms Ford, KC could say – indeed, she did say – with some force that the active ingredients of both "immediate release" and "modified release" hydrocortisone are exactly the same. And she would be right. But someone seeking to contend the contrary could say, with great justification, that "modified release" hydrocortisone is functionally very different to "immediate release" hydrocortisone for that very reason. The dosing regime is dramatically different, and that may have significant patient benefits. This, indeed, is why Plenadren has Orphan Medicine status and Ms Ford, KC's contentions are really tantamount to saying that Plenadren's Orphan Medicine status is an irrational one. We do not consider that it can be right to go so far.

231. The "functional" test's inability to answer questions like this – "Is a product a substitute where there is a broad functional similarity, but also a material divergence in functionality offered?" – represents a serious failing. For that reason we do not consider it constitutes a viable test for substitutability in and of itself. However, it is a test that has its attractions, and it is important to understand why this is the case. There are, we consider, two reasons:

(1) First, this is a market where consumer choice is remarkably elusive and difficult to capture. The ultimate consumer – the patient – actually has very limited choice, but does provide the demand for the product (in the shape of the illness the patient suffers from). The patient does not, however, articulate that demand. That is principally done by the doctor and – to a subsidiary extent, to the extent permitted by the prescription regime we have described – the pharmacist. Demand is, therefore, informed by three different persons, interacting. This is far from the usual case, where it is the ultimate consumer who decides (informed by their "values", product price and their disposable income) what to buy and what not to buy.[301]

(2) Secondly, and relatedly, there is no single price for the product. In the first place, it is actually very hard to identify, in any traditional sense, who is actually paying for a medicinal product. The regulatory intrusion that exists means that:

(i) Doctors are largely – but not completely – unaffected by price. Certainly, they do not pay for the medicinal products they prescribe. Yet there are pressures on doctors not to prescribe on grounds of cost. Plenadren is an outstanding example of this.

(ii) Patients are to a large extent – albeit not completely – unaffected by price. Most do not pay anything at all and, even where they pay for their

[301] See [74].

prescriptions, these do not differentiate between medicinal products. A subscription charge, where paid, is a one price fits all price.

(iii) Pharmacists are exposed to a degree of pressure on price, but that is (i) within a highly regulated regime and (ii) almost completely divorced from what should matter, namely patient need. We accept that a pharmacists' profit is controlled – in the marginal case – by the difference between the Drug Tariff and what the pharmacy can negotiate in terms of price with suppliers. That negotiation may itself be affected by price controls on wholesalers. But this is very far from a market price either on the cost or on the revenue side. Furthermore, the pharmacy is enormously constrained by what the doctors say should be prescribed. The pharmacy – rightly – is in the position of a middle-player, who does not and should not have very much discretion in what to supply.

The Cinven and Advanz Appellants

232. The Cinven and the Advanz Appellants proposed separate markets for "full label" and "skinny label" 10mg immediate release hydrocortisone tablets. They contended that the key question was whether there is sufficient substitution from "full label" 10mg tablets to "skinny label" 10mg tablets in the event of a price rise of the former. The Cinven and Advanz Appellants argued there was not sufficient evidence of switching to "skinny label" tablets to justify a market definition encompassing both products. Bioequivalence of full and skinny label tablets, and the widespread use of open prescriptions, was not sufficient to place them in the same market.

233. According to their analysis, the entry of "skinny label" tablets led to a bifurcation in the market, with a significant minority of total hydrocortisone tablets switching to skinny label within 12 months, and, apart from some further switching in 2017, limited switching since. The evidence suggested that pharmacies fell into a cautious group which dispensed full label tablets and provided an assured customer base, and a less cautious group which dispensed skinny label tablets. These were two distinct customer groups that only purchased full or skinny label respectively, indicating separate product markets.

234. In short, after entry of skinny label products, there was a bifurcated market reaction that needed to be understood. The problem was that the market did not behave in the manner that Dr Newton considered that it should have behaved. In very broad-brush terms:

(1) The larger pharmacies – in particular, the chains – took an approach in line with that articulated by Dr Newton and did not dispense "skinny label" immediate release hydrocortisone for adults. That tended to have a knock-on effect in what was stocked for children, in that holding only the "full label" product removed a complication in working out what product to dispense to adults and to children

with adrenal insufficiency.[302] This had an effect on the profits made by these pharmacies.[303]

(2) On the other hand, the smaller pharmacies did not take the approach articulated by Dr Newton. They took the higher margins offered by "skinny label" not merely when dispensing for children (which would be "on label") but also when dispensing for adults (which would be "off label").

235. We accept that the interaction between "full label" and "skinny label" represents an extremely odd case of substitutability. The presence of some switching is not necessarily sufficient to indicate products are in the same market. What is needed is some understanding of why switching is occurring, so that the relationship between cause and effect can be measured. In this case, 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.

236. What can be said, is that the nature of the constraint of "skinny label" on "full label" was patchy. Skinny label tablets certainly did not fully constrain "full label" prices because significant portions of the market were indifferent – or prepared to forsake – the additional margin afforded by "skinny label" products.

237. Having articulated the problem – and we accept that there is a significant difficulty in analysing the full label/skinny label interaction on the market – the Cinven Appellants did not actually provide a methodologically sound solution to the problem:

(1) The Cinven Appellants criticised the CMA's failure to conduct a SSNIP test, in favour of observing switching patterns. In his reports (Bennett 1 and Bennett 2), Dr Bennett supported the contention that the switching levels from full to skinny label were insufficient to justify the conclusion that they were substitute products. He conducted a SSNIP test and critical loss analysis on the actual prices charged by Auden/Actavis. A SSNIP test on actual prices, which he argued was possible given Auden/Actavis was a monopolist supplier, indicated they were able to maintain a significant price premium above a reasonable estimate of the competitive price of 10mg full label tablets (in this analysis, the cost of 20mg tablets post independent entry). He concluded this indicated full and skinny label were not part of the same market.

(2) According to his critical loss analysis,[304] which used the patterns of substitution and price differences between the two products, a hypothetical monopolist of full label 10mg tablets would find it profitable to raise prices by 5 or 10% above

[302] Although no party made anything of it, there is something remarkable about pharmacies declining, on prudential grounds, to dispense to adults what can be dispensed to children. Children are, generally speaking, regarded as the more vulnerable class.

[303] The Drug Tariff Reimbursement rate would have been the same for full label and skinny label, but skinny label would have been cheaper than full label.

[304] A critical loss analysis assesses what the minimum level of quantity losses is for an increase in price, before the price increase becomes unprofitable.

a competitive price (again, taken to be the price of 20mg tablets after independent entry).

(3) We are not persuaded that the approach adopted by Dr Bennett assists. We do not consider that it is pointful to conduct a SSNIP or SSNIP variant – which focuses on a reaction in the market to a price increase – when it is clear that it is not price that is informing the market. We completely accept that the analysis of the interrelationship between full label and skinny label products needs to be undertaken. The problem, as we see it, is that Dr Bennett provided no defensible form of analysis of this issue.

(5) Deciding the issue of market definition again

238. We have concluded that the CMA's market definition as stated in the Hydrocortisone Decision must be set aside. Whilst this would almost certainly be the end of the Hydrocortisone Decision were this a judicial review (where a material error has been made, a quashing of the decision is "on the cards", to put it no higher than that), this is an "on the merits" appeal. We have the jurisdiction to re-visit and re-determine this question.[305]

239. The question is whether we can properly exercise that jurisdiction – as occurred in *BGL*. We have no doubt that – if it can properly be done – this is a question that we ought to determine now, so as to be able to consider the rest of the Hydrocortisone Decision and so as to avoid the costs and delays inherent in remitting. In short, if we can exercise the jurisdiction, we should do so.

240. We are in no doubt that we can exercise the jurisdiction:

(1) We have the benefit of the very detailed findings of fact made in the Hydrocortisone Decision. These primary findings of fact we have – almost without exception – accepted. They embrace the relevant pharmaceutical products,[306] the regulatory regime,[307] and the history and description of the market.[308]

(2) On top of this, we have been provided in manipulable form the pricing data used by the CMA to inform its decision,[309] and which was the basis for the expert evidence before us, as well as the evidence of the various experts themselves.

(3) There is, in short, no further area of factual investigation that, in our judgement, needs to be undertaken in order to derive a market definition. We remind

[305] See [32(2)].

[306] Considered in Section C above.

[307] Including in particular Dr Newton's evidence as to how the market would regard "skinny label" hydrocortisone products. See, generally, Section D above.

[308] Considered in Section E above.

[309] I.e. Annex 3.

ourselves that beyond properly understanding the operation of the market in question, market definition is a counter-factual exercise that should be both intuitive and not expert-led.[310] Its outcome should be explicable to, and easily understandable by, the lay person. We consider that this is an exercise which, as an expert tribunal, we are well-able to carry out.

(6) Re-working the market definition decision

(a) Our general approach

241. We consider that the parties were entirely right to abandon the traditional SSNIP as a test for substitutability. It is impossible to see how a SSNIP could appropriately be applied in the circumstances of the present case. However, we do not consider – for the reasons we have given – that any of the alternatives to the SSNIP proposed by either the CMA (in the Hydrocortisone Decision) nor by the Appellants (as described above) properly fill the void.

242. As a starting point, any approach to substitutability that is based on existing prices that are not market prices and which are detached from true consumer choice is liable to be materially wrong. The virtue of the SSNIP is that it links effective demand to price, and seeks to work out whether an increase in price will have an effect on demand. Where that linkage does not exist – where price change does not inform demand – the rationale in favour of the traditional SSNIP falls away.

243. A different approach is therefore called for, which at one and the same time utilises the SSNIP, and yet departs from it. It builds on the approach suggested by Ms Ford, KC, but seeks to cater for the weaknesses in the therapeutic substitutability test that we have identified. We expand upon our thinking as follows:

(1) It is necessary to return to the reason why the question of substitutability is so important. It is not an end in itself, but a means of assessing market dominance. In order to assess dominance, the market needs to be defined, and (in terms of product definition) substitutability is critical. If – as we have seen – there are readily substitutable products for Product *X*, then the market will be wider than Product *X*.

(2) Substitutability on the basis of function is not consistent with a properly functioning competitive market. If that were the case, then a Mini (price say £25,000) would be a substitute for a Rolls Royce (price say £500,000). The fact is that there is a subjective element to value, which impels some people who have the money to spend it on an expensive car and others – who could do so – not so spending their available cash. It will be necessary to consider "value" in greater detail when we come to consider excessive or abusive prices, but it is worth considering the subjective nature of value and market definition in the particular context of medicinal products. As to this:

[310] See [152(6)].

(i) The reason why, in "ordinary" markets, the SSNIP test is applied to the actual market price of the focal product, without adjusting the prices of any potentially substitute product, is because (in a properly functioning market) price is a very good determinant of the relative value that consumers attach to different products. Good reason is required to take the market price out of account, because in doing so one loses the value that the market attaches to a given (expensive) product. Conduct a SSNIP where the Mini's price is increased to (say) £27,500 but the Rolls Royce's price is reduced (for no reason) to (say) £30,000, and the value of the SSNIP in assessing substitutability is so reduced as to render the test effectively useless.

(ii) Are medicinal products any different? The demand for medicinal products is (generally) based on medical need, and the value the patient attaches to the medicinal product is likely to be correlated to the seriousness of the medical need and the efficacy of the medicinal product in meeting that need. Value to the patient is likely to be capable of being computed rather more objectively than whether a consumer prefers one unnecessary good over another.

(iii) But that does not make any difference to the use of a SSNIP in ascertaining value and substitutability. Let us suppose a medicinal product that is efficacious in treating a serious medical condition. Let us also suppose an ordinary market for the supply of this product (unqualified by the sort of regulation we have described in the case of hydrocortisone[311]). Aggregate demand will be limited to those suffering from that serious medical condition. It can be presumed that those subject to the serious medical condition will value the medicinal product extremely highly. But that does not render the use of a SSNIP impossible. Let us suppose, now, two medicinal products, both efficacious in treating the hypothetical, serious medical condition we are considering. One such product (Product *A*) is less efficacious, but also less painful to administer than the other (Product *B*), which is marginally more efficacious but also marginally more painful to administer. On the assumption that patients have a free choice and must pay out of their own pocket, there is no reason why a SSNIP cannot be used to assess whether Product *A* and Product *B* are in the same market as substitutes or whether they are not substitute products. Apply a SSNIP to Product *A* (our presumptive focal product) and we will soon find out the extent to which patients value the avoidance of pain. Demand for Product *A* is already based on a less efficacious (but less painful to administer) product. The SSNIP enables us to see how valuable the avoidance of pain is to the patient population.

(3) We learn a very valuable lesson from this example. We learn that what renders the SSNIP an ineffective test in the context of patient preference is not the fact that it is a medicinal product needed by the patients taking it, but by the

[311] As described in Section D above.

regulatory and price control regime that enables medicinal products to be provided to those in need at less than the market price. This is, of course, exactly as it should be: but it does not make the competition law analysis any easier. There is much to be said in applying a SSNIP that strips away the market distortions created by a highly regulated regime so as to enable focus on what actually matters (for competition law purposes), namely the choice of the consumer, here the "captive" patient.[312]

(4) The SSNIP test is not a factual test to be solved by detailed inquiry. The present EU Commission Notice on Market Definition calls the SSNIP test a "speculative experiment", and the current (draft) version calls it a "theoretical criterion" and "conceptual framework". All of these phrases capture the true nature of the test. The SSNIP test is a speculative thought experiment, to be informed by such facts as are available, but a speculative thought experiment nonetheless.

(5) In this case, the "demand function" represented by the typical consumer is at least trifurcated between patient, doctor and pharmacy, as we have described.[313] That makes application of the traditional SSNIP impossible. Ask a doctor what the reaction would be to a SSNIP on a medicinal product they were minded to prescribe to a patient, and the answer would be "I do not care! My job is to prescribe appropriately!" Ask the patient what the reaction would be to a SSNIP, and the answer would be "I do not care! I am exempt from paying for prescriptions or I pay a flat rate that does not differentiate between medicinal products." Ask a pharmacist, and the answer would be: "I care very much, and will try to maximise my profit, and switch, but I am professionally constrained to fulfil the prescription written by the doctor." Ask a Clinical Commissioning Group and they would say "Under no account prescribe Plenadren, it is outrageously expensive, but use your clinical judgement." The short point is that no single group of persons can proxy consumer demand in this particular case.

(6) The first stage to a solution is to hypothesise the consumer whose reaction to a SSNIP we wish to gauge. We consider that it is important to synthesise a hypothetical consumer out of the salient characteristics of doctor, pharmacy and patient. We consider that such a consumer/patient ought to have or be deemed to have the following characteristics:

(i) A diagnosis of adrenal insufficiency, requiring treatment.

(ii) A responsible attitude towards dealing with that condition.

(iii) A level of knowledge about adrenal insufficiency and the various medicinal products available to treat adrenal insufficiency commensurate with that of a doctor.

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[312] "Captive" in that patients really cannot choose not to acquire the medicinal product, because of their (unavoidable) medical condition.

[313] See [74].

(iv) An understanding of the difference, in this case, between skinny and full label offerings and the regulatory regime that has created that distinction.

We consider that we should consider the effect of a SSNIP on such a consumer, fully recognising that very few such consumers will actually exist. But this simply a reflection of the counter-factual nature of the market definition process; it is, in this case, necessary instead of hypothesising a monopolist applying a SSNIP, to "invent" a consumer with certain attributes in order to get a true sense of substitutability, going beyond the rather arid debate as to therapeutic substitutability.

(7) We consider that it is necessary to hypothesise a consumer – a patient – rather than a medical professional, a doctor. The question is not "What would a medical professional prescribe?" That is a question of clinical judgement divorced from competition law. We are seeking to apply competition law in a market that is so highly regulated that it has the unusual attributes we are wrestling with. In order to do so, we first need a consumer that has all the attributes united in one (hypothetical) person so that the significance of a SSNIP can rationally be evaluated. In short, we are not disregarding a test based on therapeutic substitutability: we are incorporating it.

(8) That leaves the question of the price to which the SSNIP is applied. Identifying the (hypothetical) consumer, this does not solve the linked questions of: (i) what product the SSNIP should be applied to, (ii) what the price of that product should be regarded as being, and (iii) what the price of the substitutes should be regarded as being. We recognise that there is enormous danger of distortion and error in using in the analysis prices that are not actual prices. A departure from actual prices must be closely justified.[314] Again, this represents a difficult question of approach given the attributes of this particular market:

(i) Normally, absent "chain" pricing, tests for market definition take the prices in the market. That is because they are market prices and represent the outcome of commercial exchanges between buyers and sellers. In short, the reason market prices are generally used is because they represent the outcome of a competitive process, reflecting the choices of consumers and suppliers.

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[314] Ms Ford, KC made this point on Transcript Day 11/pp.28 - 29:

"We say there is another reason why one has to be suspicious of the pseudo-SSNIP analysis that is driving the process. We have heard from the economists a lot about the fallacies of -- the perils of the cellophane fallacy and how one has to be sure that one is starting with competitive prices in order for that exercise to be an informative one. On the CMA's case not only are Auden/Actavis's prices not effectively competitive but also the prices they are comparing them with, Plenadren on the CMA's case are not effectively competitive because they say the prices for Plenadren are not set in conditions of effective competition either, and when we come to look on for the comparators for the purposes of the excessive pricing case we will see that that is the reason the CMA gives for saying, we are not going to look at Plenadren. So if both of the products you are comparing, on the CMA's case, are not set in circumstances of effective competition then the exercise of price comparison that the CMA has purported to do and that is driving this entire exercise is doubly suspect."

(ii) Where the price is not a market price, the justification for sticking with the actual prices ceases. In this case, we do not consider that the prices for any of the products here in issue can or should be relied upon. This is for a variety of reasons.

(iii) First, this is a case where there is an alleged infringement of the Chapter II prohibition based on excessive pricing. Given that the prices of – at the very least 10mg and 20mg "full label" immediate release tablets sold under the Merck, Sharpe & Dohme MA – are alleged to have been excessive, there is no point in using these prices as a benchmark for market definition. One would be incorporating into a market definition analysis a price that might well be above the market price. In short, the current price may not be the competitive price, and if that is right, the competitive price needs to be taken, not the current price.[315]

(iv) This is only a justification for treating the actual prices of 10mg and 20mg "full label" immediate release tablets sold under the Merck, Sharpe & Dohme MA with caution. What about the prices of potential substitutes? In these cases, there is no allegation of excessive pricing and we are certainly not going to import any such implication in this judgment. Nevertheless, even assuming an absence of excessive pricing, the prices for potential substitutes to 10mg and 20mg "full label" immediate release tablets sold under the Merck, Sharpe & Dohme MA are not the outcomes of a competitive market process. Here, we are not saying that the price for, e.g. Plenadren was in any way susceptible to an infringement of competition law. But it was a price produced (i) in an atypical market generally, with (ii) a protection for orphan drugs, almost equivalent to that of a patent. Without in any way impugning the price of Plenadren in regulatory terms, we do not regard it, nor any other price in this market, as a competitive price.

(v) The prices of potential substitutes are not the outcome of consumer choice. They are not a "market price" for reasons that we have already set out in depth. To recap:

(a) There is no person in the market exercising true consumer choice. The doctor cares about prescribing in accordance with the needs of the patient, and is (largely[316]) uninfluenced by the price of the

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[315] This is the teaching of the "Cellophane Fallacy". See Posner, *Antitrust Law*, 2nd ed (2001) at 150; Whish and Bailey, *Competition Law*, 10th ed (2021) at 28. The point about the "Cellophane Fallacy", which arises in cases where a dominant position is abused particularly by way of excessive pricing, is that the "market price" is no such thing. In *United States v. EI du Pont de Nemours & Co*, 351 US 377 (1956), the case where the "Cellophane Fallacy" originated, the error committed by the court was to take a monopolist's price as the market price. As the US Supreme Court noted, prices were already so high that applying a SSNIP to these (monopoly) prices caused a (meaningless – because not competitively driven) move away from the focal product. To compensate for this distortion, it would be necessary to adjust the price to which the SSNIP was applied. That is precisely what we are doing here.

[316] As we have seen, there is some control exercised by CCGs: see [65].

medicinal products they are prescribing.[317] The patient cares about getting their prescriptions fulfilled and will pay in a manner that does not make them particularly price sensitive.[318] The pharmacy cares less about price and more about the margin between price charged and the Drug Tariff (which is not the same thing). If there is a significant cushion between the price of the medicinal product and the Drug Tariff, the pharmacy's margin is protected, and the pharmacy will be less concerned about the actual price. In this case, as we have seen, the margins earned by pharmacies were high.[319]

(b) The orphan drug status of Plenadren is distortive in two respects. First, the price of Plenadren is artificially protected by its Orphan Drug status, the effect of that status being that competitors arriving on the market after Plenadren are closed out from competing with Plenadren's stated indicated treatment of adrenal insufficiency in adults. The price of Plenadren is thus likely to be higher than it should be – it is certainly not a market price.

(c) Secondly, Plenadren's orphan drug status affected the subsequent market in a most unusual way. Instead of the "skinny label" products being rendered non-substitutes by the orphan drug regime, the pharmacologically identical nature of these skinny label products[320] combined with the off-label dispensing regime that we have described[321] meant that some pharmacies – generally the small pharmacies – regarded fully label and skinny label "immediate release" hydrocortisone tablets as substitutes, whereas other pharmacies – generally the larger pharmacies – regarded skinny label as a different and non-substitutable product. 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.

(vi) We consider that actual prices should not be used to benchmark the preferences of the hypothetical consumer/patient we have identified. That then gives rise to a question of what price should be used. A price that could be used is a price something like the prescription price of £9.65 per item,[322] which would apply to whichever of the products here under consideration. We are not nailing our colours absolutely to the prescription price, and propose to use a rounded figure of £10.00, such

[317] See [213(4)].

[318] See [61].

[319] See [214(5)].

[320] See [205].

[321] See [54] to [90].

[322] That is the present rate. It was £7.10 in 2008 rising to £8.80 in 2018.

that a SSNIP of 10% would result in a price of £11.00. We consider this price to be the right one to adopt for the following reasons:

(a) As we have said, it approximates what the ultimate consumer – the patient – might actually pay.

(b) Although we have very little information about the costs of producing the various medicinal products that we will have to consider as substitutes, we are satisfied that the price we are hypothesising is not below cost. Certainly, it will be well-above marginal cost. This is important: we would be uncomfortable in hypothesising a price that was below cost, because that in and of itself is suggestive of a market distortion.

(9) Accordingly, we propose to adopt a standard SSNIP approach, but using the hypothetical consumer we have described and a uniform product price across all products of £10/pack.

(b) Application of our approach

(i) Questions that arise

244. Our approach is to use a SSNIP to define the market using a general price in respect of the focal product and all potential substitutes to the focal product of £10/unit of medicinal product (be that pack, bottle, etc) that a doctor would prescribe.

245. We will assume a SSNIP of 10% to the focal product. Thus, the price of the focal product – but not that of any substitute or possible substitute – will rise from £10/pack to £11/pack. It is important to bear in mind that this increase will be payable (depending on dosage) at about three-weekly intervals. The £1 SSNIP is thus not a one-off, but will result in an increased payment of £1/every three weeks or about £17/year.

246. We propose to consider the effect of this SSNIP on the hypothetical consumer defined at [243(6)]. Before we can do so, however, a number of anterior questions arise:

(1) What is the focal product in question?

(2) How do we treat potential substitutes?

(3) What are the implications of the fact that we are defining a market over a period of years?

We consider these questions in turn below, before coming to the definition of the market.

(ii) What is the focal product in question?

247. This is not as straightforward as it might seem. Conscious of the importance of defining the focal product as narrowly as possible[323] we will define the focal product as (i) 10mg (ii) full label (iii) immediate release (iv) hydrocortisone tablets (v) sold under the Merck Sharpe & Dohme MA.

248. That excludes from the focal product the 20mg tablet strength of what is otherwise an identical product. We of course appreciate that the Abuse of Dominance Infringements have been found in the Hydrocortisone Decision in respect of this product as well as the 10mg variant, and that a market definition for the 20mg product will have to be derived also. We deal with this separately once we have completed the market definition process as regards the 10mg focal product (which we shall now refer to as the **10mg Focal Product**. We shall – when the time comes – refer to the 20mg product as the **20mg Focal Product**. In this way, we propose to avoid the over-expansive definition of focal product used in the Hydrocortisone Decision.[324]

249. More fundamentally, it is necessary to justify our decision not to elide into one focal product all (i) 10mg (ii) full label (iii) immediate release (iv) hydrocortisone tablets (v) sold under any Marketing Authorisation. After all, it is the case that such products would be pharmacologically identical and normally (we consider) they would be regarded as a single focal product. The reasons we do not take this course (at the risk of some repetition) are as follows:[325]

(1) First, we repeat the importance of keeping the focal product narrow. If we were to adopt a definition of the focal product that was "Marketing Authorisation blind", then that would be eliding all 10mg immediate release hydrocortisone tablets including skinny label. Abandoning the Marketing Authorisation as a definitional element of the focal product inevitably means abandoning the distinction between full label and skinny label since that difference only arises because of the Marketing Authorisation. In short, abandoning reference to the Marketing Authorisation eliminates central questions that need to be asked in attempting to understand this market.

(2) Secondly, the Marketing Authorisation under which a product is sold is an intrinsic part of that medicinal product. We have described – at some length[326] – the regulatory arrangements that ensure that the supply of medicinal products to the market is controlled – and rightly so. The Marketing Authorisation is central to these arrangements. In particular:

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[323] See [185(4)].

[324] See [7].

[325] In a very real sense, these reasons are the flip-side of the criticisms we have made of the Hydrocortisone Decision. As to this, see [200] to [211] above.

[326] See Section D.

(i) The Marketing Authorisation ensures that a medicinal product comes to market under the responsibility of a defined entity, which controls that product.

(ii) Although a Marketing Authorisation is transferable, it is personal to a particular holder, which is the only entity able to supply the product pursuant to that Marketing Authorisation.

(iii) Competition is introduced by way of multiple Marketing Authorisations for what is – pharmacologically speaking – the same product. This is the way "generic" pharmaceutical companies operate. When a medicinal product comes "off-patent" then provided a competitor has a Marketing Authorisation for that product, there can be competition. This is illustrated in Annex 3, where we have listed separately:

(a) The Waymade MA.

(b) The AMCo MA.

(c) The Skinny Label MAs.

(iii) Treatment of potential substitutes

250. What is the position where there is a potentiality to supply a medicinal product pursuant to a Marketing Authorisation vesting in a given entity, but where either the supply is not provided (as was the case, initially, in respect of the Waymade and AMCo MAs) or where there was such a supply, but it came pursuant to a supply from the holder of the Merck, Sharpe & Dohme MA – as was the case with the 10mg and 20mg Agreements.

251. In our judgment, it would be wrong to disregard such Marketing Authorisations simply because they were not used. The fact that little or no product is supplied pursuant to a Marketing Authorisation is a point relevant to market dominance but not market definition. In short, we will consider as potential substitute products tablets sold under Marketing Authorisations that have been issued even when they have not been used.

(iv) Defining a market that has been in operation over a period of years

252. As we have noted,[327] the Abuse of Dominance Infringements are found, in the Hydrocortisone Decision, to have occurred over a number of years. In that time, the market developed. Specifically, Plenadren came onto the market pursuant to the Plenadren MA, and the skinny label products came onto the market pursuant to the various Marketing Authorisations that we have described.[328]

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[327] See [366] which sets out the different phases, according to the Hydrocortisone Decision, in relation to the distribution of the total penalty amongst the legal entities liable for the infringements.

[328] See [206].

253. It follows that the substitutes that would be available in response to any SSNIP will vary with time. That is trite, but actually quite fundamental to the application of the hypothetical monopolist test. We are very conscious that we will need to consider dominance in the context of the substitutes that were available at the time of dominance. The Hydrocortisone Decision recognises this – at least partially – in bifurcating the market into the Pre-Entry Period and the Post-Entry Period. We consider that it will be necessary to view the market as it developed from time to time, but we will consider that market evolution when we come to consider the question of dominance. However, we want to stress now that we are well aware that it would be wrong to seek to define the market as at any given point in time. What we will do in this section is simply identify those substitute products whose existence on the market (at whatever time) would render the SSNIP uneconomic to the hypothetical monopolist.

(v) Focal product re-visited

254. We defined the focal product in [247] above. In light of the consideration in the immediately preceding paragraphs,[329] we consider that the definition of focal product – and substitutes to focal products – can be considerably simplified, merely by reference to the Marketing Authorisation pursuant to which medicinal products compliant with that authorisation would be supplied. The Marketing Authorisation captures all of the relevant differentiating factors.

(vi) Substitutes to the 10mg Focal Product: general consideration

255. The 10mg Focal Product is hydrocortisone sold pursuant to the Merck, Sharpe & Dohme MA, whichever company was, from time-to-time, the holder of that Marketing Authorisation. We refer, in this regard, to the five "phases" described and defined at [179]. We will, when considering the question of dominance, have specific regard to these phases, and the substitute products that existed during the period of those phases. However, we will, for the moment, consider substitutability in the abstract, and without reference to time.

256. We assume that our hypothetical consumer will be paying £10/pack of 10mg hydrocortisone supplied to the market pursuant to the Merck, Sharpe & Dohme MA. Applying a SSNIP to this price – increasing it by 10% to £11/pack, what products are, and what products are not, substitutes such that sufficient demand will move away from the 10mg Focal Product if there is a SSNIP as to make that price increase inefficient to the hypothetical monopolist:

(1) *10mg potential substitutes.* We consider that demand will shift immediately to other hydrocortisone products that are or could be supplied to the market pursuant to a Marketing Authorisation for a pharmacologically identical product that is "immediate release" and 10mg in dose. We consider that, in the case of such products, the elasticity of demand faced by the supplier of the 10mg Focal Product would be extremely high given (i) the fact that the products in question are actually identical (ii) the knowledge we are pre-supposing on the part of the consumer (iii) the increase in price and (iv) the fact that obtaining the alternative

[329] I.e. [244] to [247].

– substitute – product will not inconvenience the consumer very much, if at all. We find that the following products would be very close substitutes for the 10mg Focal Product:

- Product supplied to the market pursuant to the 10mg Agreement.[330]

(2) *20mg potential substitutes.* Turning then to a potential 20mg tablet that is otherwise pharmacologically identical to the 10mg Focal Product. The extent to which the hypothetical consumer will shift demand away from 10mg tablets to 20mg tablets will depend on (i) the extent to which the hypothetical consumer has to split 10mg tablet in order to dose themselves properly and (ii) the extent to which that consumer is discombobulated by the need to split tablets. This is an area on which the Hydrocortisone Decision is silent. The Hydrocortisone Decision notes – as do we – that doctors prescribe 10mg hydrocortisone for a reason, and that the vast majority of hydrocortisone that is prescribed is in the form of 10mg tablets, rather than 20mg tablets. Accordingly, we consider that there would be some reluctance on the part of the hypothetical consumer to shift to 20mg tablets, even in the face of the SSNIP. It would be wrong to describe price elasticity of demand as "extremely high" (as we have in relation to 10mg substitutes), but we nevertheless consider that elasticity of demand would be sufficiently high to prevent the hypothetical monopolist from raising prices. We find that the following products are substitutes for the 10mg Focal Product:

- Product supplied to the market pursuant to the 20mg Merck, Sharpe & Dohme MA.

- Product supplied to the market pursuant to the 20mg Agreement.[331]

- Product that could have been supplied to the market pursuant to the Waymade MA.

(3) *Plenadren.* Plenadren, supplied to the market pursuant to the Plenadren MA, is (in contrast to the 10mg Focal Product) not "immediate release" hydrocortisone but a "modified release" variant. The Hydrocortisone Decision does not contain very much by way of articulation of the clinical disadvantages of using Plenadren in place of the 10mg Focal Product, and there are clearly some advantages: fewer tablets need to be taken by the patient, and tablet splitting is not required. We consider – most particularly in light of our assumption that Plenadren would sell for far less than its actual price – that elasticity of demand

[330] We have thought very carefully about whether product supplied to the market pursuant to the 10mg Agreement should be treated as (i) the focal product or (ii) a substitute for the focal product. The fact that this product is supplied to the market pursuant to the Merck, Sharpe & Dohme MA is a very strong indicator that this product supply is the same focal product. Nevertheless, we consider the fact that AMCo (the entity that could, pursuant to the 10mg Agreement, supply the market) could at least in theory price independently of the holder of the Merck, Sharpe & Dohme MA means that regarding this product as a substitute product is preferable.

[331] Similar considerations apply as regards this product supply as was considered in fn 330.

faced by the supplier of the 10mg Focal Product would again be extremely high.[332] We regard Plenadren as a substitute product.

(4) *Skinny label.* The hypothetical consumer would appreciate that medicinal products supplied to the market pursuant to Skinny Label MAs were pharmacologically identical to the 10mg Focal Product and that the only reason for the exclusion of adults from the therapeutic indications for the product was the regulatory happenstance of the granting of orphan status to Plenadren. In these circumstances, we doubt very much that a hypothetical consumer would tolerate paying more (even if only £1/pack) for what was, in substance, an identical product. Demand elasticity would be extremely high. We find that all product supplied to the market under Skinny Label MAs to be substitutes for the 10mg Focal Product (whether 10mg dose or 20mg dose).

(5) *Hydrocortistab.* Hydrocortistab – as we have described[333] – is an injectable form of hydrocortisone. Even if the clinical effects of Hydrocortistab were exactly the same as hydrocortisone administered in tablet form (an assumption we are prepared to make), we consider that the mechanism of delivery represents a substantial point of differentiation between the 10mg Focal Product and injectable products like Hydrocortistab. We consider that – even in the case of a £1 SSNIP – there would be a marked reluctance on the part of the hypothetical consumer to move from tablet administered medication to an injectable form of hydrocortisone. We do not consider Hydrocortistab (or other products administered in non-tablet form) to be substitutes for the 10mg Focal Product.

(6) *Non-hydrocortisone treatments for adrenal insufficiency.*[334] We do not consider these treatments to be substitutes for the 10mg Focal Product. There are sound clinical reasons for using hydrocortisone as the "first-line" treatment for adrenal insufficiency, and we consider that the hypothetical consumer would pay significantly more than the SSNIP to obtain the correct form of treatment for a very serious condition. Non-hydrocortisone treatments for adrenal insufficiency are not substitutes for the 10mg Focal Product.

(vii) The 20mg Focal Product

257. In light of the foregoing, the substitutes for the 20mg Focal Product are exactly as for the 10mg Focal Product. We anticipate the hypothetical consumer will have been buying the 20mg dose for a reason, and that shifting away from 20mg tablets to 10mg tablets will involve some inconvenience. We therefore consider that our conclusions at paragraphs [256] – including that at [256(2)] apply *mutatis mutandis* to the 20mg Focal Product.

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[332] We should stress that we will not lose sight of the fact that Plenadren sold at a price around 40 times higher than the price we are hypothesising, and that CCGs were opposed to the prescribing of Plenadren on cost and not on clinical grounds. The price of Plenadren, and reason why demand was low, are factors that go not to substitutability, but to dominance, and we will consider the matter of Plenadren's price in this context.

[333] See [44].

[334] Described in [46] to [47].

I. DOMINANCE

(1) The meaning of dominance

258. Dominance in the market that we have defined is a prerequisite to triggering jurisdiction under the Chapter II prohibition. Unless there is dominance, there can be no abuse of a dominant position. The standard definition of a dominant position comes from *United Brands v. Commission*:[335]

> "The dominant position thus referred to by [the Chapter II prohibition] 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 affording it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers."

259. Dominance thus equates to market power. As Whish and Bailey note,[336] dominance derives from a combination of several factors each of which, taken separately, may not be determinative. Three factors that are particularly relevant are:

(1) Constraints imposed by existing supplies from, and the position on the market of, actual competitors.

(2) Constraints imposed by the credible threat of future expansion by actual competitors or entry by potential competitors.

(3) Constraints imposed by the bargaining strength of the undertaking's customers.

260. The Hydrocortisone Decision helpfully lists a number of other factors of importance, both generally, and in this case, notably: market shares (including relative market shares);[337] pricing behaviour;[338] financial performance;[339] market context, including in particular barriers to entry and expansion;[340] buyer power or its absence and state regulatory power.[341]

261. Dominance thus involves the careful consideration of multiple factors that may not all point in the same direction. We do not propose to elucidate these factors in the abstract, but rather consider them in the context of the market itself. In this regard, it is necessary to make a number of general points about the assessment of dominance.

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[335] Case 27/76.

[336] Whish and Bailey, *Competition Law*, 10th ed (2021) at 185 and 40.

[337] Hydrocortisone Decision/4.175*ff* (Ref only).

[338] Hydrocortisone Decision/4.191*ff* (Ref only).

[339] Hydrocortisone Decision/4.199*ff* (Ref only).

[340] Hydrocortisone Decision/4.202*ff* (Ref only).

[341] Hydrocortisone Decision/4.207*ff* (Ref only).

(2) Some general points on the assessment of dominance

(a) Points under consideration

262. There are four general points that we need to address before we come to the specifics:

(1) The complaint advanced by some of the Appellants in their grounds of appeal – particularly those who acquired the Merck, Sharpe & Dohme MA later on in the history – that the Hydrocortisone Decision failed to differentiate between the different holders of this Marketing Authorisation.

(2) The relevance of price.

(3) The relevance of countervailing "buyer power" and the Secretary of State's ability to intervene to control prices.

(4) The extent to which an undertaking can be dominant simply because of circumstance – in particular, regulatory circumstances – and the extent to which it bears responsibility in such a case.

We consider these four points in turn in the following paragraphs.

(i) Successive holding of the Merck, Sharpe & Dohme MA

263. As Annex 3 demonstrates, this is an unusual case because of the number of successive holders of the Merck, Sharpe & Dohme MA. We have broken the history down into five phases which we have described and defined at [179] above. To recap, they are:

(1) The Patel Phase (Phase 1).

(2) The Actavis Phase (Phase 2).

(3) The Hold Separate Regime Part I (Phase 3).

(4) The Hold Separate Regime Part II (Phase 4).

(5) The Intas Phase (Phase 5).

264. Various of the Appellants criticised in their grounds of appeal the fact that the Hydrocortisone Decision failed or failed sufficiently to take account of the fact that – even assuming that the decision was correct in finding the Abuse of Dominance

Infringements – responsibility for the "Matterhorn" was shared in sequence between the various Appellants.[342]

265. We consider that the point is significant in three respects:

(1) First, if there were only one undertaking involved in the Abuse of Dominance Infringements, doubtless a relatively broad brush could be taken in relation to the "Matterhorn". Whilst it might not be completely intellectually honest, if an undertaking were responsible for the entire "Matterhorn", then the fact that there might be an argument that for a certain period of time there was no dominance might not especially matter provided it was clear that for the bulk of the period it was dominant. Equally, one might be able to finesse, without deciding, precisely when dominance began and ended. Where, however, the "Matterhorn" has to be divided into temporal or vertical slices (as set out in Annex 4C), it is neither appropriate nor right to avoid grappling with the implications.

(2) Secondly, viewing the "Matterhorn" as a whole, instead of parsing it according to the undertakings implicated over time, runs the grave risk of failing properly to take into account the nuances of each distinct period. The point is clearest as regards the third and fourth phases, which concern the Hold Separate Regime. During the Hold Separate Regime, Actavis UK Ltd was the holder of the Merck Sharpe & Dohme MA, but that company was subject to a Hold Separate Regime which removed the parent companies who were fined from direct, day-to-day control of the companies said to have committed the infringement. Allergan contended that – by virtue of the Hold Separate Regime – they were not part of the infringing undertaking because the Decisive Influence Test[343] was not satisfied.[344] We will come to consider this question in due course. For the present we would only observe that a temporally segregated approach needs to be borne in mind, even if it is not absolutely decisive.

(3) Thirdly, and finally, the question is not merely relevant to dominance (although that is the aspect we are presently considering). It also goes to the question of abuse and penalty. We obviously do not deal with these questions in this section, but it is important – at this stage – to be aware that a failure to have regard to this question of temporal segregation is material.

In short, for these reasons, we consider that – given the facts of this case – dominance must be considered by reference to specific periods. Although we consider that the CMA would be entitled to a margin of appreciation in terms of how it chose to parse these

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[342] See for example [6] and [7] of the Intas NoA: "The Decision states that it is not required to carve up the analysis of dominance and abuse based on who owned Accord-UK at the relevant time. This is not disputed in the abstract. However, it remains necessary to consider whether the key developments that took place in or by the time of the Intas Period – the last 18 months of an alleged 10-year infringement – were such (either individually or cumulatively) that any dominance might have been established in any of the earlier periods (which is not admitted) might have been lost…The Decision's approach of conflating large periods of time leads to irrelevant and immaterial findings from earlier periods being applied to the analysis of the Intas Period…".

[343] See [173] to [175].

[344] See [11], [74] to [109] of the Allergan NoA.

periods, we consider (i) that it would be a material error not to parse them at all and (ii) that the CMA, in the Hydrocortisone Decision, could have been far clearer in the manner that it did parse these periods, particularly given the points advanced by the Appellants both before the CMA and before us so far as the Abuse of Dominance Infringements are concerned.[345] The best instance of the importance of this point occurred when Professor Valletti denied the point any relevance at all: [346]

Q: Mr Palmer	So in order to evaluate that claim it will be necessary for the Tribunal, will it not, to look at market conditions at the time of the Intas period.
A: Professor Valletti	Again, I am sure it is a very interesting legal question. As an economist that is not my understanding, because there has been a change of ownership, a change of ownership in itself. For me, just – it is a year. One year this firm was owned by A, this other year it was owned by B. So that would be the same as saying you have to do a market assessment 2016, 2017, 2018 which is what we did, because in my analysis I considered throughout – dominance in this case throughout.
Q: Mr Palmer	Professor Valletti, it is a simple point. No one is suggesting that a mere change of ownership changes anything in itself, just the fact that a different parent company is involved. No one suggests that. But Intas's case before this tribunal is that by this time market conditions had sufficiently changed that Accord was no longer dominant.
A: Professor Valletti	In my assessment. Sorry, maybe we are on the same page.
Q: Mr Palmer	My simple question to you, I know you disagree with that case, we know that.
A: Professor Valletti	Maybe –
Q: Mr Palmer	My simple question to you is that in order to evaluate that claim you have to look at market conditions and the sufficiency and extent of competitive constraints at that time.
A: Professor Valletti	So I have analysed market definition throughout the entire period, therefore including Intas because of the amount of time. I have analysed dominance throughout the period, including the Intas period. So I have analysed it.
Q: Mr Palmer	You told me yesterday you had not conducted any dominance assessment in respect of the Intas period specifically.
A: Professor Valletti	Specifically, so I have not extracted one year. I have not done separate analysis because there is a single and continuous infringement. I haven't done in paragraph 1, 2016, in paragraph 2 – I have analysed and we have looked, I have looked at the data and following what the CMA had said I was looking in the data if I saw any structural changes within the period. Within this period you are talking about I do not see any structural change. I have analysed the period. I have not done, you know, extracting a year on itself

[345] We accept that when considering penalty, the Hydrocortisone Decision appropriately considered these temporal questions.

[346] Transcript Day 10/pp.39 to 43.

because part of the evidence is looking what is happening before and what is happening after. It is part of the exercise.

Q: Mr Palmer It is necessary to look at that -

Q: The President Professor, this is a somewhat unusual situation. Normally if one has no change of ownership you can look at a period more in the round and you can say, well, actually it does not really matter when the dominance ended or indeed when it began, because you have a single entity that is responsible for that. So you find dominance, you find an abuse and you slap that entity with a great fine to make sure it does not happen again. So, nice and easy. The point that is being put here is that although the general analysis of dominance remains the same and is unchanged by ownership of firm, when one is considering the incidence of a fine on a separate organisation the question of dominance and abuse is sharpened such that one needs to consider more carefully the beginning and end of dominance and so the beginning and end of abuse, not because it affects the market analysis but because it affects the incidence of a penalty. I think that is the point that is being put. So it requires a finer degree of parsing of events than would ordinarily be the case, and that is why you are being pressed on this. So there is, I think, an unfortunate difference between the economic analysis of a phenomenon and the legal analysis of a phenomenon. So you are being put, I am afraid, points that matter to the lawyer, or may matter to the lawyer, where the economic input is extremely important but where you are being asked to address the question of dominance in a somewhat unusual way. So it is absolutely no criticism of you that this is not the way you would normally do things, but that is why counsel is pressing you on this, and that is why your answers on this point are of particular importance. So that is why we have this tension between the economic view and the legal view, and I hope that will help you answer these rather important questions so that we have the benefit of your expert opinion. I hope that helps, Mr Palmer.

A: Mr Palmer It very much assists, I am very grateful.

A: Professor Valletti I am grateful, and it you said, it sharpens a lot my understanding, and I am very happy perhaps to qualify my response of yesterday when I said I did not analyse the Intas period. I meant I was not instructed to look at the Intas period alone. That is all I meant, nothing more, nothing less. But when it comes to what is called the Intas period, which is early January 2017 until mid-2018, of course I have analysed it and I have analysed it, and in the context of my analysis on the basis of the parameters which I consider I do find that there was dominance by Intas in that period. So I have analysed it.

266. We consider that, in light of the grounds of appeal articulated by the Appellants, it is necessary, when considering the question of dominance (and – relatedly – abuse of dominance), to "parse the Matterhorn". For reasons which are related to the manner in which the Appellants advanced their grounds of appeal, the Hydrocortisone Decision did not approach matters in quite this way, and it will be necessary (in order to deal with the grounds of appeal) to re-visit this question. We do so below, when we consider, *seriatim* and separately, dominance in the five phases that we have identified. We will – when considering each phase – decide the extent of the undertaking involved in the

Abuse of Dominance Infringements at each phase, paying particular regard to the Hold Separate Regime in Phase 3 and Phase 4.

(b) The relevance of price

267. It is often said that an ability to price at will is a strong indicator of dominance. Thus, the *EU Commission Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings* states:[347]

> "The Commission considers that an undertaking which is capable of profitably increasing prices above the competitive level for a significant period of time does not face sufficiently effective competitive constraints and can thus generally be regarded as dominant."

268. Whilst this may be right in the general case (we do not comment), particular care needs to be exercised where the allegation of abuse of dominance turns on excessive pricing. We have stressed the dangers of reasoning backwards from outcome in [153] to [155] above. We consider that it is extremely dangerous to infer dominance simply from an ability to price without constraint. We consider, instead, that it is more rigorous to consider why it is that an undertaking can price without constraint. Take, for example, the case of an owner of a patent that has real market significance. Not, in other words, a patent conferring a monopoly of no economic significance.[348] In such a case, the owner of the patent will no doubt be able to extract monopoly rents either in licensing the patent to third parties at high rates or differentiating a product it sells and charging a higher price for it. In each case, the undertaking will be pricing "without constraint", but the reason for the dominance is not the ability to price "without constraint", but the patent.

269. Accordingly, when we come to consider the question of abuse, we will, of course, consider the ability to price, but we will be asking ourselves why the ability to price without competitive constraint exists. We do not consider that too much weight should be placed on the ability to price at will when considering the question of dominance in a case where the abuse allegation is one of excessive pricing. Of course, such matters cannot completely be taken out of account; but they should not be given excessive weight and should be treated with caution for the reasons we have given.

(i) The relevance of countervailing "buyer power" and the Secretary of State's ability to intervene to control prices

270. The Auden/Actavis Appellants were at the forefront of this contention. They submitted that the CMA erred in its assessment of dominance by failing to have regard to countervailing buyer power on the part of the NHS arising from the Department of Health's powers under sections 261 to 266 of the National Health Service Act 2006 and its role in exercising monopsony pricing powers in respect of hydrocortisone tablets.[349]

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[347] 2009/C 45/02 [11].

[348] See [155(1)].

[349] Auden/Actavis NoA/6.1.2, 54 – 65. Intas adopted these submissions – see Intas NoA/98.

The Department of Health had powers under section 262 of the 2006 Act regarding Auden, and under section 261 and Scheme M regarding Actavis-UK, to intervene to limit prices charged by a manufacturer for medicines.

271. The Department of Health's possession of these powers, it was argued, regardless of whether they were exercised, took the form of countervailing buyer power, since the Department of Health represents the Clinical Commissioning Groups who paid for the hydrocortisone tablets and the Department of Health was a monopsony purchaser.[350]

272. We have described the regime for the purchase, prescription, dispensation and reimbursement of medicinal products in Section D above. It is entirely fair to say that the regime is a highly regulated one, and that there is certainly a high degree of theoretical buyer power on the part of CCGs. Equally, the Drug Tariff controls reimbursement rates, and there are other price controls, including (in particular) the Secretary of State's power to intervene in prices both generally[351] and through voluntary schemes.[352]

273. To this extent – but to this extent only – we accept the Appellants' contentions. But to suggest that this regime operates as a constraint on market power so as to negate dominance is, in our judgment, fundamentally misconceived and we reject it:

(1) The fact is that – notwithstanding the panoply of highly complex regulation that we have described – the regime has not been used even to attempt to constrain price.

(2) Yet there was ample indication that a consideration of the use of these powers was called for. For an unpatented medicinal product to rise in price from £0.70[353] to £65.83[354] to £87.89,[355] then to fall – not quickly – to £82.15[356] to £74.57[357] to reach an end-point (when Annex 3 ends its record) of £25.08[358] tells not of regulatory constraint on dominance but of a complete and utter regulatory failure which we find disturbing.[359] The Hydrocortisone Decision records that the

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[350] *Ibid.*

[351] See [100] to [104].

[352] See [105] to [107].

[353] The price for 10mg "immediate release" hydrocortisone sold under the Merck, Sharpe & Dohme MA in Period 1 in Annex 3.

[354] The price at Period 89, the end of Phase 1.

[355] The price at Period 98, the end of Phase 2.

[356] The price at Period 103, the end of Phase 3.

[357] The price at Period 108, the end of Phase 4.

[358] The price at Period 127, when Annex 3 ends. The price of course fell further to reach between £1 and £4 at the time of the Decision (Hydrocortisone Decision/5.346).

[359] We stress that we are neither – by reference to price – presuming dominance nor presuming an abuse. Here we are considering the converse point, namely dominance on the side of the buyer, by virtue of the buyer's market

holders of the Merck, Sharpe & Dohme MA "made a profit of at least £145 million from the Unfair Pricing Abuses".[360]

(3) What we have here is a theoretical constraint on dominance that existed on paper only. We have seen no evidence of these powers being used in this case; and no evidence of them acting as any kind of control over what participants in the market did. We reject the suggestion that a state of dominance does not exist in this case by reason of a cumbersome, ineffectual and unused scheme of regulation.

274. We cannot leave this point without identifying a number of specific deficiencies in the regime for the regulation of prices of medicinal products, in the hope that these deficiencies can be addressed. As we will come to, these deficiencies will become relevant when we consider the question of abuse:

(1) If the Secretary of State has general powers to intervene in prices – as we have found exist[361] – then they should be used.

(2) It is incomprehensible to us that the Drug Tariff can be calculated by reference to a single product, such that the Drug Tariff simply follows the price of that product upwards until market forces – not the Drug Tariff – take control.[362]

(3) We find it extraordinary that the regime for Orphan Drugs can provide a form of competitive protection well in excess of that conferred by patent rights. The notion that, for a 10-year period, functionally very similar products ("immediate release" hydrocortisone in contrast to the Plenadren "delayed release" hydrocortisone) can be relegated to "second class" products and generate real uncertainty in dispensing pharmacies as to what they should and should not be able to dispense is both a failure of regulatory clarity and wanton over-protectionism.[363]

(4) The process for the granting of Marketing Authorisations can act as a significant barrier to entry, for medicinal products can only properly be sold by the holder of such an authorisation.[364] It is imperative that Marketing Authorisations be granted – when appropriate – quickly.

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position and (in this case) the swingeing statutory powers vesting in the buyer (which was, or was very closely connected to, the state). We consider that it is important to understand what constraints in practice existed on price, not whether those prices were abusive or the result of an abuse of a dominant position. It is quite clear from Annex 3 – from which we have drawn these examples – that buyer power is, in any real sense, non-existent.

[360] Hydrocortisone Decision/1.75(a) (Ref only).

[361] See [273].

[362] See [214].

[363] See [89] to [90].

[364] See [52] to [55].

(ii) Dominance through circumstance

275. Dominance does not necessarily arise through the efforts and actions of the dominant undertaking, although it can do so. Dominance can equally arise in a taking advantage of circumstance which may have been unplanned and unanticipated by the (allegedly) dominant undertaking. We revert to our Face Mask Example: this is a case where monopoly rents as a result of the uninduced (by face mask manufacturers, at least) worldwide tragedy that was COVID-19 can be justified as a means of encouraging new market entrants.[365] But that does not mean that such happenstance – being in the right place, at the right time – does not, as well as create the opportunity of high profit, also create the special obligations of dominance.

276. That is the position here. The very deficiencies in the regime, that we have articulated,[366] have created opportunities – in terms of supressing competition – that form part of the hinterland that must be taken into account when considering whether a state of market dominance exists.

(3) An assessment of dominance by phase

(a) Approach

277. We turn to a more specific consideration of the question of dominance, but we do so 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. For the reasons we have given, we regard such factors as background factors to be accorded a secondary weight.[367] But it is important to appreciate that they point towards, and not away from, dominance.

278. In this case, we propose to consider the question of whether a state of dominance existed by reference primarily to market share on a "phase-by-phase" basis, considering each phase separately. More specifically:

(1) We have defined the market in which the 10mg and 20mg Focal Products were sold in Section H, and have a clear understanding of the substitutes that existed in relation to these Focal Products.

(2) The Focal Products were themselves close substitutes for each other. But, on the facts of this case, the holder of the Merck, Sharpe & Dohme MA for 10mg immediate release hydrocortisone tablets was always the same as the holder of the Merck, Sharpe & Dohme MA for 20mg immediate release hydrocortisone tablets. When it comes to considering market share, the market shares of these

[365] See [152(4)].

[366] See [274].

[367] That is particularly so as regards price itself. In excessive pricing cases, price level must be treated with a degree of caution, for the reasons given at [267] to [269].

two products will fall to be aggregated and treated as one single share of the market.

(3) We calculate market share by reference to:[368]

(i) Volume (i.e. numbers of units sold, irrespective of price, set out both in absolute terms and as a percentage of the total market).

(ii) Revenue (i.e. numbers of units sold multiplied by price, again set out both in absolute terms and as a percentage of the total market).

(4) As we have stated, we will approach the question of dominance on a phase-by-phase basis. Even then, we recognise that these phases spanned months, and sometimes years. We will therefore look at market share (by volume and by revenue) in each phase calculated by reference to:

(i) The beginning of the Phase (i.e. the first Period of that Phase).

(ii) The end of the Phase (i.e. the last Period of the Phase).

(iii) The average across the Phase. The average simply aggregates the volumes and revenues in each Period falling within the Phase, and divides by the number of Periods whose data has been aggregated.

279. Because it is convenient to do so, after we have considered the market share for each phase, we express our concluded view as to the nature and extent of the undertaking involved during that phase. When we come to consider Phases 3 and 4, we will consider the significance of the Hold Separate Regime. We express our conclusions in relation to dominance generally after we have conducted our phase-by-phase analysis of market share.

[368] The data underlying these calculations are drawn from the data provided by the CMA (see footnote 1 above). Note that the data provided by the CMA was given, where relevant, to more than two decimal places, and it is those full figures which have been used to produce the revenue and totals in each of the dominance tables. This does give rise to an impression that accuracy to several decimal places matters. It does not. The conclusions we draw would be exactly the same if a process of rounding had been adopted. Equally, our calculations (because of the figures being divided) suggest that fractions of packets were being sold, when clearly this would not have been the case. Readers should pay regard to the substance of the data, and not be distracted by these (and other) immaterial questions.

(b) The Patel Phase (Phase 1)

280. We have defined the Patel Phase (Phase 1) at [179(1)] as beginning with Period 10 and ending with Period 89. In terms of market share, the position for this Period is as follows:[369]

	Holder of Marketing Authorisation	Price sold per pack	Volumes Sold	Revenue	% by Volume	% by Revenue
Period 10 Oct 2008	The market comprising (a) + (b)	N/A	74,335	£1,666,197.94	100%	100%
(a)	AM Pharma 10mg	£22.28	67,476	£1,503,365.28	91%	90%
(b)	AM Pharma 20mg	£23.74	6,859	£162,832.66	9%	10%
Period 89 May 2015	The market comprising (a) to (f)	N/A	75,315	£4,265,481.73	100%	100%
(a)	AM Pharma 10mg	£54.99	61,882	£3,402,891.18	82%	80%
(b)	AM Pharma 20mg	£64.03	3,505	£224,425.15	5%	5%
(c)	10mg Agreement sale	£57.19	9,277	£530,589	12%	12%
(d)	20mg Agreement sale	£66.02	260	£17,165	<1%	<1%
(e)	Plenadren 5mg	£212.20	337	£71,511.40	<1%	1.6%
(f)	Plenadren 20mg	£350.00	54	£18,900.00	<1%	<1%
Average Periods 10 to 89	The market comprising (a) to (f)	N/A	89,324.06	£3,210,613.29	100%	100%
(a)	AM Pharma 10mg	£33.39	76,283.08	£2,573,822.51	85.4%	80.3%
(b)	AM Pharma 20mg	£35.41	4,248.26	£147,236.47	4.8%	4.6%
(c)	10mg Agreement sale	£43.50	8,133.2	£370,001.43	9.1%	11.5%
(d)	20mg Agreement sale	£44.69	190.09	£8,198.32	<1%	<1%
(e)	Plenadren 5mg	£212.13	384.23	£81,534.11	<1%	2.5%
(f)	Plenadren 20mg	£350	85.20	£29,820.44	<1%	<1%

[369] We have shaded the relevant Focal Products in colours consistent with Annex 3. Thus, data concerning 10mg immediate release hydrocortisone sold under the Merck, Sharpe & Dohme MA is coloured yellow, and data concerning 20mg immediate release hydrocortisone sold under the Merck, Sharpe & Dohme MA is coloured green. The designation of the holder of the Marketing Authorisation is as per Annex 3.

281. We consider that during the Patel Phase (Phase 1) the undertaking comprised: AM Pharma; Auden Mckenzie Holdings Ltd;[370] Mr Amit Patel; and Mrs Meeta Patel. This was not a matter of dispute before us.[371]

(c) The Actavis Phase (Phase 2)

282. We have defined the Actavis Phase (Phase 2) at [179(2)] as beginning with Period 90 and ending with Period 98. In terms of market share, the position for this Period is as follows:

	Holder of Marketing Authorisation	Price sold per pack	Volumes Sold	Revenue	% by Volume	% by Revenue
Period 90 June 2015	The market comprising (a) to (f)	N/A	95,010.24	£5,378,701.54	100%	100%
(a)	Actavis UK Ltd 10mg	£55.06	73,824	£4,064,749.44	77.7%	75.57%
(b)	Actavis UK Ltd 20mg	£64.26	3,783	£243,095.58	3.98%	4.52%
(c)	10mg Agreement sale	£57.17	16,845	£963,055	17.73%	17.90%
(d)	20mg Agreement sale	£67.25	120	£8,070.00	<1%	<1%
(e)	Plenadren 5mg	£212.20	389.35	£82,620	<1%	1.5%
(f)	Plenadren 20mg	£350	48.89	£17,111.52	<1%	<1%
Period 98 February 2016	The market comprising (a) to (g)	N/A	88,409	£6,297,371.78	100%	100%
(a)	Actavis UK Ltd 10mg	£70.84	53,155	£3,765,500.20	60%	60%
(b)	Actavis UK Ltd 20mg	£67.54	3,147	£212,548.38	4%	3%
(c)	10mg Agreement sale	£71.59	12,000	£859,080	14%	14%
(d)	Plenadren 5mg	£212.20	426	£90,397.20	<1%	<1%
(e)	Plenadren 20mg	£350	102	£35,700	<1%	1.4%
(f)	Waymade 20mg	£69.19	964	£66,696	1.1%	1.1%
(g)	Alissa 10mg	£68.09	18,615	£1,267,450	21%	20%

[370] For those periods where this company was part of the corporate structure holding AM Pharma: see [119] above.

[371] Although the Hydrocortisone Decision did not make a finding in this regard.

Average Periods 90 to 98	The market comprising (a) to (h)	N/A	104,910.76	£7,026,795.3	100%	100%
(a)	Actavis UK Ltd 10mg	£66.14	75,886.67	£4,975,186.31	72%	71%
(b)	Actavis UK Ltd 10mg	£68.58	3,241.11	£222,046.66	3.1%	3.16%
(c)	10mg Agreement sale	£67.19	12,527	£837,976.56	11.94%	11.93%
(d)	20mg Agreement sale	£68.16	86.67	£5,900	<1%	<1%
(e)	Plenadren 5mg	£212.20	440.33	£93,438.73	<1%	1.3%
(f)	Plenadren 20mg	£350	91.56	£32,044.44	<1%	<1%
(g)	Waymade 20mg	£70.90	1,304.43	£92,363	1.24%	1.32%
(h)	Alissa 10mg	£67.68	11,333	£767,839.60	10.8%	10.93%

283. We consider that during the Actavis Phase (Phase 2) the undertaking comprised: AM Pharma; Auden Mckenzie Holdings Ltd and then Actavis UK Ltd; Actavis plc and then Allergan plc. This was not a matter of dispute before us.[372] It was accepted that as regards the parent entities, the Decisive Influence Test was met, and accordingly, we consider this matter no further.

(d) Hold Separate Regime Part I (Phase 3)

284. We have defined the Hold Separate Regime Part I (Phase 3) at [179(3)] above as beginning with Period 99 and ending with Period 103. In terms of market share, the position for this Period is as follows:

	Holder of Marketing Authorisation	**Price sold per pack**	**Volumes Sold**	**Revenue**	**% by Volume**	**% by Revenue**
Period 99 March 2016	The market comprising (a) to (k)	N/A	101,816	£7,232,448.08	100%	100%
(a)	Actavis UK Ltd 10mg	£72.14	56,006	£4,040,272.84	55%	56%
(b)	Actavis UK Ltd 20mg	£62.43	3,058	£190,910.94	3%	3%
(c)	10mg Agreement sale	£73.45	10,000	£734,500	9.82%	10.2%

[372] See Hydrocortisone Decision/table 9.1 (Ref only) which sets out the undertaking and legal entities involved for each of the infringements.

(d)	Plenadren 5mg	£212.20	536	£113,739.20	<1%	1.57%
(e)	Plenadren 20mg	£350	117	£40,950	<1%	<1%
(f)	Waymade 20mg	£65.22	687	£44,808	<1%	<1%
(g)	Alissa 10mg	£67.85	16,252	£1,102,768	15.96%	15.39%
(h)	Bristol 10mg	£65.60	11,690	£766,859	11.48%	10.6%
(i)	Bristol 20mg	£67	120	£8,040	<1%	<1%
(j)	Resolution Chemicals 10mg	£56.63	3,270	£185,180.10	3.2%	2.56%
(k)	Resolution Chemicals 20mg	£55.25	80	£4,420	<1%	<1%
Period 103 July 2016	The market comprising (a) to (l)	N/A	92,205	£5,160,861.81	100%	100%
(a)	Actavis UK Ltd 10mg	£58.60	58,123	£3,406,007.80	63%	66%
(b)	Actavis UK Ltd 20mg	£53.83	2,026	£109,059.58	2.2%	2.1%
(c)	10mg Agreement sale	£52.80	3360	£177,400	3.64%	3.4%
(d)	Plenadren 5mg	£239.05	622	£148,690	<1%	2.9%
(e)	Plenadren 20mg	£393.02	242	£95,110	<1%	1.8%
(f)	Waymade 20mg	£42.81	323	£13,827	<1%	<1%
(g)	Alissa 10mg	£42.10	6,578	£276,964	7.13%	5.4%
(h)	Bristol 10mg	£44.95	16,221	£729,125.73	17.60%	14.1%
(i)	Bristol 20mg	£41.73	230	£9,598	<1%	<1%
(j)	Resolution Chemicals 10mg	£42.31	2,590	£109,593.5	2.8%	2.1%
(k)	Resolution Chemicals 20mg	£48.62	10	£486.2	<1%	<1%
(l)	AMCo (Aesica) 10mg	£45.21	1,880	£85,000	2%	2%
Average Periods 99 to 103	The market comprising (a) to (l)	N/A	106,476	£6,602,707.09	100%	100%
(a)	Actavis UK Ltd 10mg	£66.03	61,065.2	£4,029,847.69	57.35%	61.03%
(b)	Actavis UK Ltd 20mg	£59.27	2,891.40	£172,299.53	2.7%	2.6%
(c)	10mg Agreement sale	£63.32	6,076.40	£396,224	5.7%	6%
(d)	Plenadren 5mg	£222.54	548.80	£123,216.96	<1%	1.9%

(e)	Plenadren 20mg	£358.79	155	£56,352	<1%	<1%
(f)	Waymade 20mg	£53.24	450.40	£25,124.2	<1%	<1%
(g)	Alissa 10mg	£56.33	9,719.20	£572,033.56	9.1%	8.66%
(h)	Bristol 10mg	£56.77	12,015.20	£668,307.95	11.3%	10.12%
(i)	Bristol 20mg	£53.97	270.6	£14,414.80	<1%	<1%
(j)	Resolution Chemicals 10mg	£45.36	9,205.6	£337,743.11	8.7%	5.1%
(k)	Resolution Chemicals 20mg	£43.62	417	£14,356.96	<1%	<1%
(l)	AMCo (Aesica) 10mg	£51.74	3,671.33	£192,781.33	3.5%	2.92%

285. As we have indicated,[373] the Hold Separate Regime was specifically relied upon by Allergan plc as rendering the undertaking substantially smaller during this Phase than it was during the anterior Actavis Phase (Phase 2). In short, it was contended that the Hold Separate Regime caused Allergan plc to cease to be part of the undertaking because the Decisive Influence Test was no longer met.

(1) The effect of the Hold Separate Regime was that the conduct of Actavis UK Ltd was transferred to a Hold Separate Manager, who was obliged to carry on Actavis UK Ltd's business independently and in the best interest of that business, with a view to ensuring its continued economic viability, marketability and competitiveness, and its independence from Allergan. The Hold Separate Manager reported to a Monitoring Trustee who oversaw the management of the business and took on the role of the board of the divestment business.[374] The Hold Separate Manager was obliged to manage and oversee the business to ensure commercial efforts dedicated to the promotion and commercialisation of the divesting assets remained substantially unaltered. Allergan was permitted no involvement in the day-to-day business during the Hold Separate Period,[375] and the Hold Separate Commitments imposed a number of negative obligations on Allergan, including a prohibition on stifling the divested business by, for example, failing to provide sufficient operating capital.[376] A number of boundaries were imposed between Allergan and the divestment business, including a prohibition on anyone within the divestment business reporting to anyone outside of it, and a functional separation by ensuring there was no

[373] See [265(2)].

[374] Hydrocortisone Decision/9.181; Allergan Written Closings/82.

[375] Hydrocortisone Decision/9.183.

[376] Allergan NoA/79.

transfer of confidential information between the businesses.[377] Allergan was required to establish separate IT platforms, for example.[378]

(2) Although there was dispute between the parties as to the precise effect of the Hold Separate Regime in terms of how far Allergan plc was removed from having influence over its subsidiary, it cannot be denied that under this arrangement Allergan plc irrevocably denied itself influence over Actavis UK Ltd's affairs and disabled itself from involving itself in the business (even if it had wanted to do so). We do not consider it to be arguable that the CMA can rely on any presumption of decisive influence by reason of Allergan plc's shareholding in Actavis UK Ltd.[379] It seems to us that any presumption arising out of shareholding either cannot arise because of the Hold Separate Regime or else is displaced by it.

(3) The true question is whether the Decisive Influence Test is met or is not met in these circumstances. We consider that, viewing the situation (as we presently are) on a phase-by-phase basis, and so looking at the Hold Separate Regime Part I (Phase 3) in isolation, it cannot seriously be contended that that test is met during Phase 3 viewed in isolation of Phase 2. Accordingly, considering Phase 3 in isolation, we find that Allergan plc was not part of the infringing undertaking. The moment the Hold Separate Regime incepted, at the beginning of Phase 3, the Decisive Influence Test (as generally understood) ceased to be met, and Allergan plc ceased to be a part of the undertaking that it had previously been part of.

(4) However, that is not how the CMA decided the question of decisive influence. The Hydrocortisone Decision finds as follows (Ref only):

> "9.185 The Hold Separate Manager was therefore appointed (at Allergan's ultimate expense) to ensure that the business of Accord-UK, and especially its approach to commercialising its products, remained substantially unaltered until the divestment completed.
>
> 9.186 In the circumstances the CMA considers that Allergan continued to exercise decisive influence over Accord-UK during the Hold Separate Period. The commercial strategy of Accord-UK was set under Allergan's decisive influence in the previous nine months, during which Allergan also acted to transfer AM Pharma's business to Accord-UK. This preceding period, when Allergan exercised decisive influence over AM Pharma and Accord-UK unencumbered by the Commitments, is vital context for the Hold Separate Period. The Court of Justice has recently reiterated in Goldman Sachs that an authority may have regard to factors from a prior period as demonstrating the exercise of decisive influence during a later period, provided it can show their continued relevance. In this case, by the time the Commitments came into force on 10 March 2016, Accord-UK's strategy in relation to hydrocortisone tablets was well-established

[377] Allergan Written Closings/84.

[378] *Ibid*.

[379] As to this, see Whish and Bailey, *Competition Law*, 10th ed (2021) at 97.

under Allergan's decisive influence. The Hold Separate Period cemented the status quo ante…"

Thus, the Hydrocortisone Decision explicitly bases itself on what happened prior to the inception of the Hold Separate Regime. The question is no longer how the regime that pertained during Phase 3 is to be classified in terms of the Decisive Influence Test, but whether the Hold Separate Regime was sufficient to cause Allergan plc to cease to be part of the undertaking of which it was a part prior to the Hold Separate Regime incepting.[380] The CMA's reason for finding that Allergan plc did not cease to be part of the undertaking was because the commercial strategy of the subsidiary during Phase 3 was not – and could not be – independently determined by the subsidiary, but rather was "pre-ordained" by decisions and arrangements made by Allergan plc during Phase 2.

(5) This, so far as we are aware, is a novel question, on which there is no authority. None was cited to us by the parties. Two questions arise in relation to the findings in the Hydrocortisone Decision.

(i) First, is it permissible to look to what happened in Phase 2 in order to define the extent of the undertaking in Phase 3?

(ii) Secondly, if it is permissible, did the Hold Separate Regime remove the decisive influence that Allergan had in Phase 2, such that it had no decisive influence in Phase 3, thus failing the Decisive Influence Test and ceasing to be part of the relevant undertaking?

We consider both of these questions below.

(6) We do not consider that it is pointful to set out the law regarding the Decisive Influence Test, for it is not the Decisive Influence Test that is controversial before us. That test turns on whether a subsidiary enjoys "real autonomy" from its parent.[381] We accept that, considering the position as at the commencement of the Hold Separate Period Part I (Phase 3) without reference to what had gone before,[382] it cannot be said that the Decisive Influence Test is met. In other words, if Phase 3 is considered in isolation, the answer is clear: Allergan plc is not part of the relevant undertaking.

(7) That brings us to the first of the two questions articulated above: is it relevant to consider whether the position as it pertained during the course of the Actavis Phase (Phase 2) persisted in Phase 3 albeit in a different form (namely by way of the Hold Separate Regime)?

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[380] As we have described, during the Actavis Phase (Phase 2), it was accepted that Allergan plc comprised part of the same undertaking as Actavis UK Ltd: see [283].

[381] Whish and Bailey, *Competition Law*, 10th ed (2021) at 96*ff*.

[382] I.e. without reference to the fact that during the course of the Actavis Phase (Phase 2), Allergan plc did have decisive influence, such that Actavis UK Ltd did not have "real autonomy".

(8) In our view, each of the phases as we have defined them cannot properly be viewed in complete isolation from the phases that precede (or succeed) them. We bear in mind that our parsing of the history in phases is in accordance with phases we have defined, in order to deal with the Appellants' grounds of appeal. Where the CMA has decided the Decisive Influence Test in Phase 3 by explicit reference to what went on in Phase 2, it would be wrong in principle to apply our phased schema so as to exclude all consideration of the CMA's findings. In short, we consider that what occurred in Phase 2 can, at least in theory, be relevant in defining the extent of the infringing undertaking in Phase 3 and certainly needs to be considered. We therefore answer the first question in the affirmative.[383]

(9) This, then, gives rise to the second question arising out of the findings in the Hydrocortisone Decision, namely: in what circumstances and how can anterior events define the nature and extent of a later undertaking? As to this:

(i) The question cannot just be whether the parent had decisive influence over the subsidiary in the earlier period. That says little, if anything, about the existence or otherwise of decisive influence in the later period. Equally, the question cannot simply be whether – viewed in isolation – there was decisive influence on the part of the parent over the subsidiary in the later period. That is simply avoiding the question posed by the Hydrocortisone Decision.

(ii) The question is whether the decisive influence that existed in an earlier period persisted, in another form, in a later period. If the effect of the parent's conduct was such as to oblige the subsidiary to continue to act in a certain way laid down in the past by the parent, such that the subsidiary had no effective independence, then we consider it to be arguable that the decisive influence of the parent continued. On this basis, it is necessary to consider not merely the decisive influence of the parent, but also the independence of action of the subsidiary from the parent. This, in effect, was the CMA's decision ("In the circumstances the CMA considers that Allergan continued to exercise decisive influence over Accord-UK during the Hold Separate Period. The commercial strategy of Accord-UK was set under Allergan's decisive influence in the previous nine months…", to quote again from Hydrocortisone Decision/9.186 (Ref only)).

(iii) To take an extreme – and we stress entirely hypothetical instance – suppose Parent *A*, with decisive influence over Subsidiary *B*, creates a state of affairs where Parent *A* relinquishes all future control over Subsidiary *B* but obliges Subsidiary *B* to act in accordance with a minutely framed plan of action, giving Subsidiary *B* no discretion, influence or power over its own affairs. In effect, Subsidiary *B* would be a corporate "zombie", acting entirely in line with the past corporate

[383] This is consistent with general authority, as the Hydrocortisone Decision itself noted: Hydrocortisone Decision/9.186, quoted at [285(4)].

diktat of Parent *A*. In such (admittedly rather extreme) circumstances, Parent *A* would – by virtue of their earlier conduct – continue to have decisive influence over Subsidiary *B*, despite actually relinquishing it in the later period.

(iv) On this basis, the relevant question becomes whether the undertaking at the end of Phase 2 (i.e. in Period 98) comprising Actavis UK Ltd (as subsidiary) and Allergan plc (as parent satisfying the Decisive Influence Test) ceased in that form by virtue of the Hold Separate Regime. In other words, has Allergan plc effectively divested itself of the decisive influence that it had throughout Phase 2? The answer to that question lies in the independence of action that was ceded by Allergan plc to Actavis UK Ltd. What, in short, was Actavis UK Ltd's independence of action in Phase 3?

(v) It is at this point that we must note that the characterisation of the Hold Separate Regime in the Hydrocortisone Decision was not accepted by Allergan plc. Thus, Allergan plc contended that:[384]

> "This is, with respect, a clear misreading of the Commitments, which takes them out of their context. The Commitments the CMA relies upon are those that oblige Allergan not to take steps to stifle the Divestment Business. It is in that context that it had to make resources available to that business for its survival. The level of resources that Allergan provided were then set by reference to the existing business plans. But that does not mean that Allergan could require the Divestment Business to carry out any particular prior commercial strategy or that the Divestment Business was obliged so to do. As set out above, the Commitments were clear that: (i) Allergan was precluded from exercising any influence over the Divestment Business; and (ii) the Hold Separate Manager was to operate the Divestment Business independently and in its best interests."

(vi) We do not consider that it is pointful to descend into a detailed parsing of Allergan plc's Commitments assumed by it pursuant to the Hold Separate Regime, because the differences between the CMA and Allergan plc are really ones of emphasis. The question, in these circumstances, involves consideration of the extent to which a discretion in Actavis UK Ltd to depart from a business strategy (previously determined at a time when a parent exercised a decisive influence over the subsidiary) was afforded to the subsidiary, in circumstances where amongst other things (i) the subsidiary was precluded from communicating with its parent and from receiving instructions from the parent and (ii) the dynamic of the market and the subsidiaries' business will have been changing from day-to-day and week-to-week. In short, even accepting the CMA's characterisation of the Hold Separate Regime, we consider that this regime afforded a very considerable ministerial discretion (and so control) to Actavis UK Ltd. We do not see how the commercial value of that business could sensibly have been

[384] Allegan NoA/[96].

maintained without such a discretion existing – without permitting Actavis UK Ltd to react to changing commercial circumstances.

(vii) Furthermore, whilst Actavis UK Ltd was obliged to follow the commercial strategy that had been laid down (subject always to the discretion we have described), we do not consider that this would have been sufficient to preclude the Hold Separate Manager from investigating a commercial strategy that they considered legally questionable; or from changing that strategy if it was considered to be unlawful. We consider that the Hold Separate Regime proceeds on the basis that the commercial strategy laid down was and continued to be a lawful one.

Accordingly, we conclude in relation to the second question that Allergan plc did enough to divest itself of the decisive influence that they had during Phase 2 so as to cause Allergan plc to cease (at the beginning of Phase 3) to be a part of the undertaking comprising it and Actavis UK Ltd.

286. We conclude that the CMA erred in treating Allergan plc as part of the infringing undertaking during Phase 3.

(e) Hold Separate Regime Part II (Phase 4)

287. We have defined the Hold Separate Regime Part II (Phase 4) at [179(4)] above as beginning with Period 104 and ending with Period 108. In terms of market share, the position for this Period is as follows:

	Holder of Marketing Authorisation	Price sold per pack	Volumes Sold	Revenue	% by Volume	% by Revenue
Period 104 August 2016	The market comprising (a) to (l)	N/A	100,628	£5,344,107.19	100%	100%
(a)	Actavis UK Ltd 10mg	£62.73	51,977	£3,260,517.21	51.7%	61.0%
(b)	Actavis UK Ltd 20mg	£53.45	2,750	£146,987.50	2.7%	2.8%
(c)	10mg Agreement sale	£55.40	8,020	£444,300	8.0%	8.1%
(d)	Plenadren 5mg	£243.88	345	£84,138	<1%	1.6%
(e)	Plenadren 20mg	£425.81	54	£22,994	<1%	<1%
(f)	Waymade 20mg	£36.68	585	£21,457	<1%	<1%
(g)	Alissa 10mg	£40.55	10,030	£406,745	10.0%	7.6%
(h)	Bristol 10mg	£40.12	15,285	£613,201	15.2%	11.5%

(i)	Bristol 20mg	£32.99	345	£11,380.75	<1%	<1%
(j)	Resolution Chemicals 10mg	£27.52	9,580	£263,607.40	9.52%	4.93%
(k)	Resolution Chemicals 20mg	£27.78	307	£8,529.33	<1%	<1%
(l)	AMCo (Aesica) 10mg	£44.63	1,350	£60,250	1.3%	1.1%
Period 108 December 2016	The market comprising (a) to (l)	N/A	124,313	£5,474,546.77	100%	100%
(a)	Actavis UK Ltd 10mg	£57.57	68,113	£3,921,265.41	54.8%	71.6%
(b)	Actavis UK Ltd 20mg	£40.76	2,882	£117,470.32	2.3%	2.2%
(c)	10mg Agreement sale	£50	398	£19,900	<1%	<1%
(d)	Plenadren 5mg	£241.5	725	£175,091	<1%	3.2%
(e)	Plenadren 20mg	£399.01	129	£51,472	<1%	<1%
(f)	Waymade 20mg	£22.35	945	£21,118	<1%	<1%
(g)	Alissa 10mg	£25.49	8,618	£219,656	6.9%	4.0%
(h)	Bristol 10mg	£24.83	15,090	£374,639.12	12.1%	6.8%
(i)	Bristol 20mg	£24.87	140	£3,482.25	<1%	<1%
(j)	Resolution Chemicals 10mg	£24.28	11,488.4	£272,237.87	9.2%	5.0%
(k)	Resolution Chemicals 20mg	£27.64	338.2	£9,534.91	<1%	<1%
(l)	AMCo (Aesica) 10mg	£20.28	5,957	£120,837.50	4.8%	2.21%
Average Periods 104 to 108	The market comprising (a) to (l)	N/A	97,596.7	£4,699,075.07	100%	100%
(a)	Actavis UK Ltd 10mg	£60.43	49,682	£2,993,734.89	51%	63.7%
(b)	Actavis UK Ltd 20mg	£51.55	2,628.4	£133,154.82	2.7%	2.8%
(c)	10mg Agreement sale	£51.44	4,404.5	£231,862.50	4.5%	4.9%
(d)	Plenadren 5mg	£241.98	504.20	£121,930	<1%	2.6%
(e)	Plenadren 20mg	£404.37	92.6	£37,238	<1%	<1%
(f)	Waymade 20mg	£29.97	961.4	£27,691.90	<1%	<1%

(g)	Alissa 10mg	£32.31	9,493	£310,534	9.7%	6.6%
(h)	Bristol 10mg	£32.38	12,617.6	£411,222.4	12.9%	8.8%
(i)	Bristol 20mg	£28.82	287	£8,191.3	<1%	<1%
(j)	Resolution Chemicals 10mg	£24.28	11,488.4	£272,220.87	11.8%	5.8%
(k)	Resolution Chemicals 20mg	£27.64	£338.20	£9,534.18	<1%	<1%
(l)	AMCo (Aesica) 10mg	£30.92	5,099.4	£141,742.5	5.2%	3.0%

288. It follows from the conclusion we have expressed in relation to Phase 3 that on the commencement of the Hold Separate Regime Part II (Phase 4), Teva did not become part of the undertaking. Teva's position is *a fortiori* that of Allergan plc (and the CMA did not seek to contend otherwise).

(f) The Intas Phase (Phase 5)

289. We have defined the Intas Phase (Phase 5) at [179(5)] above as beginning with Period 109 and ending with Period 127. In terms of market share, the position for this Period is as follows:

	Holder of Marketing Authorisation	**Price sold per pack**	**Volumes Sold**	**Revenue**	**% by Volume**	**% by Revenue**
Period 109 January 2017	The market comprising (a) to (k)	N/A	69,872	£2,880,631.54	100%	100%
(a)	Actavis UK Ltd 10mg	£54.21	36,736	£1,991,458.56	52.58%	69.1%
(b)	Actavis UK Ltd 20mg	£51.28	2,448	£125,533.44	3.5%	4.4%
(c)	Plenadren 5mg	£241.50	370	£89,355	<1%	3.1%
(d)	Plenadren 20mg	£399	78	£31,122	<1%	1.1%
(e)	Waymade 20mg	£22.64	576	£13,040	<1%	<1%
(f)	Alissa 10mg	£22.08	7,912	£174,693	11.32%	6.1%
(g)	Bristol 10mg	£22.03	10,780	£237,496	15.43%	8.2%
(h)	Bristol 20mg	£22.42	530	£11,881.48	<1%	<1%
(i)	Resolution Chemicals 10mg	£18.32	5,262	£96,376.16	7.53%	3.4%
(j)	Resolution Chemicals 20mg	£25	230	£5,750	<1%	<1%

(k)	AMCo (Aesica) 10mg	£20.99	4,950	£103,925	7.1%	3.6%
Period 127 July 2018	The market comprising (a) to (q)	N/A	87,879	£1,380,895.74	100%	100%
(a)	Accord UK Ltd 10mg	£20.23	44,031	£890,747.13	50.1%	64.51%
(b)	Accord UK Ltd 20mg	£7.78	1,852	£14,408.56	2.11%	1.0%
(d)	Plenadren 5mg	£242	330	£79,860	<1%	5.8%
(e)	Plenadren 20mg	£399.5	615	£245,693	<1%	17.8%
(f)	Waymade 20mg	£7.53	180	£1,355	<1%	<1%
(g)	Alissa 10mg	£3.74	15,054	£56,319.5	17.13%	4.1%
(j)	Resolution Chemicals 10mg	£3.77	3,105	£11,694.94	3.53%	<1%
(k)	Resolution Chemicals 20mg	£3.94	1,117	£4,398.32	1.27%	<1%
(l)	AMCo Focus 10mg	£3.60	300	£1,080	<1%	<1%
(m)	AMCo Focus 20mg	£3.92	156	£612	<1%	<1%
(n)	Teva 10mg	£3.42	12,814	£43,780.52	14.58%	3.2%
(o)	Teva 20mg	£3.75	374	£1,400.96	<1%	<1%
(p)	Genesis Pharmaceuticals 10mg	£3.70	7,654	£28,282.56	8.71%	2.1%
(q)	Genesis Pharmaceuticals 20mg	£4.25	297	£1,263.25	<1%	<1%
Average Periods 109 to 127	The market comprising (a) to (r)	N/A	106,706.88	£2,419,879.4	100%	100%
(a)	Actavis UK Ltd 10mg	£35.66	43,244	£1,529,901.81	40.5%	63.2%
(b)	Actavis UK Ltd 20mg	£22.16	2,162.58	£50,068.23	2.0%	2.1%
(d)	Plenadren 5mg	£241.96	345.53	£83,567.66	<1%	3.5%
(e)	Plenadren 20mg	£401.48	296.79	£118,550.87	<1%	4.9%
(f)	Waymade 20mg	£11.23	784.26	£8,200.89	<1%	<1%
(g)	Alissa 10mg	£9.14	12,757.21	£106,690.76	12.0%	4.4%
(h)	Bristol 10mg	£10.56	9,888.75	£106,444.54	9.3%	4.4%
(i)	Bristol 20mg	£24.68	619.20	£15,253.08	<1%	<1%

(j)	Resolution Chemicals 10mg	£8.36	7,311.74	£53,285.25	6.9%	2.2%
(k)	Resolution Chemicals 20mg	£11.33	529.88	£5,029.24	<1%	<1%
(l)	AMCo (Aesica) 10mg	£19.47	7,354.5	£131,412.9	6.9%	5.4%
(m)	AMCo Focus 10mg	£10.19	3,605	£41,617.44	3.4%	1.7%
(n)	AMCo Focus 20mg	£7.31	315.50	£2,547.25	<1%	<1%
(o)	Teva 10mg	£13.83	9,869.72	£128,025.08	9.3%	5.3%
(p)	Teva 20mg	£15.79	473.22	£7,266.72	<1%	<1%
(q)	Genesis Pharmaceuticals 10mg	£5.05	6,807	£30,257.76	6.4%	1.3%
(r)	Genesis Pharmaceuticals 20mg	£6.02	342	£1,759.75	<1%	<1%

290. We consider that during the Intas Phase (Phase 5) the undertaking comprised: Actavis UK Ltd and subsequently Accord-UK Ltd, Accord Healthcare Limited and Intas. This was not a matter of dispute before us.[385] It was accepted that as regards the parent entities, the Decisive Influence Test was met, and accordingly, we consider this matter no further.

(4) Conclusions

291. We conclude that the undertakings as we have found them to be during all five phases had a dominant position in the markets as we have defined them. There are a number of indicators that justify this conclusion, in particular, (i) the ability of the holder of the Merck, Sharpe & Dohme MAs to raise the price of 10mg and 20mg immediate release hydrocortisone substantially, (ii) in circumstances where demand did not fall away as a result of such price increases and (iii) where constraints on the holder (whether competitive or regulatory) appear to have been either minimal or non-existent.

292. However, because these indicators are all directly or indirectly related to price, and this is a case of an infringement of the Chapter II prohibition by way of excessive pricing, we are cautious about placing too much weight on these factors – although, clearly, they are relevant. We prefer to have primary regard to market share, and to consider market share by reference to the various temporal phases that we have defined.

293. It is clear from the analysis set out above, that the relevant market shares (by volume and by revenue) of the undertakings in question clearly denoted dominance, and we regard this conclusion as inevitable from the data we have set out. It is true that market

[385] See Hydrocortisone Decision/table 9.1 (Ref only) which sets out the undertaking and legal entities involved for each of the infringements.

share fell over time. In Phase 1 it was 100%, but it was rarely (if ever[386]) less than 50% whether by volume or by revenue. Furthermore, the remaining share of the market was highly fragmented amongst a number of other competitors.

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.

296. In regard to the question of dominance, we are therefore upholding the finding of dominance in the Hydrocortisone Decision. We appreciate that our approach has been different to that of the CMA, but we do not consider that we are materially disagreeing with the CMA's decision in this regard. The differences in approach arise for two reasons:

(1) First, we have considered the question of dominance using the market definition we have derived and have described in Section H(6) above. Although that has had an effect on the products that can be regarded as substitutes to the Focal Products (for instance, we include as substitutes (i) Plenadren, (ii) 20mg immediate release hydrocortisone tablets and (iii) "skinny label" products), the market shares of these products are so small that they make no material difference. (Of course, it is necessary properly to define the market in order to state such a conclusion with any confidence.)

(2) Secondly, we have (in order to dispose of the grounds of appeal) had to approach the "Matterhorn" in the phased way that we have described at length. It seems to us that – given the way in which the appeals were advanced – there was no choice but to address these points head-on, and that is what we have done. In doing so, we have been somewhat critical of what we have termed the CMA's monolithic approach. In terms of "correctness" of approach, we consider that a phased approach has much to recommend it and is to be preferred over the CMA's monolithic approach. However, we doubt whether the CMA's approach could properly be characterised as a material error: it is because of the way the appeals have been framed that we have taken the approach that we have. Had

[386] The average figures need to be treated with some caution. In some months, there were no sales of certain products, and that does distort – although the significance of that distortion is moot and not, we think, material.

the issue not arisen on appeal, such that we needed to consider it in the detail that we have, we doubt if we would have differed from the CMA's approach.

297. Accordingly, although our approach to the question of dominance might be said to be very different from that of the CMA, that difference in approach is caused by the factors set out in [296] and not because of any material error by the CMA in regard to its assessment of dominance.

J. ABUSE OF DOMINANCE

(1) Introduction

(a) The implication of our prior findings

298. The Hydrocortisone Decision finds that there was an abuse of a dominant position in the markets for the supply of 10mg and 20mg immediate release hydrocortisone tablets by imposing unfair selling prices.[387]

299. Given that we are substantially upholding the finding of dominance in the Hydrocortisone Decision, albeit for differently articulated reasons, we can turn to the question of abuse of dominance without more. Because of the manner in which the Appellants approached the question of abuse (i.e. by reference to their different temporal roles), we will approach the question of abuse bearing in mind the phased manner in which we considered the question of dominance. That implies no criticism of the Hydrocortisone Decision. As we have already noted, this reflects the manner in which the arguments before us were developed.

(b) Findings made by the CMA as regards excessive pricing

300. Prices are determined by the market, and competition law has long steered clear of seeking to determine what is, and what is not, a market price – it being rightly considered that this is a matter for the market and not the courts. That being said, courts have not been slow to impose price outcomes on parties in a whole variety of cases, notably reviews of rent in leases and in the assessment of FRAND rates in cases of patent infringement. The difference – and it is an important one – is that in these cases all the court is doing is imposing a rate where the parties cannot agree. Here, a price chosen by a market participant (a seller) – and at which the buyer bought – is being characterised as an infringement of competition law, with all of the stigma that attaches to a finding of anti-competitive conduct. We are conscious that these are quasi-criminal proceedings, and that we are reviewing findings which are quasi-criminal in nature.

301. The CMA's conclusion is stated as follows:[388]

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[387] Hydrocortisone Decision/5.1 (Ref only).

[388] Hydrocortisone Decision/5.4 (Ref only).

"The CMA finds…that Auden/Actavis' prices were excessive…This is because when Auden/Actavis' prices are compared to its costs plus a reasonable rate of return (**Cost Plus**), the resulting differences are material, i.e. sufficiently large to be deemed excessive, particularly at the peak of Auden/Activis' prices (around £72 per pack for both 10mg and 20mg hydrocortisone tablets."

(c) The Appellants' grounds of appeal

302. The Appellants did not seek to challenge the CMA's Cost Plus assessment, and we heard no evidence in regard to the CMA's calculation of Cost Plus. Accordingly, if a price exceeding Cost Plus was an excessive price – and so abusive – the Appellants would have no answer to the CMA's finding that there had been Abuse of Dominance infringements.

303. Of course, the Appellants did not accept that a price in excess of Cost Plus was – for that reason alone – an abuse of a dominant position. Rather, it was contended that a finding of an abuse of a dominant position based upon a comparison between Cost Plus and the actual prices charged was an incorrect approach as a matter of law, and that the Hydrocortisone Decision was wrong in finding to the contrary. Furthermore, in addition to adopting an incorrect test for the ascertainment of an excessive price:

(1) The CMA failed to take into account the prices of comparable products (notably, Hydrocortistab and Plenadren), which were (i) sufficiently comparable products and (ii) priced well above the 10mg and 20mg Focal Products.

(2) The CMA failed to take into account the economic value of the 10mg and 20mg Focal Products and the nature of pricing structures for pharmaceutical products, whereby products were priced in portfolios (with an element of cross-subsidisation as between products in those portfolios).

(3) The CMA failed to take account of the fact that on the downward "slopes" of the "Matterhorn", the Appellant's prices ceased to be abusive. This point was advanced by the Appellants in the later phases (specifically those in Phases 4 and 5) to suggest an absence of dominance. We have rejected that contention by taking a rigorous phase-by-phase approach to the question of dominance, and by considering each phase separately. We have concluded, on this basis, that there was dominance in respect of each phase. However, the same point can and was made in connection with the question of abuse, and we will consider that point in due course.

304. There are a number of other grounds of appeal, that we can deal with now. It was suggested that Accord-UK's prices were not imposed on its customers, but that its customers exercised choice in favour of the product because it had additional value to them. This adds nothing to the point we have set out at [303(2)] above.

305. It was also suggested that the prices charged could not be abusive because the Secretary of State did not consider them to be so, as the Secretary of State did not intervene to limit these prices. This is a re-run of the point considered in [270] to [274], which we reject for similar reasons.

306. Finally, it was suggested that the CMA's approach did not accord with legal certainty, particularly as regards the later phases. It was suggested that these undertakings could not have known that they were abusing a dominant position in circumstances where prices were declining rapidly, there was widespread market entry and there was extensive switching away from 10mg and 20mg Focal Products.

(d) Structure of this section

307. We begin by setting out the key paragraphs in the leading case on excessive pricing (Section J(2) below). As will be seen, one of the concepts deployed in that case is the economic concept of "value", which we consider in (Section J(3) below). We then consider, in light of this framework, the prices charged by the Appellants over the course of the five phases we have already identified and state whether they can be said to be excessive (Section J(4) below).

(2) The decision in *United Brands*

308. The starting point is the decision of the European Court of Justice in Case 27/76, *United Brands v. Commission*:[389]

> "248. The imposition by an undertaking in a dominant position directly or indirectly of unfair purchase or selling prices is an abuse to which exception can be taken under article 86 of the Treaty.
>
> 249. It is advisable therefore to ascertain whether the dominant undertaking has made use of the opportunities arising out of its dominant position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.
>
> 250. In this case, charging a price which is excessive because it had no reasonable relation to the economic value of the product supplied would be such an abuse.
>
> 251. This excess could, *inter alia*, be determined objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its cost of production, which would disclose the amount of the profit margin; however, the Commission has not done this since it has not analysed UBC's costs structure.
>
> 252. The questions, therefore, to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.
>
> 253. Other ways may be devised – and economic theorists have not failed to think up several – of selecting the rules for determining whether the price of a product is unfair."

[389] [1978] ECR 207.

309. These paragraphs have been expanded, explained and considered in the later case law, to which we will come. Before we do so, however, we need to consider the notion of "value" which – as *United Brands* rightly recognises – is an economic concept (hence "economic value"[390]).

(3) "Economic value"

(a) Defining our terms

310. We propose to define two terms. Those terms are "consumer surplus" and "producer surplus". Consumer surplus is best understood in the unreal – but analytically valuable – model of "perfect competition". Producer surplus we will consider in the light of the meaning of consumer surplus, but outside the "perfect competition" model. That is because the assumptions that underlie the model do not actually recognise "producer surplus".

311. It is in the maximising of consumer and producer surplus that "economic value" derives its meaning.

(i) Consumer surplus

312. Consumer surplus is an economic measurement of consumer benefits resulting from market competition. A consumer surplus arises when the price that consumers pay for a product or service is less than the price they are willing to pay. It is, in short, a measure of the additional benefit that individual consumers receive because they are paying less for something than what they would have been prepared to pay.

313. Consumer surplus is an individual value, subjective to the individual consumer. In some cases, these subjective values will converge in that consumers will generally value something in a similar way (e.g. food, medical products, other "essential" goods), but even here subjectivity reigns (e.g. how a consumer might choose between food or a medical product). Consumer surplus is based on value to the consumer, measured in monetary terms. Assuming a consumer has the ability to pay, they will pay a price for a product up to and including the monetary value they place on it – but no more.

314. Consumer surplus can be aggregated, and when economists speak of consumer surplus, it is usually a reference to the aggregate consumer surplus of all individual consumers. If it were possible to identify the monetary value each consumer attached to the product they had bought, the aggregate consumer surplus would be the difference between the price and each purchaser's value of the product purchased added together. Aggregate consumer surplus is a helpful term, provided it is not forgotten that individual consumer surplus is subjective and will vary from consumer to consumer.

315. As a side issue, we should make clear that our references throughout this section to "consumers" bear no necessary relation to the hypothetical consumer that we defined for the purpose of market definition. We explained in Section H(6) why it was

[390] The term is used in [250] of *United Brands* and is considered (but not defined in detail) in the later case law.

necessary, in order to define the market, to have a particular consumer in mind. The market having been defined, the utility of the concept ceases.

(ii) Producer surplus

316. Producer surplus is the difference between how much a supplier would be willing to accept for a product versus how much they can receive by selling the product at the market price. Again, it is a measure that varies according to individual producer. The difference or surplus amount is the benefit a particular producer receives for selling the good in the market.

317. Producer surplus turns on two factors: (i) relative efficiency between producers; and (ii) the extent to which, through product differentiation,[391] any given producer can differentiate themselves from their competitors and by such differentiation induce consumers to pay more for their product. As with consumer surplus, producer surplus can be aggregated. Producer surplus is susceptible of a little greater certainty of calculation, because it is possible to achieve an understanding of industry, sector and individual costs. But, once again, the market is a far better determinant of business viability and profitability than any judicial process.

(b) Perfect competition and consumer surplus

318. Perfect competition is based on a series of assumptions that bear very little resemblance to the real world. Since the model is not especially descriptive, but exists in order to aid analysis, there are a number of variants. Our model is as follows:

(1) The market here under consideration operates in circumstances where there is no latency. Unlike in the "real world", where changes occur dynamically over time, changes occur immediately, and have immediate effects.

(2) The market contains only two protagonists: **Buyers** and **Sellers**. Each Buyer is what we have termed an ultimate consumer. There are no supply chains: Sellers make or do everything themselves in order to create their product.

(3) Sellers (actual and potential) sell a single **Product** to a universe of (actual and potential) Buyers. Price is the sole determinant of (i) whether Sellers are willing to sell and (ii) whether Buyers are willing to buy. There is, in short, no product diversity.

(4) Aggregate demand (from Buyers) is limited, varying only by reference to price. Aggregate supply (from Sellers) is (or can be presumed to be) potentially infinite, such that no Seller has market power. The market is perfectly contestable, in the sense that entry and exit is cost-free.

[391] We define the term "product differentiation" more fully below.

(5) Price informs the buying and selling decisions of Buyers and Sellers differently. An individual Buyer will buy Product if the value that the Buyer attaches to the Product exceeds the Price. Value, as we have noted, is subjective to the individual Buyer. Aggregating demand at any given price gives the shape of the demand curve.

(6) An individual Seller will sell Product if marginal revenue equals or exceeds marginal cost. Marginal revenue and marginal costs are – in the case of perfect competition – the relevant measures for the Seller, because the market is perfectly contestable. Fixed costs of entry and exit do not act as constraints, because there are none. All costs are effectively variable.

(7) Buyers have good market knowledge, such that their demand will move, immediately,[392] to the Seller selling Product at the lowest price. Although the market demand curve will be shaped normally, each Seller will be faced with an individual demand curve that is perfectly elastic.

(8) Marginal cost includes – or, for the purposes of our analysis, we deem it to include – a proper return to the Seller. We shall refer to cost as containing a **proper return**[393] to the Seller (but no producer surplus) as **Cost**.

319. On the basis of these assumptions, Sellers will have to price at Cost. More specifically:

(1) If the Seller is inefficient, then even if that Seller prices at Cost (meaning the Cost to that Seller), the Seller will have to leave the market because they will not be able to match the price of the most efficient Seller in the market. Demand, which is perfectly elastic in relation to that Seller, will move in its entirety to other Sellers who are able to sell Product for less. One of the assumptions that perfect competition does not make is that all Sellers are equally efficient. Sellers can be differently efficient, and inefficient Sellers are driven from the market.

(2) Sellers that are operating at maximum efficiency will be the only Sellers in the market. Because no Seller has market power, and because of the elasticity of demand arising in these circumstances, every Seller in the market will have to price at Cost. Failure to do so will result in a total loss of demand to that Seller. Thus, all Sellers will have to price at the level of the most efficient Seller.

320. It follows from this that under conditions of perfect competition, Sellers cannot arrogate to themselves the consumers' surplus. Since such a step would inevitably involve an increase in price above Cost, the Seller seeking to erode the Buyers' consumer surplus would fail. In this way, one aspect of economic value is maximised – namely that of the consumers' surplus.

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[392] See [318(1)] above: there is no latency.

[393] We have no intention of defining more specifically the quantum of this return, but it is intended to refer to the cost of entrepreneurship, which is one of the (and one of the more elusive) factors of production. An entrepreneur – a Seller – will not put together all the factors of production necessary to produce Product to sell without that cost being rewarded.

(c) The real world and producer surplus

321. Only under conditions of perfect competition will a Seller's price inevitably sit at Cost. Generally speaking, because conditions of perfect competition do not prevail, the price a Seller can charge (the **Price**) will be above cost. Perfect competition rests upon a number of assumptions which will not pertain in the real world. Many of the departures from the perfect competition model are consistent with a competitive market, and not deleterious to it.[394]

322. In a world where the assumptions of the perfect competition model do not pertain, there are three reasons why Price might exceed Cost:

(1) *Relative inefficiency amongst Sellers.* In the real world, it is not the case that a Seller who cannot match the efficiency of the most efficient Seller will be driven from the market (as under perfect competition). That is because the Seller in the real world will not be faced with a perfectly elastic demand curve. A Seller will, for a variety of reasons, be able to price at above Cost and nevertheless stay in business. In this way, the less efficient Seller can stay in business selling at a Price equal to that Seller's (inefficient) Cost. A more efficient Seller, whose costs are lower, might – depending on elasticities of demand – elect (i) to undercut the inefficient Seller or (ii) to set a similar Price to that of the inefficient Seller. In this second case, the efficient Seller's Price will be above their Cost (which already contains a proper return) and so will have an element of producer surplus.[395] This form of producer surplus arises because of relative efficiency between Sellers. They produce the same Product, but one does so more efficiently than the other. In the real world, unlike in the modelled world of perfect competition, there will always be a range of (in)efficiencies amongst Sellers, with the result that – even for exactly the same Product – Price will exceed the Cost of the most efficient Seller. The same point was put in a different way in *Optis Cellular Technology LLC v. Apple Retail UK Ltd*:[396]

> "In a competitive market, the general effect of the inter-relationship between supply and demand is to maximise consumer surplus, so that price will fall to a level somewhere around the average producer surplus. I am presuming a state of imperfect competition. In perfect competition, the price of the product would fall to the level of the most efficient seller. Less efficient sellers would leave the market. Here less efficient sellers will not necessarily be eliminated (although insolvency is always a possible outcome), but will survive, albeit earning less producer surplus than more efficient sellers. Hence the reference to an "average producer surplus", rather than the producer surplus of the most efficient competitor. Even so, competition between producers will generally result in prices of a given product falling to this level. The

[394] The label "perfect competition" does not imply perfection, but only an extreme of sorts.

[395] If the efficient Seller prices at their Cost, then only a proper return is obtained, but the Price charged by that Seller will be lower than that of the inefficient Seller (which may be profit maximising). On the other hand, the profit maximising approach may be for the efficient Seller to price at the inefficient Seller's Cost/Price (the two values are here the same), in which case the efficient Seller achieves a producer surplus.

[396] [2023] EWHC 1095 (Ch) at [449].

consequence is that consumer surplus trends to the maximum, subject to an average producer surplus, below which prices should not fall."

In this case, producer surplus varies not according to value but according to Seller efficiency. The more efficient the Seller, the greater the surplus. Of course, competition may drive out the most inefficient Sellers[397] but – absent perfect competition – there will be significant fluctuations in producer surplus.[398]

(2) *Generation of additional value through the provision of distinctive value.* One of the most unrealistic limiting assumptions of the perfect competition model is that it presupposes only one (undifferentiated) Product. Another is that the model presupposes that the supply of each Seller is infinitesimal relative to total supply. These assumptions exclude from consideration the second key means (the first being increased efficiency, as described in [319(1)] above) that enables Sellers to maximise producer surplus. 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. More specifically:

(i) This form of generation of producer surplus can often involve the generation of additional value through "product differentiation". But we have quite deliberately eschewed this label in favour of the provision of "distinctive value", for we intend to refer to any definable aspect of a Seller's offering that adds value to the Buyer, in the sense that this aspect represents 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.

(ii) That said, product differentiation is the prime example of such generation of additional value. Product differentiation can exist in many different forms: it is not confined merely to innovation (although that is important), but to providing a better quality product in other ways, and in catering to the subjective tastes or preferences of Buyers.[399] Product differentiation, in terms of process, can be achieved in many different ways also. Thus:

(a) In the real world, markets are not perfectly contestable. There are costs of entry and costs of exit that are necessary in order to create

[397] One of the functions of insolvency law.

[398] See *Optis Cellular Technology LLC* at [448].

[399] In the real world, there is no single Product, but competition between different products which meet – to different extents – the same demand. Unsurprisingly, the Seller who taps closest into what Buyers' value will accrue a demand that may be quite inelastic, and will be able to price accordingly. That is no more than a proper reward for the Seller's response to Buyer demand. Investment in brand is also an example of this: for reasons that may well be objectively indefensible, Buyers will pay a premium for a "brand", even though the identical product is available unbranded. The owner of a (valued) brand may command a higher price, but will always be at risk from unbranded competition (or other brands).

products that Buyers want. Take, for example, the mobile telephone network, constructed by a Seller with considerable investment. Throughout the development phase, the Seller will obtain no revenue. The intention is that costs will be covered by future revenue streams, and the risk that this will not occur falls on the entrepreneur, the Seller. A typical mobile network will have low marginal costs, and the Seller will (entirely justifiably) price at above marginal cost, and quite possibly well in excess of cost more generously understood.[400] Provided the market remains contestable, such prices in excess of cost will serve to attract other Sellers, and competition will ensure that prices trend back to cost, and that consumer surplus is protected. Indeed, this is a variant of our Face Mask Example.

(b) The law has evolved many rights – notably intellectual property rights – intended to protect and reward innovation. Patents are a good example. Where an inventor claims an invention which has market significance then – as we have described[401] – that inventor will be able to command a premium either in licensing the invention or in selling product at a higher price.

(iii) It is worth noting that there is no inconsistency between the maximisation of producer surplus and the maximisation of consumer surplus. If, through product differentiation (or other ways of providing distinctive value), a Seller creates a product that Buyers value more highly – measured, as ever, by willingness (and ability) on the part of Buyers to pay – then the reward is producer surplus. Consumer value is maximised: Buyers get the products they value and are prepared to pay for. The higher price containing the producer's surplus acts as an incentive for others to enter the market (cf the Face Mask Example), and so producer surplus is (in time) controlled by competition emanating from competing producers. Consumer surplus is thus maximised, and Price will trend towards Cost.

(iv) The provision of distinctive value extends beyond product differentiation *stricta sensu* to e.g. pricing models and, indeed, the Face Mask Example itself. On the face of it, the Face Mask Example appears to be an instance falling outside this form of producer surplus generation, since there is (on the facts) no product differentiation at all, merely an excess of unanticipated demand over existing supply. Nevertheless, 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

[400] Calculation of cost is in itself not straightforward. Even if the marginal cost can be calculated, the calculation of fixed costs, sunk costs and common costs (in the case of a multi-product firm) are both difficult and controversial. For our purposes, it is simply necessary to note the existence of these complexities, without needing to resolve or understand them further.

[401] See paragraphs 155 and 269 above.

"product differentiation". The Seller of face masks is entitled to a premium because they have Product to sell, when other Sellers do not.

(3) *Generation of producer surplus without added value to Buyers.* The third case where producer surplus is generated (i.e. where Price sits above Cost, whether that be the average Cost of all Sellers or the individual Cost of a single Seller) arises where the Seller possesses market power that does not generate additional value in Buyers. In such cases, Buyers are obliged to pay more for what is the same Product. It follows that in such cases, the ability for the high producer surplus causing the high Price[402] to attract competition in the form of new entrants is somehow inhibited: otherwise the normal operation of the market would control the situation. There is thus likely to be a correlation between the Seller's market power (enabling them to impose producer surplus without creating value) and the ability to exclude competition. To take some very trite examples, this case will exist where Sellers combine rather than compete[403] or where a single Seller is able to create sufficient barriers to contestability so as to exclude other competitors.[404]

We shall, for convenience, refer to these three, very different, cases of producer surplus as **Case 1** (i.e. [322(1)]), **Case 2** (i.e. [322(2)]) and **Case 3** (i.e. [322(3)]).

323. The distinction between the Case 2 (generation of distinctive value) and Case 3 (generation of producer surplus without added value to Buyers) is by no means easy to draw. It is the function of competition law to draw the line. Before, however, we turn to this line, it is important to make two points regarding the distinction:

(1) There will, doubtless, be many cases which might be said straddle Cases 2 (generation of distinctive value: [322(2)]) and 3 (generation of producer surplus without added value to Buyers: [322(3)]). For example, a Seller able to differentiate their Product may charge "too much". For reasons which we will come to, it is helpful to regard such a case as an abusive instance of the second case, rather than as an example of third case.

(2) There is, clearly, likely to be a temporal differentiation between Case 2 and Case 3. As we have noted, provided the market is contestable, Prices in excess of Cost will serve to attract other Sellers, and competition by way of new entry will ensure that Prices trend back to Cost.[405] Thus, high prices in Case 2 enhance

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[402] It is trite that it is very difficult to differentiate a "high" price from a "low" price or a "fair" or a "proper" price from an "abusive" or "excessive" price. The better point of reference may well be the cause of the price level, which may be due producer surplus, as we define it. If so, then the question that follows is this: why is the Seller earning this producer surplus? If there is a legitimate explanation, then prices might properly be classified as "fair" or "reasonable" or "proper". If, on the other hand, there is no legitimate explanation, then prices might properly be classified as "abusive" or "excessive". As we will come to describe, the borderline between the legitimate and the illegitimate is the province of competition law not competition economics.

[403] Matters usually falling within the province of the UK's Chapter I prohibition and its international equivalents.

[404] Matters usually falling within the province of the UK's Chapter II prohibition and its international equivalents.

[405] See [322(ii)(a)].

rather than diminish competition in the longer run. However, if circumstances exist that render the market unjustifiably incontestable or more difficult to contest, such that competition by way of new entry is precluded or impeded, then the instance will transit from Case 2 to Case 3. This would be so in the Face Mask Example if Sellers of face masks colluded with other potential competitors to ensure they stayed out of the market, enabling the duration of high prices to be protracted.

(4) The case law following *United Brands*

(a) A general approach

324. Subsequent case law has expanded and explained the decision in *United Brands*. Unsurprisingly, given the nature of the question at hand, the *United Brands* test is not intended as a "brightline" test for determining excessive prices or an abuse of dominance by excessive pricing. There is no fixed, definitive, methodology for ascertaining excessive prices, and it would be wrong to read *United Brands* in this way.[406]

325. But the decision does constitute a helpful articulation of general principle and approach. The test for abusive pricing is fairness,[407] which implies a respect for the legitimate interests of both Buyers and Sellers. Put another way, "fairness" must ensure that an over-emphasis on Buyer consumer surplus does not override the interest of Sellers in legitimate producer surplus;[408] and that illegitimate producer surplus does not defeat Buyers' interest in maximising consumer surplus. In *Flynn Pharma*, Green LJ unpacked this notion of "fairness" very succinctly, referring to the paragraphs in *United Brands* we have set out above:[409]

> "Then (in [249] and [250] the court describes two central economic features of an abuse of fairness. These are (i) that the undertaking has reaped "trading benefits" which could not have been obtained in "normal and sufficient competitive" conditions; and (ii) that a selling price that is "excessive" in that it bears no reasonable relation to the economic value of the product or service in question is an example of an abuse…"

326. Further assistance in understanding the courts' approach in these cases is derived from the decisions of the Court of Appeal in *Attheraces* and (on the narrower question of regulatory context) *Humber Oil*. We consider these decisions next, before turning to the sort of evidence that can be deployed when considering excessive or abusive pricing cases.

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[406] *Competition and Markets Authority v. Flynn Pharma*, [2020] EWCA Civ 339 (***Flynn Pharma***), [63] to [67].

[407] *United Brands*, [248]; *Flynn Pharma*, [60].

[408] I.e. the producer surplus arising in Cases 1 and Case 2 (but not Case 3).

[409] *Flynn Pharma* at [61].

(b) The decision of the Court of Appeal in Attheraces

327. The inter-relationship between cost and price was considered in *Attheraces Ltd v. British Horseracing Board Ltd* by Mummery LJ.[410] Mummery LJ began his consideration with *United Brands*,[411] holding that the judgment in *United Brands* posed two questions for the purpose of determining whether a price charged constituted an infringement of the Chapter II prohibition:[412]

(1) *The first condition.* The first condition was whether the difference between the costs actually incurred and the price actually charged is excessive.[413] In itself, this is not a straightforward question. But what is clear from Mummery LJ's judgment is that a "cost plus" test for abusive pricing can only ever be a threshold condition, necessary to establish an infringement, but not in itself sufficient. More specifically:

(i) In a market economy, Sellers must be able to make a proper return for the costs they incur, including a proper reward to the entrepreneur and costs of capital. That is why we have defined Cost in the way we have, so as to include and not exclude these returns to the Seller.

(ii) In any case of complexity, calculating the true costs of selling a product is likely to be both difficult and contentious. Were the law to approach cost in an excessively conservative way then it is likely that precisely the sort of entrepreneurship that leads to differentiated products and the maximisation of consumer value would be discouraged.[414]

(iii) Furthermore, producer surplus arising out of one Seller's relative efficiency to other Sellers is to be encouraged, not discouraged.[415]

(2) *The second condition.* Assuming the first condition is met, the next question is whether a price has been imposed which is unfair in itself or when compared with competing products.[416] Mummery LJ identified the central concept in an abuse of a dominant position by excessive and unfair pricing as not the cost of producing the product or the profit made in selling it, but the "economic value of the product supplied". The selling price of a product is excessive and an abuse "if it has no reasonable relation to its economic value". As to the meaning of

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[410] [2007] EWCA Civ 38

[411] At [114].

[412] At [116]. Of course, the court was considering the equivalent European Union provisions, but nothing turns on this.

[413] At [116].

[414] I.e. Case 2.

[415] I.e. Case 1.

[416] At [116].

"economic value", Mummery LJ interpreted *United Brands* in the following way:[417]

> "…the court did not say that the economic value of a product is always ascertained by reference to the cost of producing it plus a reasonable profit (cost +), or that a higher price than cost + is necessarily an excessive price and an abuse of a dominant position. The court was indicating that one possible way ("inter alia") of objectively determining whether the price is excessive and an abuse is to determine, if the calculation were possible, the profit margin by reference to the selling price and the cost of production."

Finally, Mummery LJ gave the following warning:[418]

> "…it has to be borne in mind that, as stated in *Oscar Bronner Gmbh & Co KG v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co KG* (Case C-7/97) [1998] ECR I-7791, the law on abuse of dominant position is about distortion of competition and safeguarding the interests of consumers in the relevant market. It is not a law against suppliers making "excessive profits" by selling their products to other producers at prices yielding more than a reasonable return on the cost of production, i.e. at more than what the judge described as the "competitive price level". Still less is it a law under which the courts can regulate prices by fixing the fair price for a product on the application of the purchaser who complains that he is being overcharged for an essential facility by the sole supplier of it."

These passages make clear that:

(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*,[419] 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

[417] At [118].

[418] At [119].

[419] [2002] CAT 1 at [390].

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."

The temporal aspect we referenced in [323(2)] is very clearly stated this passage.

(c) The decision of the Court of Appeal in Humber Oil

328. In *Humber Oil Terminals Trustee Ltd v. Associated British Ports*,[420] the Court of Appeal upheld the strike out at first instance of a claim that the defendant landlord had abused its dominant position by demanding excessive rents in return for the grant of a new lease. Although the landlord was dominant, demanding an excessive price in the course of negotiation was not an abuse, at least where the court had jurisdiction to fix the rent pursuant to a statutory procedure. At [38], Etherton LJ noted:

> "…if it is established that [*Humber Oil*] is entitled under the 1954 Act to new leases and the parties cannot agree the rent, the rent will be determined by the court pursuant to section 34 of the 1954 Act. The statutory measure to be determined by the court is the rent at which the holding might reasonably be expected to be let in the open market by a willing lessor to a willing lessee. That measure excludes any ransom element. It is unclear to me in those circumstances what concern [*Humber Oil*] could legitimately have that the court will fix a rent that is abusive in competition terms. It may be argued that, in ignoring any ransom element, established competition principles would be helpful to the court in fixing the open market rent pursuant to section 34 of the 1954 Act in the case of a monopolist landlord or one in a dominant position in the relevant market…That, however, certainly does not require any pleaded reference to past, unsuccessful, negotiations. I do not consider that the Chancellor has ruled out such assistance of competition law principles as a matter of law, although I confess I am highly sceptical about it. If it remains an issue, the relevance of those principles will be determined in due course as part of the process of the fixing of rent by the court."

329. The point is not unrelated to the question of whether a statutory control or regime can render what would otherwise be a dominant position not dominant. Clearly, the manner in which a market operates – including in particular the legal regime governing such markets[421] – can be highly relevant to both questions of dominance and abuse, as *Humber Oil* demonstrates. We would only add the following points:

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[420] [2012] EWCA Civ 36, at [22], [37] and [38].

[421] See Roth, *Who Gets What and Why*, 1st ed (2015) at 7:

"Most markets and marketplaces operate in the substantial space between Adam Smith's invisible hand and Chairman Mao's five year plans. Markets differ from central planning because no one but the participants themselves determines who gets what. And marketplaces differ from anything-goes laissez faire because participants enter the marketplace knowing that it has rules.

Boxing was transformed from brawl to sport when John Douglas, the ninth Marquess of Queensberry, endorsed the rules that bear his name. The rules make the sport safe enough to attract competitors but don't dictate the outcome. In just this way, marketplaces from big ones like the New York Stock Exchange to little ones like a neighborhood farmers' market, operate according to rules. And those rules, which are tweaked from time to time

(1) Depending on its nature, a regulatory regime governing a market may either create or exacerbate dominance and/or the potential for abuse (as is the case here) or eliminate or reduce it (as was the case in *Humber Oil*).

(2) What matters is not the theoretical position (the rights or controls as they might in theory be applied) but the actual position (the manner in which any rights or controls which may exist are in practice exercised).

(d) Evidence

330. There is no single method for ascertaining whether a price is unlawful in terms of its excess or not, and any given method will have some inherent weaknesses.[422] When considering whether a price is or is not excessive, a tribunal must have careful regard to "regulatory overreach", in that interference in an outcome that may actually be competitive is as bad as failing to call out as infringements excessive prices.

331. Any appropriate method is likely to be informed by that which is being valued: identifying costs and linking them to a particular product is a problem in almost every case, but particularly so where intangible property is concerned or (as here) products commanding a high price at a low marginal cost. The following methods or approaches are discernible:

(1) Comparators are of particular importance, even where they may not be clear or compelling. Comparators can include: (i) comparators on different markets; (ii) comparators on the same market at the same time; and (iii) comparators separated by time. In all cases, the critical question for the court is whether anything probative can be derived from the comparator in question.[423]

(2) The inter-relationship between price and cost is obviously significant. Bearing in mind always that cost can be extraordinarily difficult to relate to a product's price, if (nevertheless) cost can reliably be derived, a price well in excess of cost will be an indicator of unfairness.[424] That being said, simply taking a cost-plus approach may mean wrongly appropriating a producer's surplus to the consumer.

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to make the market work better, are the market's design. *Design* is a noun as well as a verb; even markets whose rules have evolved slowly have a design, although no one may have consciously designed them."

Of course, markets can be well-designed (so as to promote and further competition) or badly designed (so as to inhibit it). In the present case, we have identified a number of instances where a competitive market is inhibited by the regulatory regime: [274].

[422] *Autortiesibu un komunicesanas* konsultaciju *agentura / Latvijas Autoru apvieniba*, Case C-177/16,EU:C:2017:286 at [36] to [48]; *Flynn Pfizer*, [63].

[423] On this question, *Optis Cellular Technology LLC v. Apple Retail UK Ltd*, [2023] EWHC 1095 (Ch) provides a useful lesson. A large number of comparables were produced to the court: a considerable number of these were rejected as unhelpful.

[424] *Flynn Pharma*, [62].

(3) In *Napp* itself, the Tribunal identified as "among the approaches that may reasonably be used to establish excessive prices": (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.[425] 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.

(5) Abusive or excessive prices in the present case: analysis

(a) Cost Plus

332. The CMA concluded that the prices charged for 10mg and 20mg immediate release hydrocortisone tablets were excessive throughout the five phases we have identified and defined because those prices were excessive on a Cost Plus basis.[426]

333. We accept that the CMA have satisfied the first condition for showing an abuse of the Chapter II prohibition through excessive pricing, as Mummery LJ described that requirement in [327(1)]. We consider that it is plain to the point of irrefutability that this necessary (albeit not sufficient) condition is met in the present case; and it is significant that no Appellant challenged the specifics of the CMA's finding in this regard. We can, therefore, deal with this aspect relatively briskly. We see no prospect for contending that, in this case, the prices commanded during the five phases were explicable as consumer surplus arising because of relative efficiencies between different Sellers of the same Product: i.e. Case 1.[427] There is no such prospect because: (i) the margin between Cost Plus and prices charged is so large as to be inexplicable on this basis; and (ii) the various Sellers of 10mg and 20mg immediate release hydrocortisone under the Merck, Sharpe & Dohme MA had no real competition, such that the price was set by a single seller.[428] There were no "relative efficiencies" to justify or explain any significant producer surplus.

334. The CMA's conclusion, as we have set it out in [296] is thus unimpeachable, undeniably correct and not challenged by the Appellants. But it is <u>insufficient</u> to justify a finding that the Chapter II prohibition has been infringed, although it is (as we have said) a necessary condition to such a finding.

335. The second condition for showing an abuse of the Chapter II prohibition through excessive pricing, as Mummery LJ described that requirement in [327(2)], was regarded by the CMA as adding nothing, at least on the facts of this case: see <u>Hydrocortisone</u>

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[425] At [392].

[426] See [296].

[427] See [322(1)], where producer surplus in excess of Cost (which we equate to the CMA's Cost Plus) can be justified on the basis of relative efficiencies between Sellers of the same Product.

[428] In this regard, we refer to the analysis of dominance in Section I.

Decision/5.430*ff* and 5.432 in particular. This is the question of economic value, to which we will now turn.

(b) "Economic value"

(i) Introduction

336. We have considered the meaning of "economic value" in detail in the foregoing paragraphs. The question of whether this is a case falling within Case 2 ([322(2)], where "economic value" is generated) or within Case 3 ([322(3)], where producer surplus is generated without any "economic value") is considered after we have disposed of a "red herring" relied upon by the Appellants in this matter.

(ii) The "red herring"

337. In [303(2)], we describe the Appellants' contention that the CMA failed sufficiently to take "economic value" into account, and we substantially agree with that point so far as it goes.

338. However, the Appellants then criticised the CMA for failing to take into account the "value" placed on hydrocortisone by patients. Thus, a number of the Appellants argued that the CMA erred in its assessment of the economic value of hydrocortisone tablets as being no higher than Cost Plus, by reference to the value placed on them by patients, to whom they are a life-saving drug. For example:

> "The CMA concludes that there "are no non-cost related factors associated with either 10mg or 20mg hydrocortisone tablets that increase their economic value beyond that already reflected in Cost Plus" [5.432]. This is wholly unsustainable when assessing the economic value of a product that provides life-saving (or at least very considerable life enhancement) benefits to patients. The cost to individuals, families and society caused by adrenal insufficiency (absent any reliable treatment) is very considerable. This must be reflected in any assessment of whether the price of hydrocortisone "bears no reasonable relation to the economic value" of the product (Flynn Pharma (Court of Appeal) [97(ii)]. Whether as part of the cost-plus analysis, or otherwise, the CMA's reasoning must take this value into account (Flynn Pharma (Court of Appeal) [166ff]). The CMA has fallen into a clear error of assessment by concluding that the only value of hydrocortisone lies in its cost of production plus a small margin for profit. In doing so, it treats hydrocortisone as a standard commoditised product and takes no account of the medical, social and personal benefits it provides."[429]

And:

> "It was particularly imperative that the CMA inform its cost-plus analysis by reference to appropriate comparators given the economic value to be accorded to what the CMA acknowledges is a life-saving drug which would not have been available at all if Auden had not taken over the licence in 2008 and the fact that, had Auden/Actavis-UK charged the cost plus

[429] Allergan NoA/71(a).

prices as determined by the CMA for hydrocortisone tablets at the time, its entire portfolio of pharmaceuticals would have been heavily loss-making for a number of years."[430]

339. We do not accept these contentions as justifying any excess of Price over Cost. Indeed, we would go so far as to say that if the case law is properly understood, such propositions are unarguable:

(1) Of course patients will value life-saving medicaments. That is a proposition that is so trite as not to require statement. But that fact, obvious as it is, does not justify a Seller charging more. It does explain why prices of such a Product need to be examined with particular care, because elasticity of demand will be extremely low as regards such a Product and its substitutes: patients will not lightly fail to seek to acquire life-saving medicaments precisely because they value them so highly. Where such a Product has no substitutes, or few substitutes, a Seller's market power is exacerbated, and the ability to price at above Cost enhanced – simply because the Buyer, the patient, must buy the Product. But that does not mean that consumer surplus is maximised. Rather, it is diminished.

(2) We return to the significance of the perfect competition model, where Price is ineluctably driven down so as to equal Cost because of the perfect competition between Sellers. The margin between what Buyers must pay (Price) and what they are willing to pay – the consumer surplus – is thereby maximised, and "value" to consumers thereby maximised also.

(3) The Appellants' proposition amounts to no more than this: "Because I, the Seller, can charge high prices to you, the Buyer, and you the Buyer pay them" the Seller is transferring value to the Buyer. The Seller is not: the Seller may very well be taking value away from the Buyer. In reality, the Appellants' point amounts to an unacceptable, and wrong, elision of the case for legitimate consumer surplus (Case 2: [322(2)]) and the case of an illegitimate exercise of market power (Case 3: [322(3)]).

(4) Whilst we entirely accept that the line between these two classes may be hard to draw, and that the distinction between an abuse of market power on the one hand and the sale of a Product that enhances or increases economic value on the other may be hard to draw, it unquestionably exists.

(iii) Was economic value provided in this case?

340. During the course of argument, we asked the parties to consider the answer to this question:[431]

If we had to explain the "Matterhorn" to the interested party on the Clapham omnibus, what explanation would we give?

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[430] Auden NoA/6.1.3.

[431] Transcript Day 10/pp.221 to 223; Day 17/pp.95 to 97.

Mr Holmes, KC, for the CMA, took some time in his closing submissions to say that there was no explanation, by which we understood him to mean that there was no pro-competitive explanation.[432] This, for the reasons we have given, is the essential question when differentiating Case 2 under [322(2)] from Case 3 under [322(3)]. The question is not, at this stage, "Does Price exceed Cost?", but rather "Why does Price exceed Cost?"

341. If the explanation for the producer surplus excess is consistent with a competitive market, then it may be that it must be asked whether the excess is too great to be justified. However, where Price exceeds Cost for no pro-competitive reason that can be discerned, then the question of whether the excess of Price over Cost is itself an abuse does not arise. Whilst normal market inefficiencies will explain some excess,[433] where one has a level of price substantially exceeding Cost or (in this case) the Cost Plus value as calculated by the CMA, then (absent an articulated and pro-competitive explanation) any excess will be abusive.

342. We will now turn to a phase-by-phase consideration of the prices charged by the various holders of the 10mg and 20mg Merck, Sharpe & Dohme MAs. It is helpful to have reference to the graphs at Annex 4C, which visualise the "Matterhorn" and identify – through coloured vertical tranches – the five phases that we are concerned with:

(1) We begin with the trite, but very important, point that the five phases in the graphs at Annex 4C are bookended by two periods where the CMA has not considered whether there was or was not an infringement of the Chapter II prohibition. This was for administrative reasons, which we entirely accept. The importance of the bookends (which excluded from consideration those periods where the price of the Focal Product fell below a certain level – £20 in the case of 10mg immediate release hydrocortisone tablets) is that the prices for the Focal Products during the five phases under consideration were already high and well in excess of Cost Plus. In our judgment, therefore, if the case is a Case 3 case and not a Case 2 case, these prices are abusive because they cannot be justified by Case 1, and no competitive reason for the excess producer surplus can otherwise be articulated.[434]

(2) It is significant that none of the Appellants advanced any explanation for the excess that was consistent with a competitive market or which justified a producer surplus through the maximisation of economic value through product differentiation. We find that telling. This is a case where there was, as we have found, dominance on the part of all holders of the Merck, Sharpe and Dohme

[432] See Transcript Day 17/pp.69 to 92: Mr Holmes KC considered and rejected the following possible explanations for the "Matterhorn": there had not been a change in the nature of the product itself, or an innovation or development which increased its value and / or its costs of production. There was no change in demand for the product leading to temporary spikes in demand such that demand exceeded supply, nor were there changes in availability of supply or capacity constraints in the market. There was also no change in the underlying costs of supplying the tablets. Another possible explanation, portfolio pricing, was supported by no contemporaneous or factual evidence.

[433] Case 1 under [322(1)], which we have already considered.

[434] Which, of course, is the difference between Case 3 (where no justification for the producer surplus arises) and Case 2 (where producer surplus in excess of Case 1 is capable of being justified).

MAs. There was, therefore, an absence of competition that provided a platform for the generation of producer surplus without any added value to Buyers.

(3) We accept that the shape of the "Matterhorn" is in no way indicative of whether the situation falls within Case 2 or Case 3. It is very likely that the Face Mask Example would generate a graph rather similar to those in Annex 4C. But that is nothing to the point. The Face Mask Example is explicable by reference to a sudden and unexpected increase in demand, causing an increase in price, which would in turn incentivise new entry. The present case contains none of these features:

(i) There was no sudden or unexpected increase in demand. The number of patients requiring treatment for adrenal insufficiency remained broadly constant, and certainly never demonstrated unexpected spikes in demand.

(ii) Yet, during Phase 1 and Phase 2, the price for 10mg and 20mg Focal Products rose.

(iii) More to the point, the duration where the trend was one of increasing prices persisted for months and years, with no sign of new entry and no legitimate explanation for its failure to emerge.

(4) We regard Phases 1 and 2 as *par excellence* cases where the prices charged throughout were an abuse of the Chapter II prohibition. That brings us to Phases 3, 4 and 5, which are characterised by a trend of decreasing prices, albeit that those prices remained significantly above Cost Plus. Here, too, we consider these phases to be cases where the prices charged throughout were abusive and an infringement of the Chapter II prohibition. We do not consider the downward trend of prices in Phases 3, 4 or 5 to affect this conclusion. Of course, 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. That will be so, whether the situation falls within Case 2 or Case 3. The difference between the two cases is that in Case 2 the producer surplus is justifiable and in Case 3 it is not. 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 (or Cost Plus, in this case) they infringe the Chapter II prohibition.

343. Subject to the points we consider further below, we find the prices charged by the Appellants to have been abusive during each of Phases 1 to 5.

(c) Postscript: excessive or abusive prices – Case 2

344. This is not, as we have found, a case within Case 2 ([322(2)]), where some level of producer surplus subsisting above Cost can be justified. This is, therefore, not a case we need to consider further. Such a case might arise, for example, where the Seller of a medicinal product had a patent which served to differentiate that Seller's product from

all other products in the market in a manner that caused Buyers to value that product more highly and so pay more.

345. Clearly, Prices significantly in excess of Cost – a high producer surplus – would be justifiable in Case 2: but we are not saying that any Price level above Cost is defensible under the Chapter II prohibition in this case. All we are saying is that the present is not a Case 2 instance; and that where a case falls within Case 2 (as this does not) careful consideration will have to be given as how and where the line between the abusive price and the merely high price is to be tested for. In short, we are not saying that the mere fact that high prices well above Cost can be justified as falling within Case 2 means that any Price, no matter how high, can be justified. That is obviously wrong: but the question does not arise in the present case, and we do not consider it further.

(d) Other points that require determination

(i) Introduction

346. Although they do not affect the conclusion we have expressed in [345], a number of other points were raised before us in these appeals which we need to dispose. They are considered in this section.

(ii) Comparables

347. The case law stresses that comparables can provide valuable information as to whether a Price of a given Product infringes the Chapter II prohibition or is merely in excess of Cost. In a competitive market, one would expect comparable products to act as a competitive constraint on the Focal Product. Where comparable products sell at different prices, that may be valuable evidence for or against an infringement.

348. 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.

349. On the other hand, we do consider that the Focal Products themselves act as their own comparators, when considered on a temporal basis. This is to repeat the question we asked at [340]:

> If we had to explain the "Matterhorn" to the interested party on the Clapham omnibus, what explanation would we give?

350. This is to ask why, either side of the "Matterhorn", were the prices of the Focal Products so low? Why did they approach Cost so much more closely? That is a comparison worth exploring: but we have already done so.

(iii) The regulatory environment of the market

351. We have been somewhat critical of the regulatory environment that has at least facilitated these overcharges. We have been even more critical of – and have rejected in terms – arguments that seek to justify these overcharges by reference to the regulatory environment. We want to be clear that the fact that a misbegotten regulatory environment has engendered a dominant position which is then abused in no way justifies the abuse.

(iv) Portfolio pricing

352. As we have noted, there was some suggestion that the prices in this case could be justified by some form of "portfolio" prices, where the price of certain medicinal products was subsidised by the prices charged for other medicinal products. Portfolio pricing – which generally will involve some form of cross-subsidisation – cannot automatically justify a higher price. Indeed, because portfolio pricing has aspects of both over- and under-charging, it will warrant careful consideration in those cases where it arises. Portfolio pricing certainly cannot be raised as an abstract justification for a price that is higher than it otherwise would be.

353. In this case, we need say no more. Had a detailed justification of price based on portfolio pricing been advanced, we would have considered it. But no such justification was advanced.

(v) A lack of clarity in the law

354. It was suggested that the law in regard to abusive pricing was so unclear that undertakings in this market – particularly when prices were falling – simply did not know what their legal position was. We do not accept this submission:

(1) The law – as we have described it – is clear. In this case, we consider that all of the undertakings holding the Marketing Authorisations to the Focal Products would have been well-aware of both the Cost of and the Price charged for these Focal Products. They would have been aware that (in this case) the latter (Price) significantly exceeded Cost. The pricing of products sold is one of the key functions of the entrepreneur, and entrepreneurs will or ought to know why their products are commanding the price(s) that they do. That kind of market awareness is a prerequisite to setting price, particularly in a market not characterised by overt competition.

(2) The distinction between the generation of additional value through product differentiation (Case 2) and the generation of producer surplus without added value to Buyers (Case 3) ought, as a general proposition, to be more visible to the entrepreneur than to the court, which comes as an outsider to the market.

(3) The ability to differentiate between an abusive price and a merely high price that is not abusive does not depend on an understanding or value judgment in relation to what has gone before. We have been assiduous in adopting a phased consideration both in relation to the question of dominance and the question of

abuse. Our conclusions have been reached on a phase-by-phase basis, without making any assumptions about an infringement of the Chapter II prohibition subsisting or not subsisting in a prior period.

(vi) Intention

355. For these reasons, we consider that the Abuse of Dominance Infringements were committed intentionally by the various holders of the 10mg and 20mg Merck, Sharpe and Dohme MA, which is what the Hydrocortisone Decision found. This, of course, is not relevant to infringement, but it does go to the question of penalty, to which we now turn.[435]

K. PENALTY FOR THE ABUSE OF DOMINANCE INFRINGEMENTS

(1) The position we have reached

356. We have, thus, reached – in terms of outcome – a similar position to the CMA in regard to the Abuse of Dominance Infringements. Our process of reasoning has been different:

(1) We have defined the market differently to the CMA.

(2) We have reached similar findings in relation to dominance, but by adopting a phased rather than monolithic approach to the "Matterhorn".

(3) Although we accept that in this case a price exceeding Cost Plus is abusive, that is not always the case and the Hydrocortisone Decision errs in following what was in effect a pure Cost Plus approach, instead of justifying it. (Although, in this case, it can be justified.)

357. Nevertheless, we have reached the same outcome in relation to the Abuse of Dominance Infringements as the CMA and it follows – although, of course, we must review the penalties imposed by the CMA in the Hydrocortisone Decision with an independent mind – that our starting point must be the penalties imposed by the CMA in the Hydrocortisone Decision.[436] It is to these that we now turn.

(2) The CMA's findings on penalty

358. Although we have expressed our views regarding the terminology in the Hydrocortisone Decision[437] – particularly as regards the designation "Auden/Actavis" – we adopt these terms for the purposes of setting out the CMA's approach.

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[435] The Appellants contended that this was neither a case of intention nor negligence, and that the CMA therefore lacked jurisdiction to impose penalties.

[436] See the comments of Green LJ in *Flynn Pharma* at [135] – [141], in particular that an appeal under section 46 is "not a *de novo* hearing but takes the decision as its starting, middle and end point".

[437] See [4] above.

359. On the basis of the CMA's findings regarding Auden/Actavis' infringement of the Chapter II prohibition, the Hydrocortisone Decision imposed financial penalties on Allergan, Accord Healthcare Limited, Accord-UK and Intas.[438] The Hydrocortisone Decision found that the 10mg and 20mg Abuse of Dominance Infringements constituted separate and distinct infringements, thereby attracting separate fines.[439] The paragraphs below set out the CMA's approach for the penalty for the Abuse of Dominance Infringements.

360. The Hydrocortisone Decision found that the Infringements had been committed intentionally or at the very least negligently, thereby meeting the requirements of section 36(3) of the Competition Act 1998 (see paragraphs 175 to 176 above).[440] It found that the Auden/Actavis undertaking knew or should have known the essential facts justifying the CMA's findings regarding excessive pricing i.e. that it was a dominant undertaking in the relevant market(s), and that its prices were unfair.[441]

361. The Hydrocortisone Decision found it was not necessary to establish intention or negligence at the level of each entity held liable for the infringement committed by the undertaking, in light of the wording of section 36(3) which refers to intention or negligence on the part of the undertaking. As the CMA established intention/negligence in respect of the Auden/Actavis undertaking, it did not need to establish intention/negligence again in the separate legal entities constituting the undertaking.[442]

362. In support of the conclusion that Auden/Actavis knew or should have known that as the sole and subsequently major supplier of hydrocortisone tablets, it was dominant, the Hydrocortisone Decision cites evidence from internal emails and presentations, as well as evidence that Intas and Accord Healthcare Limited were aware of the CMA's investigation about the potential abuse of a dominant position prior to the acquisition of Actavis UK Limited.[443]

363. In support of its conclusion that the Auden/Actavis undertaking knew or should have known the essential facts establishing that its prices during the infringements were unfair, the Hydrocortisone Decision points to evidence including the price increases from less than £1 to over £72 without accompanying increases in production costs or R&D costs, the maintenance of prices in excess of what the CMA deemed a reasonable measure of its costs plus a proper return, and awareness of the disparity between costs and prices.[444]

364. The CMA rejected representations from the parties that there was/is genuine uncertainty as to the applicable legal tests for excessive pricing, and this should be taken into

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[438] Hydrocortisone Decision/10.1, 10.130.

[439] Hydrocortisone Decision/10.3.

[440] Hydrocortisone Decision/10.8.

[441] Hydrocortisone Decision/10.21.

[442] Hydrocortisone Decision/10.22.

[443] Hydrocortisone Decision/10.25.

[444] Hydrocortisone Decision/10.28.

account for intention/negligence (and as a mitigation), and that the CMA's approach to determining a reasonable price and level of lawful price was not known at the time of conduct.[445] The Hydrocortisone Decision found that excessive pricing was not a new legal concept or type of abuse, with the seminal case on the test, *United Brands*, delivered in 1978.[446] Gradual clarifications of the law since then, including in the *Flynn Pharma* judgment, did not make the legal test unclear or uncertain.[447]

365. The Hydrocortisone Decision found that in light of the serious nature of the infringements, and to deter similar conduct in future, it was appropriate to impose financial penalties on the Auden/Actavis undertaking.[448] It imposed fines of **£147,078,300** in total on Allergan, Accord-UK, Accord and Intas for the 10mg Abuse of Dominance Infringement, and **£8,082,119** on Allergan and Accord-UK for the 20mg Abuse of Dominance Infringement.[449]

366. In calculating how the total penalty was to be distributed between the entities liable for the 10mg and 20mg Infringements, the CMA divided liability for infringement into separate periods, which reflect the changes in ownership of the hydrocortisone tablets business:

(1) **Accord-UK** was held liable:

(i) Between 1 October 2008 and 31 August 2015 for the Abuse of Dominance Infringements as the economic successor of AM Pharma.[450]

(ii) Between 1 September 2015 and 31 July 2018 / 8 January 2017 respectively for the 10mg and 20mg Abuse of Dominance Infringements as a direct participant.[451]

(2) **Allergan** was held liable for the Abuse of Dominance Infringements between 29 May 2015 (when it acquired AM Pharma) to 1 August 2016 (when it sold Accord UK to Teva) as a parent who exercised decisive influence over the direct participant in the Infringement.

(3) **Accord** was held liable for the 10mg Abuse of Dominance Infringement between 9 January 2017 (when its parent Intas acquired Actavis UK Limited) to 31 July 2018 as a parent who exercised decisive influence over the direct participant in the Infringement.

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[445] Hydrocortisone Decision/10.117 - 118.

[446] Hydrocortisone Decision/10.118.

[447] Hydrocortisone Decision/10.119.

[448] Hydrocortisone Decision/10.11, 10.129.

[449] Hydrocortisone Decision/table 10.1.

[450] The CMA defined 1 October 2008 – 28 May 2015 as **Period A1 / B1**, and 29 May 2015 – 1 August 2016 as **Period A2 / B2**.

[451] The CMA defined 2 August 2016 – 8 January 2017 as **Period A3 / B3**.

(4) **Intas** was held liable for the 10mg Abuse of Dominance Infringement between 9 January 2017 (when it acquired Actavis UK Limited) to 31 July 2018 as the parent of the direct participant (**Period A4**).[452]

367. In determining the level of fines, the CMA applied a six-step approach as set out in the CMA penalties guidance. As to this:

(1) The first step involves an application of a percentage rate of up to 30% to the "relevant"[453] turnover of the infringing undertaking depending on the seriousness of the infringement. At this stage, the turnover in respect of the 10mg and 20mg Focal Products of the entire Auden/Actavis undertaking was used (without division by time period or legal entity). This was £17,058,504 for the 10mg Abuse of Dominance Infringement, and £2,606,883 for the 20mg Infringement.

(2) The CMA applied the maximum percentage rate, 30%, in light of the seriousness of the Infringements.[454] Factors including the likelihood of the infringements to harm competition, the essential nature of the product to UK patients with adrenal insufficiency, Auden/Actavis' position as the sole supplier during the majority of the relevant period, the harm to end customers, the need for general deterrence, the exploitative nature of the abuse, and the persistent effects of abusive prices are cited in the Hydrocortisone Decision as relevant to seriousness.[455]

(3) At the second stage, the CMA adjusted the fine to account for the duration of the infringement. As the duration of the 10mg Infringement lasted 9 years and 10 months, a multiplier of 10 was applicable,[456] whilst a multiplier of 8.25 was applied to the 20mg Infringement.[457]

(4) The CMA at the third stage adjusted the fine to account for aggravating and mitigating factors. The CMA applied an uplift of 15% to the overall fine against Auden/Actavis for the Abuse of Dominance Infringements to account for Auden/Actavis's director/senior management involvement in that abuse, including because directors and senior management were involved in price setting for hydrocortisone tablets at all stages of the Infringement period.[458] It applied a 5% discount to Allergan, Accord-UK, Accord Healthcare Limited and Intas (i.e. all of the entities fined within the Auden/Actavis undertaking)[459] to

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[452] Hydrocortisone Decision/table 9.1.

[453] Meaning turnover of the undertaking in the relevant product and geographic market affected by the infringement in the undertaking's last business year - Hydrocortisone Decision/10.163.

[454] Hydrocortisone Decision/10.162 – 10.185.

[455] Hydrocortisone Decision/10.172 – 10.174.

[456] Hydrocortisone Decision/10.187.

[457] Hydrocortisone Decision/10.187.

[458] Hydrocortisone Decision/10.196 – 10.198.

[459] And Advanz and Amdipharm, but this fine related to the Agreements.

recognise the steps the companies had taken to ensure compliance with competition law.[460]

(5) At the fourth stage, the CMA apportioned the fine to each specific period of ownership i.e. into periods A1 – A4 / B1 – B3 (see above at paragraph 366). The CMA then applied an adjustment for specific deterrence and proportionality separately in relation to the Infringements.

(6) The CMA calculated an estimated minimum financial benefit to be attributed to each period of ownership with respect to the 10mg Infringement, and found that the penalties at the end of stage three were significantly less than that estimate.[461] It also found that the penalty at the end of stage three did not reflect the serious nature and severe impact of the Infringement. Additional factors supporting a further uplift (according to features of the entities involved in the different ownership periods) were the size and financial position of the entities and the accompanying need for a penalty to represent more than a small proportion of worldwide turnover (for deterrence purposes), the need to address the scale of the Infringement during the period of ownership, and whether a CMA investigation into excessive pricing of hydrocortisone tablets was open at the time that the parent acquired the entity directly participating in the Infringement.[462]

368. After these adjustments, the fines for the 10mg Abuse of Dominance Infringement were £87,650,000 for Periods A1 and A3 (Accord UK); £74,300,000 for Period A2 (Allergan); and £44,400,000 for Period A4 (Accord-UK, Accord and Intas). The total uplift applied to the step three fines were a multiplier of 2.16 to the fine for Periods A1 and A3; a multiplier of 10.93 to the fine for Period A2; and a multiplier of 5 for Period A4.[463] (We should note that the eventual fine for Accord-UK in periods A1 and A3 was significantly less than the estimated financial benefit from the excessive pricing abuse (due to the statutory cap).)

369. Regarding the 20mg Infringement, the CMA concluded that the estimated minimum financial benefit to be attributed to Periods B1 and B3 was already exceeded by the proposed fines in stage three, and so no adjustments were made. However, for Period B2, the penalty proposed was exceeded by this estimated benefit, and so the CMA uplifted the penalty by £1,000,000.[464] No further adjustment was made at this stage. After these adjustments, the fines for the 20mg Infringement for Periods B1 and B3 (Accord-UK) was £6,082,119 and for Period B2 (Accord-UK and Allergan) was £2,000,000.[465]

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[460] Hydrocortisone Decision/10.215 – 218.

[461] Hydrocortisone Decision/10.260 – 10.262.

[462] Hydrocortisone Decision/10.260 – 10.284.

[463] Hydrocortisone Decision/10.296.

[464] Hydrocortisone Decision/10.301 – 10.303.

[465] Hydrocortisone Decision/10.308.

370. At step five, the CMA considered adjustments to prevent the maximum penalty i.e. the statutory cap being exceeded (10% of worldwide turnover in the last business year) and to avoid double jeopardy.[466] Only the fines relating to the 10mg Infringement were considered here:

(1) The fine imposed on Accord-UK for Periods A1 to A3 was deemed subject to the statutory cap and so was reduced to the maximum cap: £28,378,300.

(2) Because Accord-UK was solely liable for Periods A1 and A3 and due to the application of the statutory cap, its penalty for Period A2 was reduced to zero.

(3) The CMA found Allergan did not benefit from the statutory cap for Period A2 as it was no longer the parent company of Accord-UK.[467]

371. The CMA then considered the four penalties it was imposing on the Auden/Actavis undertaking in the round. It concluded these multiple penalties reflect the serious nature of each individual infringement, and that none of them involved double counting or any uplifts for specific deterrence for the same infringement twice. Further, the financial positions of the undertakings concerned indicated the overall fines were not disproportionate or excessive in the context of the serious and harmful infringements.[468] The total penalty in relation to the 10mg Abuse of Dominance Infringement for Allergan, Accord-UK and the Accord-UK/Accord Healthcare Limited/Intas undertaking amounted to 0.2%, 1.7% and 2.7% of worldwide turnover.[469] The fines for the 20mg Infringement represented 0.1% and 0.5% of Allergan and Accord-UK's worldwide turnover.[470]

372. This resulted in fines for the 10mg Abuse of Dominance Infringement of £28,378,000 for Accord-UK, £74,300,000 for Allergan, and £44,400,000 for Accord-UK, Accord Healthcare Limited, and Intas (jointly and severally).[471] The fines for the 20mg Infringement were £6,082,119 for Accord-UK and £2,000,000 for Allergan and Accord-UK (jointly and severally).[472]

(3) Appellants' submissions

373. All of the Appellants fined by the CMA for the Abuse of Dominance Infringements challenged those fines as excessive and / or disproportionate. These challenges focused in particular on the 30% starting point at stage 1 (see paragraph 367(2) above), the 15% uplift and 5% credit at stage 3 (see paragraph 367(4) above), and the uplifts applied at

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[466] Hydrocortisone Decision/10.392.

[467] Hydrocortisone Decision/10.393 - 10.395.

[468] Hydrocortisone Decision/10.405 – 10.407, 10.413, 10.415.

[469] Hydrocortisone Decision/10.411 – 413.

[470] Hydrocortisone Decision/Table 10.14, 10.15.

[471] Hydrocortisone Decision/10.417.

[472] Hydrocortisone Decision/10.417.

stage 4 (see paragraph 367(6) above). The Appellants also all submitted that the Abuse of Dominance Infringements, if committed, were not committed intentionally or negligently.[473]

374. This is, as we have noted, a merits review, and the Tribunal may revoke or vary the amount of any penalty imposed.[474] The Tribunal's approach in previous cases has been to review the CMA's application of its guidance, and then to make its own assessment of the level of the penalty on the basis of a "broad-brush" approach, taking the case as a whole.[475] That is the approach we propose to take here. Accordingly:

(1) Given that we have substantially affirmed the outcome of the Hydrocortisone Decision, our starting point must be the penalties that the CMA imposed. We do not propose to explore the CMA's approach in a granular manner, but will consider the case as a whole, using a "broad-brush".

(2) 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.

(4) Assessment on appeal

375. The CMA's six-step approach to penalty is described in general terms in Whish and Bailey,[476] and we have set out in Section K(2) the manner in which the CMA applied that approach in the case of the Abuse of Dominance Infringements. 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.

376. In these circumstances, we consider that the penalties imposed should be affirmed, and certainly should not be reduced in the round. More specifically:

(1) We are *ad idem* with the CMA in terms of the seriousness of these infringements. We consider that the infringements were entered into by the relevant undertakings intentionally, and not negligently. This was a case where the mismatch between cost and price was extreme. The 10mg and 20mg Focal Products were priced at multiples of marginal cost, indeed at multiples of the CMA's Cost Plus figure. Any business person with any understanding of the pharmaceutical business would have appreciated that these margins were only defensible if there was some legitimate means of differentiating the 10mg and

[473] Intas NoA/144 – 205, Auden/Actavis NoA/194 – 218, Allergan NoA/126 – 173.

[474] See [32(2)] above.

[475] Whish and Bailey, *Competition Law*, 10th ed (2021) at 444 and the authorities there cited.

[476] Whish and Bailey, *Competition Law*, 10th ed (2021) at 423 to 434.

20mg Focal Products from the competition. Such legitimate differentiation did not exist: for the reasons we have given above, we consider that the dominance that the undertakings in question had, and the abuses that that dominance gave rise to, arose out of the illegitimate exploitation of the regulatory weaknesses in the market.

(2) We do not accept that the law in this area was unclear. The law as we have found it to be aligns very closely with what should be the objective of entrepreneurs the world round: making profits substantially in excess of cost by creating consumer value through the development and sale of products that differentiate themselves from the products of competitors by appealing to what consumers want to buy. Entrepreneurs should not expect to make profits in excess of cost plus through the illegitimate exploitation of market power. The Hydrocortisone Decision and the record of this appeal demonstrates very clearly an illegitimate exploitation of market power to leverage price well in excess of what was fair.

(3) 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.

(4) Our findings with regard to the Hold Separate Regime do require an adjustment in that the fine levied against Allergan plc needs to be set aside, for the reasons we have given.

L. CONCLUSION

377. For the reasons we have given:

(1) We find that the Abuse of Dominance Infringements have been made out by the CMA.

(2) Subject to the penalty against Allergan plc in respect of Phase 3, which must be set aside, we affirm the penalties imposed by the CMA, having considered on the merits the basis upon which those penalties were calculated. As regards the position of Allergan plc in Phase 3, we consider that the penalty against Allergan plc should be reduced on a *pro rata* basis by reference to time period. We trust that this can be agreed, but will rule further if necessary.

378. This Judgment (Abuse of Dominance Infringements) is unanimous but does not represent the end of these appeals. We are conscious that the Judgment (Cartel Infringements) is to follow. We invite the parties to draw up an order consequential upon this Judgment (Abuse of Dominance Infringements). Our provisional view is that

interest on the penalties determined by the CMA is appropriate, but we would want to hear the parties on this, as well as on the rate of interest that ought to be applied.

Sir Marcus Smith
President

Simon Holmes

Professor Robin Mason

Charles Dhanowa OBE, KC (Hon)
Registrar

Date: 18/09/2023

ANNEX 1

TERMS AND ABBREVIATIONS USED IN THE JUDGMENT (ABUSE OF DOMINANCE INFRINGEMENTS)

(Judgment (Abuse of Dominance Infringements) at [1], fn 2)

TERM/ABBREVIATION	FIRST (BOLDED) USE IN THE JUDGMENT
10mg Agreement	[10]
10mg Focal Product	[248]
10mg immediate release hydrocortisone tablets	[5(4)(ii)]
20mg Agreement	[10]
20mg Focal Product	[248]
20mg immediate release hydrocortisone tablets	[11]
ABPI Code	[89(1)]
Abuse of Dominance Infringements	[9]
Accord-UK Ltd	[131]
Actavis Phase (Phase 2)	[179(2)]
Actavis plc	[122]
Actavis UK Limited	[125]
Actavis UK/Accord-UK Ltd	[131]
Advanz Appellants	[2(2)]
Aesica	[26(4)]
Allergan Appellant	[2(1)]
Allergan plc	[124]

Contract Manufacturing Organisation	[66]
Decisive Influence Test	[174]
doctor	[75(1)]
Drug Tariff	[64(3)]
Face Mask Example	[152(4)]
First Written Agreement	[149]
focal product	[185(3)]
Full Label MA	[140(2)]
Hold Separate Regime	[128]
Hold Separate Regime Part I (Phase 3)	[179(3)]
Hold Separate Regime Part II (Phase 4)	[179(4)]
Human Medicines Regulations	[52] (footnote)
Hydrocortisone Decision	[1]
Hydrocortisone Infringements	[1]
Hypothetical Monopolist Test	[185(7)]
Intas Appellants	[2(5)]
Intas Phase (Phase 5)	[179(5)]
Intermediate consumers	[74(1)]
Judgment (Abuse of Dominance Infringements)	[5]
Judgment (Cartel Infringements)	[16]
MA	[109]
Marketing Authorisation	[5(4)(i)]

Merck, Sharpe & Dohme	[110]
Merck, Sharpe & Dohme MA	[111]
MHRA	[52]
Mr Amit Patel	[5(4)(v)]
Mrs Meeta Patel	[5(4)(v)]
NHS Reimbursement Price	[114(9)]
non-prescription	[56]
off-label	[54(2)]
off-label facilitation	[54(2)]
off-label use	[54(2)]
on-label	[54(2)]
on-label facilitation	[54(3)]
on-label use	[54(3)]
Orphan Medicine	[92]
Orphan Regulation	[92]
Patel Phase (Phase 1)	[179(1)]
patient	[60]
Pharmaceutical Price Regulation Scheme	[106(1)]
pharmacy	[75(2)]
Plenadren	[43]
Plenadren MA	[136]
Post-Entry Period	[190]
PPRS	[106(1)]

Pre-Entry Period	[190]
prescription	[56]
prescription-only	[59]
pre-wholesalers	[69]
proper return	[318(8)]
Second Written Agreement	[149]
Skinny Label MA	[140(2)]
SmPC	[53]
SSNIP	[185(7)]
Summary of the Product Characteristics	[53]
therapeutic indications	[53]
ultimate consumer	[74(1)]
Waymade MA	[146]

ANNEX 2

DESCRIPTION OF DOCUMENTS UNDERLINED IN THE JUDGMENT

(Judgment (Abuse of Dominance Infringements) at [1], footnote 3)

DOCUMENT TERM	DESCRIPTION
Advanz NoA	Notice of Appeal filed pursuant to section 46 of the Competition Act 1998 by Amdipharm UK Limited, Amdipharm Limited, Advanz Pharma Services (UK) Limited and Advanz Pharma Corp. Limited on 15 September 2021.
Allergan NoA	Notice of Appeal filed pursuant to section 46 of the Competition Act 1998 by Allergan plc on 15 September 2021 and amended on 26 January 2022.
Auden/Actavis NoA	Notice of Appeal filed pursuant to section 46 of the Competition Act 1998 by Auden McKenzie (Pharma Division) Limited and Accord UK Limited on 6 October 2021 and amended on 9 March 2022.
Beighton 1	Witness statement of Mr John Beighton, dated 10 September 2021, filed on behalf of the Advanz Appellants.
Bennett 1	Economic expert report of Dr Matthew Bennett, of Charles River Associates, dated 30 September 2021, filed on behalf of the Cinven Appellants.
Bennett 2	Second economic expert report of Dr Matthew Bennett, of Charles River Associates, dated 25 February 2022, filed on behalf of the Cinven Appellants.
Bishop 1	Economic expert report of Simon Bishop, of RBB Economics, dated 6 October 2021, filed on behalf of the Intas Appellants.
Bishop 2	Second economic expert report of Simon Bishop, of RBB Economics, dated 25 February 2022, filed on behalf of the Intas Appellants.
Cinven NoA	Notice of Appeal filed pursuant to section 46 of the Competition Act 1998 by Cinven

	(Luxco 1) SARL, Cinven Capital Management (V) General Partner Ltd and Cinven Partners LLP on 30 September 2021.
Cinven Written Closing	Written closing submissions dated 10 December 2022 filed by the Cinven Appellants.
Defence	Defence filed by the CMA of its decision here under appeal, dated 1 December 2021 as amended on 10 May 2022.
Holt 1	Economic expert report of Derek Holt, of Alix Partners, dated 15 September 2021, filed on behalf of the Advanz Appellants.
Hydrocortisone Decision	The decision of the CMA dated 15 July 2021 here under appeal.
Intas NoA	Notice of Appeal filed pursuant to section 46 of the Competition Act 1998 by Accord UK Limited, Accord Healthcare Limited and Intas Pharmaceuticals Limited on 6 October 2021 and amended on 11 March 2022.
Lifton 1	Witness statement of Ms Kelly Lifton dated 22 November 2022 filed on behalf of the Advanz Appellants.
Middleton 1	Witness statement of Mr Wayne Middleton dated 22 November 2022 filed on behalf of the Advanz Appellants.
Newton 1	Expert report of Dr Rina Newton, of Pharmalex, dated 21 November 2022, filed on behalf of the Advanz Appellants.
Stewart 1	Witness statement of Mr Robert Stewart dated 14 September 2021 filed on behalf of the Allergan Appellant.
Sully 1	Witness statement of Mr Robert Sully, dated 4 November 2022, filed on behalf of the Advanz Appellants.
Valletti 1	Economic expert report of Professor Tommaso Valletti, dated 26 November 2021, filed on behalf of the CMA.

ANNEX 3

PRICES OF 10mg "IMMEDIATE RELEASE" HYDROCORTISONE TABLETS SOLD UNDER THE MERCK, SHARPE & DOHME MA

PRICES OF 20mg "IMMEDIATE RELEASE" HYDROCORTISONE TABLETS SOLD UNDER THE MERCK, SHARPE & DOHME MA

PRICES OF 5mg AND 20mg "MODIFIED RELEASE" HYDROCORTISONE TABLETS SOLD UNDER THE PLENADREN MA

PRICES OF SKINNY LABEL MAs

PRICES AT WHICH WAYMADE SOLD 20mg "IMMEDIATE RELEASE" HYDROCORTISONE TABLETS ACQUIRED PURSUANT TO THE 20mg AGREEMENT

PRICES AT WHICH 10mg "IMMEDIATE RELEASE" HYDROCORTISONE TABLETS WERE SOLD PURSUANT TO THE 10mg AGREEMENT

(Judgment (Abuse of Dominance Infringements)[1] at [5])

(1) Date or date range	(2) Holder of Marketing Authorisation	(3) Parent or holding company or companies or persons	(4) Price sold (per pack)	(5) Applicable price control	(6) Drug Tariff Price[2]	(7) Volumes sold
From 1955	Sale, by Merck, Sharpe & Dohme of Hydrocortone from around this time: Judgment at [110].					
11 May 1987	This is the date on which the Waymade MA in respect of 20mg "immediate release" hydrocortisone tablets was granted: Judgment at [138].[3]					
23 Feb 1989	This is the date the Merck, Sharpe & Dohme MA was granted: Judgment at [112]. There is no data available for sales until May 2005, when annualised data exists.					
Period 1 May 2005 to Apr 2006	Merck, Sharpe & Dohme 10mg	Not applicable	£0.70	PPRS	£0.70	[58,842][4] 706,100
	Merck, Sharpe & Dohme 20mg	Not applicable	£1.07	PPRS	£1.07	[4,775][5] 57,300
Period 2	Merck, Sharpe & Dohme 10mg	Not applicable	£0.70	PPRS	£0.70	[60,575][6] 726,900

[1] All further references to the "Judgment" in this Annex are to the Judgment (Abuse of Dominance Infringements).

[2] In fact the NHS Reimbursement price, which we have used in preference. Nevertheless, we have used the term "Drug Tariff" throughout.

[3] A different date is given in Hydrocortisone Decision/3.345, which we have taken as an (immaterial) error.

[4] This converts the annual sales into a monthly figure, for comparison purposes.

[5] This converts the annual sales into a monthly figure, for comparison purposes.

[6] This converts the annual sales into a monthly figure, for comparison purposes.

May 2006 to Apr 2007						
	Merck, Sharpe & Dohme 20mg	Not applicable	£1.07	PPRS	£1.07	[4,617][7] 55,400
Period 3 May 2007 to Apr 2008	Merck, Sharpe & Dohme 10mg	Not applicable	£0.70	PPRS	£0.70	[62,650][8] 751,800
	Merck, Sharpe & Dohme 20mg	Not applicable	£1.07	PPRS	£1.07	[4,308][9] 51,700
21 Apr 2008	Merck, Sharpe & Dohme sell the "Hydrocortone" brand and the MA for both 10mg and 20mg "immediate release" hydrocortisone tablets to AM Pharma: Judgment at [117]*ff*.					
Period 4 Apr 2008	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£4.54	None applicable	£0.70	6,890
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£5.14	None applicable	£1.07	2,500
Period 5 May 2008	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£4.54	None applicable	£0.70	108,873
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£5.15	None applicable	£1.07	7,627
Period 6 Jun 2008	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£9.67	None applicable	£2.76	62,192
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£15.66	None applicable	£2.89	4,047
Period 7 Jul 2008	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£13.25	None applicable	£6.47	75,213
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£14.70	None applicable	£4.33	3,961
Period 8 Aug 2008	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£13.27	None applicable	£7.85	66,921
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£14.59	None applicable	£8.25	4,027
Period 9 Sep 2008	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£12.86	None applicable	£13.15	55,371
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£9.03	None applicable	£13.86	5,755
Period 10 Oct 2008	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£22.28	None applicable	£23.72	67,467

[7] This converts the annual sales into a monthly figure, for comparison purposes.

[8] This converts the annual sales into a monthly figure, for comparison purposes.

[9] This converts the annual sales into a monthly figure, for comparison purposes.

	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£23.74	None applicable	£22.96	6,859
Period 11 Nov 2008	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£22.60	None applicable	£25.24	65,779
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£15.42	None applicable	£25.19	4,585
Period 12 Dec 2008	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£23.27	None applicable	£29.87	49,713
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£24.60	None applicable	£31.28	2,489
Period 13 Jan 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£22.37	None applicable	£30.13	74,396
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£9.27	None applicable	£31.48	5,246
Period 14 Feb 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£22.93	None applicable	£30.18	58,247
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£20.75	None applicable	£31.80	2,593
Period 15 Mar 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£23.22	None applicable	£30.27	66,394
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£24.67	None applicable	£31.65	2,218
Period 16 Apr 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£22.16	None applicable	£30.25	77,426
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£10.31	None applicable	£31.70	6,440
Period 17 May 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£23.27	None applicable	£30.27	58,570
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£24.49	None applicable	£31.70	2,586
Period 18 Jun 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£23.15	None applicable	£30.25	72,961
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£24.85	None applicable	£31.52	4,886
Period 19 Jul 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£23.29	None applicable	£39.74	77,237
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£18.15	None applicable	£41.84	8,385
Period 20 Aug 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£26.64	None applicable	£39.76	66,429

	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.56	None applicable	£41.50	4,530
Period 21 Sep 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.85	None applicable	£39.94	56,377
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£25.69	None applicable	£41.98	1,901
Period 22 Oct 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.80	None applicable	£39.96	64,413
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.94	None applicable	£41.99	2,116
Period 23 Nov 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.64	None applicable	£39.96	67,237
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.91	None applicable	£42.00	3,168
Period 24 Dec 2009	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.23	None applicable	£39.96	53,954
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£30.79	None applicable	£42.01	3,280
Period 25 Jan 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£28.55	None applicable	£39.95	70,574
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£26.01	None applicable	£42.01	5,220
Period 26 Feb 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.15	None applicable	£39.96	59,405
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£32.20	None applicable	£42.02	2,140
Period 27 Mar 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.51	None applicable	£39.97	53,149
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.30	None applicable	£42.00	2,563
Period 28 Apr 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£28.90	None applicable	£48.76	48,238
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£30.81	None applicable	£51.25	1,538
Period 29 May 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£27.62	None applicable	£48.74	139,725
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£29.19	None applicable	£51.22	11,852
Period 30 Jun 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.60	None applicable	£44.37	75,267

	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£35.34	None applicable	£46.62	2,259
Period 31 Jul 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£27.72	None applicable	£45.33	52,819
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.47	None applicable	£48.43	2,745
Period 32 Aug 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£16.42	None applicable	£43.95	69,486
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£32.95	None applicable	£46.57	2,014
Period 33 Sep 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£30.20	None applicable	£44.21	45,558
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£32.95	None applicable	£47.17	2,014
Period 34 Oct 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£28.07	None applicable	£43.22	116,670
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.21	None applicable	£45.70	4,607
Period 35 Nov 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£28.11	None applicable	£42.87	79,900
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£32.63	None applicable	£45.48	2,841
Period 36 Dec 2010	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£30.92	None applicable	£42.49	56,712
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£33.93	None applicable	£45.17	2,894
Period 37 Jan 2011	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.59	None applicable	£42.98	61,032
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£30.76	None applicable	£45.65	6,563
Period 38 Feb 2011	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£28.55	None applicable	£42.85	64,018
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£32.13	None applicable	£45.58	2,079
Period 39 Mar 2011	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.81	None applicable	£43.05	161,110
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.85	None applicable	£45.75	10,438
Period 40 Apr 2011	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£28.16	None applicable	£43.01	108,879

	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£30.17	None applicable	£45.69	4,739
Period 41 May 2011	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.43	None applicable	£43.09	51,507
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.16	None applicable	£45.92	1,943
Period 42 Jun 2011	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£27.71	None applicable	£43.09	59,862
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£30.27	None applicable	£45.99	13,871
11 Jul 2011	According to the Hydrocortisone Decision/3.370, the 20mg Agreement was made on this date.					
Period 43 Jul 2011	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.15	None applicable	£43.12	124,126
	AM Pharma 20mg	Mrs Amit Patel Mrs Meeta Patel	£32.56	None applicable	£45.90	2,386
	Waymade 20mg	Not applicable	£36.12	None applicable	£45.90	50
Period 44 Aug 2011	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£30.19	None applicable	£43.10	40,728
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£32.29	None applicable	£46.01	2,068
	Waymade 20mg	Not applicable	£32.94	None applicable	£46.01	174
Period 45 Sep 2011	AAM Pharma 10mg	Mrs Amit Patel Mrs Meeta Patel	£30.28	None applicable	£43.41	43,304
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.93	None applicable	£46.02	4,403
	Waymade 20mg	Not applicable	£36.63	None applicable	£46.02	73
Period 46 Oct 2011	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£30.24	None applicable	£43.41	53,281
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£36.52	None applicable	£46.04	5,625
	Waymade 20mg	Not applicable	£34.84	None applicable	£46.04	140
3 Nov 2011	The European Medicines Agency grants a centralised European MA for Plenadren as an Orphan Drug: see Judgment at [132].					
Period 47 Nov 2011	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£30.43	None applicable	£43.51	85,850
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.62	None applicable	£46.03	2,809
	Waymade 20mg	Not applicable	£35.43	None applicable	£46.03	203
Period 48 Dec 2011	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£30.81	None applicable	£43.55	94,814

	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.37	None applicable	£45.97	5,200
	Waymade 20mg	Not applicable	£36.94	None applicable	£45.97	17
Period 49 Jan 2012	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£31.25	None applicable	£44.91	76,079
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.60	None applicable	£46.11	1,726
	Waymade 20mg	Not applicable	£36.95	None applicable	£46.11	80
Period 50 Feb 2012	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£30.78	None applicable	£45.37	112,613
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£30.46	None applicable	£46.07	9,802
	Waymade 20mg	Not applicable	£36.90	None applicable	£45.90	29
Period 51 Mar 2012	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£30.73	None applicable	£45.50	111,469
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£34.25	None applicable	£46.10	2,910
	Waymade 20mg	Not applicable	£36.99	None applicable	£46.10	71
Period 52 Apr 2012	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£32.47	None applicable	£45.39	46,949
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£30.84	None applicable	£46.07	2,892
	Waymade 20mg	Not applicable	£36.96	None applicable	£46.07	50
Period 53 May 2012	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£29.33	None applicable	£45.54	100,336
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£30.84	None applicable	£46.06	9,017
	Waymade 20mg	Not applicable	£32.40	None applicable	£46.06	596
Period 54 Jun 2012	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£31.94	None applicable	£45.58	66,161
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£32.03	None applicable	£46.10	4,476
	Waymade 20mg	Not applicable	£33.32	None applicable	£46.10	579
Period 55 Jul 2012	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£31.81	None applicable	£45.67	76,279
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.15	None applicable	£45.44	4,318
	Waymade 20mg	Not applicable	£31.89	None applicable	£45.44	333

Period 56 Aug 2012	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£31.92	None applicable	£46.37	80,720
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.73	None applicable	£47.16	2,530
	Waymade 20mg	Not applicable	£32.72	None applicable	£47.16	146
Period 57 Sep 2012	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£31.80	None applicable	£46.63	66,641
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.63	None applicable	£47.87	5,028
	Waymade 20mg	Not applicable	£34.64	None applicable	£47.87	146
27 Sep 2012	Waymade obtain a Marketing Authorisation in respect of 10mg "immediate release" hydrocortisone: Judgment at [338].					
Oct 2012	According to the CMA, the 10mg Agreement was concluded on this date.					
Period 58 Oct 2012	AM Pharma 10mg	Mr Amit Patel Mrs Meeta Patel	£31.55	None applicable	£46.76	79,953
	AM Pharma 20mg	Mr Amit Patel Mrs Meeta Patel	£31.77	None applicable	£48.16	5,291
	Waymade 20mg	Not applicable	£34.35	None applicable	£48.16	337
	10mg Agreement sale	Not applicable	£36.14	Scheme M	£46.63	3,575
31 Oct 2012	Waymade's 10mg Marketing Authorisation, 10mg product development and relevant staff become part of AMCo: Judgment at [370].					
1 Nov 2012	On 1 November 2012, Auden Mckenzie Holdings Ltd was interposed between AM Pharma and Mr Amit and Mrs Meeta Patel: Judgment at [114(6)].					
Period 59 Nov 2012	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£32.00	None applicable	£46.79	92,048
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£32.13	None applicable	£48.27	3,510
	Waymade 20mg	Not applicable	£34.43	None applicable	£48.27	315
	10mg Agreement sale	Not applicable	£36.29	Scheme M	£46.79	2,329
Period 60 Dec 2012	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£32.65	None applicable	£48.49	70,978
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£32.30	None applicable	£48.31	2,207
	Waymade 20mg	Not applicable	£33.45	None applicable	£48.31	185

	10mg Agreement sale	Not applicable	£36.96	Scheme M	£48.49	1,084
Period 61 Jan 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£33.94	None applicable	£49.17	80,600
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£31.74	None applicable	£50.00	7,259
	Waymade 20mg	Not applicable	£34.64	None applicable	£50.00	147
	10mg Agreement sale	Not applicable	£34.50	Scheme M	£49.17	7,887
Period 62 Feb 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£34.31	None applicable	£49.46	60,497
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£33.48	None applicable	£50.68	4,114
	Waymade 20mg	Not applicable	£31.38	None applicable	£50.68	273
	10mg Agreement sale	Not applicable	Nil	Scheme M	£49.46	Nil
Period 63 Mar 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£33.07	None applicable	£49.57	73,640
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£35.70	None applicable	£50.86	1,723
	Waymade 20mg	Not applicable	£34.52	None applicable	£50.86	183
	10mg Agreement sale	Not applicable	Nil	Scheme M	£49.57	Nil
Period 64 Apr 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£34.09	None applicable	£49.60	115,338
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£32.75	None applicable	£51.05	6,948
	Waymade 20mg	Not applicable	£37.46	None applicable	£51.05	65
	10mg Agreement sale	Not applicable	£38.00	Scheme M	£49.60	1,500

Period 65 May 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£33.83	None applicable	£50.18	67,147
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£34.86	None applicable	£51.03	3,703
	Waymade 20mg	Not applicable	£37.57	None applicable	£51.03	92
	10mg Agreement sale	Not applicable	£37.72	Scheme M	£50.18	5,700
Period 66 Jun 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£35.45	None applicable	£50.40	76,821
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£33.96	None applicable	£51.09	5,265
	Waymade 20mg	Not applicable	£38.50	None applicable	£51.09	40
	10mg Agreement sale	Not applicable	£38.00	Scheme M	£50.40	10,800
Period 67 Jul 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£35.70	None applicable	£50.49	74,338
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£35.33	None applicable	£51.10	4,580
	Waymade 20mg	Not applicable	£37.89	None applicable	£51.10	83
	10mg Agreement sale	Not applicable	£38.00	Scheme M	£50.49	7,200
Period 68 Aug 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£34.75	None applicable	£50.53	66,065
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£34.89	None applicable	£51.11	3,754
	Waymade 20mg	Not applicable	£37.36	None applicable	£51.11	368
	10mg Agreement sale	Not applicable	£38.01	Scheme M	£50.53	6,510
Period 69 Sep 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd	£35.47	None applicable	£50.54	58,054

		Mr Amit Patel Mrs Meeta Patel				
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£35.47	None applicable	£51.11	3,297
	Waymade 20mg	Not applicable	£40.12	None applicable	£51.11	49
	10mg Agreement sale	Not applicable	£38.00	Scheme M	£50.54	4,290
Period 70 Oct 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£35.50	None applicable	£50.55	100,214
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£36.47	None applicable	£51.08	6,123
	Waymade 20mg	Not applicable	£47.54	None applicable	£51.08	69
	10mg Agreement sale	Not applicable	£38.00	Scheme M	£50.55	8,710
Period 71 Nov 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£35.64	None applicable	£50.54	80,426
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£39.15	None applicable	£56.13	4,113
	Waymade 20mg	Not applicable	£47.31	None applicable	£56.13	51
	10mg Agreement sale	Not applicable	£37.99	Scheme M	£50.54	6,490
Period 72 Dec 2013	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£36.03	None applicable	£50.55	72,066
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£41.39	None applicable	£58.12	4,024
	Waymade 20mg	Not applicable	£45.07	None applicable	£58.12	321
	10mg Agreement sale	Not applicable	£38.00	Scheme M	£50.55	6,500
Period 73 Jan 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£37.20	None applicable	£50.61	104,133

	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£39.13	None applicable	£59.02	1,793
	Waymade 20mg	Not applicable	£46.00	None applicable	£59.02	308
	10mg Agreement sale	Not applicable	£38.00	Scheme M	£50.61	8,300
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	Nil
	Plenadren 20mg	Not applicable	£350.00	PPRS	None	Nil
Period 74 Feb 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£41.22	None applicable	£59.77	73,926
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£41.51	None applicable	£65.03	6,014
	Waymade 20mg	Not applicable	£45.75	None applicable	£65.03	355
	10mg Agreement sale	Not applicable	£43.50	Scheme M	£59.77	6,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	Nil
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	Nil
24 Feb 2014	AMCo executes the First Written Agreement with Auden.					
Period 75 Mar 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£41.66	None applicable	£59.22	88,919
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£41.99	None applicable	£65.03	3,221
	Waymade 20mg	Not applicable	£47.58	None applicable	£65.03	426
	10mg Agreement sale	Not applicable	£43.50	Scheme M	£59.22	6,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	Nil
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	Nil
31 Mar 2014	Termination of supply under the First Written Agreement.					
Period 76 Apr 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£37.80	None applicable	£58.51	70,256
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd	£41.20	None applicable	£65.03	3,564

		Mr Amit Patel Mrs Meeta Patel				
	Waymade 20mg	Not applicable	£47.72	None applicable	£65.03	155
	10mg Agreement sale	Not applicable	£43.50	Scheme M	£58.51	6,500
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	Nil
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	Nil
Period 77 May 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£53.65	None applicable	£66.84	74,502
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£59.62	None applicable	£71.66	3,667
	Waymade 20mg	Not applicable	£75.28	None applicable	£71.66	36
	10mg Agreement sale	Not applicable	£49.14	Scheme M	£66.84	5,500
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	Nil
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	Nil
Period 78 Jun 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£46.76	None applicable	£66.83	75,836
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£49.69	None applicable	£72.59	2,530
	Waymade 20mg	Not applicable	£67.85	None applicable	£72.59	27
	10mg Agreement sale	Not applicable	£46.81	Scheme M	£66.83	11,999
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	Nil
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	Nil
25 June 2014	Conclusion of the Second Written Agreement.					
Period 79 Jul 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£45.77	None applicable	£58.56	94,414
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£49.60	None applicable	£72.96	4,089
	Waymade 20mg	Not applicable	£69.40	None applicable	£72.96	20

	10mg Agreement sale	Not applicable	£47.15	Scheme M	£58.56	12,000
	Plenadren 5mg	Not applicable	£212.20	PPRS	£242.50	274
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	86
Period 80 Aug 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£44.69	None applicable	£58.54	72,969
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£48.63	None applicable	£73.11	2,535
	Waymade 20mg	Not applicable	£58.52	None applicable	£73.11	82
	10mg Agreement sale	Not applicable	£47.40	Scheme M	£58.54	12,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	335
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	73
Period 81 Sep 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£46.05	None applicable	£58.05	99,650
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£50.64	None applicable	£77.02	3,499
	Waymade 20mg	Not applicable	£59.21	None applicable	£77.02	70
	10mg Agreement sale	Not applicable	£47.40	Scheme M	£58.05	12,001
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	544
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	89
Period 82 Oct 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£48.22	None applicable	£64.78	111,693
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£54.77	None applicable	£78.53	5,538
	Waymade 20mg	Not applicable	£58.47	None applicable	£78.53	139
	10mg Agreement sale	Not applicable	£47.40	Scheme M	£64.78	12,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	333
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	65

Period 83 Nov 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£50.67	None applicable	£64.81	78,164
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£59.78	None applicable	£83.38	3,080
	Waymade 20mg	Not applicable	£60.16	None applicable	£83.38	616
	10mg Agreement sale	Not applicable	£45.00	Scheme M	£64.81	7,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	343
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	84
Period 84 Dec 2014	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£50.65	None applicable	£64.81	83,463
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£60.64	None applicable	£85.33	4,831
	Waymade 20mg	Not applicable	£62.85	None applicable	£85.33	136
	10mg Agreement sale	Not applicable	£48.00	Scheme M	£64.81	10,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	745
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	120
Period 85 Jan 2015	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£51.79	None applicable	£66.10	85,086
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£61.02	None applicable	£86.10	2,329
	Waymade 20mg	Not applicable	£64.94	None applicable	£86.10	322
	10mg Agreement sale	Not applicable	£49.61	Scheme M	£66.10	14,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	112
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	52
Period 86 Feb 2015	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£53.43	None applicable	£66.13	71,529

	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£70.40	None applicable	£86.42	6,407
	Waymade 20mg	Not applicable	£67.54	None applicable	£86.42	260
	10mg Agreement sale	Not applicable	£54.35	Scheme M	£66.13	17,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	436
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	123
Period 87 Mar 2015	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£53.64	None applicable	£66.12	82,715
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£61.80	None applicable	£86.48	4,790
	Waymade 20mg	Not applicable	£61.00	None applicable	£86.48	20
	10mg Agreement sale	Not applicable	£55.21	Scheme M	£66.12	12,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	390
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	97
Period 88 Apr 2015	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£54.07	None applicable	£65.78	75,359
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£62.45	None applicable	£86.43	3,499
	10mg Agreement sale	Not applicable	£56.12	Scheme M	£46.63	9,844
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	378
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	94
Period 89 May 2015	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£54.99	None applicable	£65.83	61,882
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Mr Amit Patel Mrs Meeta Patel	£64.03	None applicable	£88.56	3,505
	10mg Agreement sale	Not applicable	£57.19	Scheme M	£65.82	9,277

	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	337
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	54
29 May 2015	Actavis plc acquired AM Pharma and Auden Mckenzie Holdings Ltd, and so (indirectly) the 10mg and 20mg Merck, Sharpe & Dohme MAs: Judgment at [123]*ff*. Actavis plc changed its name to Allergan plc at about this time.					
Period 90 Jun 2015	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Actavis plc, then Allergan plc[10]	£55.06	None applicable	£65.81	73,824
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Actavis plc, then Allergan plc[11]	£64.26	None applicable	£89.53	3,783
	10mg Agreement sale	Not applicable	£57.17	Scheme M	£65.81	16,845
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	389
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	49
Period 91 Jul 2015	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Allergan plc	£59.54	None applicable	£78.37	103,971
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Allergan plc	£65.67	None applicable	£89.80	4,238
	10mg Agreement sale	Not applicable	£62.49	Scheme M	£78.37	12,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	384
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	121
Period 92 Aug 2015	AM Pharma 10mg	Auden Mckenzie Holdings Ltd Allergan plc	£65.50	None applicable	£78.52	100,362
	AM Pharma 20mg	Auden Mckenzie Holdings Ltd Allergan plc	£70.27	None applicable	£93.95	3,693
	10mg Agreement sale	Not applicable	£67.58	Scheme M	£78.52	11,898
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	470
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	102
1 Sep 2015	This is the date on which AM Pharma's business was transferred to Actavis UK Ltd: Judgment at [125]. AM Pharma and Auden Mckenzie cease to be relevant from this point on.					
Period 93 Sep 2015	Actavis UK Ltd 10mg	Allergan plc	£66.76	None applicable	£78.56	74,188

[10] This is the date on which Actavis plc changed its name to Allergan plc: paragraph 111 of the Judgment.

[11] This is the date on which Actavis plc changed its name to Allergan plc: paragraph 111 of the Judgment.

	Actavis UK Ltd 20mg	Allergan plc	£69.47	None applicable	£95.50	2,075
	10mg Agreement sale	Not applicable	£67.65	Scheme M	£78.56	12,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	508
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	107
Period 94 Oct 2015	Actavis UK Ltd 10mg	Allergan plc	£67.74	None applicable	£84.41	89,710
	Actavis UK Ltd 20mg	Allergan plc	£72.19	None applicable	£94.40	3,575
	10mg Agreement sale	Not applicable	£68.31	Scheme M	£84.41	5,500
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	414
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	64
	Alissa Healthcare 10mg	Not applicable	£67.52	None applicable	£84.41	5,530
Period 95 Nov 2015	Actavis UK Ltd 10mg	Allergan plc	£69.16	None applicable	£84.43	58,844
	Actavis UK Ltd 20mg	Allergan plc	£70.86	None applicable	£94.17	2,682
	10mg Agreement sale	Not applicable	£69.13	Scheme M	£84.43	18,480
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	404
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	101
	Alissa Healthcare 10mg	Not applicable	£67.55	None applicable	£84.43	7,310
Period 96 Dec 2015	Actavis UK Ltd 10mg	Allergan plc	£71.70	None applicable	£84.53	70,764
	Actavis UK Ltd 20mg	Allergan plc	£71.72	None applicable	£93.93	3,525
	10mg Agreement sale	Not applicable	£70.00	Scheme M	£84.53	20
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	668
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	Nil
	Alissa Healthcare 10mg	Not applicable	£67.49	None applicable	£84.53	12,150
Period 97 Jan 2016	Actavis UK Ltd 10mg	Allergan plc	£68.93	None applicable	£87.75	58,162
	Actavis UK Ltd 20mg	Allergan plc	£65.20	None applicable	£93.52	2,452

	10mg Agreement sale	Not applicable	£70.80	Scheme M	£87.75	24,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	300
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	178
	Alissa Healthcare 10mg	Not applicable	£67.73	None applicable	£87.75	13,060
Period 98 Feb 2016	Actavis UK Ltd 10mg	Allergan plc	£70.84	None applicable	£87.89	53,155
	Actavis UK Ltd 20mg	Allergan plc	£67.54	None applicable	£99.38	3,147
	10mg Agreement sale	Not applicable	£71.59	Scheme M	£87.89	12,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	426
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	102
	Alissa Healthcare 10mg	Not applicable	£68.09	None applicable	£87.89	18,615
10 Mar 2016	This is the date when – in anticipation of Teva's acquisition of Allergan plc's generic's division, Actavis UK Ltd had to be held separate: see the Judgment at [128].					
Period 99 Mar 2016	Actavis UK Ltd 10mg	Allergan plc Hold Separate Regime	£72.14	None applicable	£87.90	56,006
	Actavis UK Ltd 20mg	Allergan plc Hold Separate Regime	£62.43	None applicable	£102.75	3,058
	10mg Agreement sale	Not applicable	£73.45	Scheme M	£87.90	10,000
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	536
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	117
	Alissa Healthcare 10mg	Not applicable	£67.85	None applicable	£87.90	16,252
	Bristol Laboratories 10mg	Not applicable	£65.60	None applicable	£87.90	11,690
	Bristol Laboratories 20mg	Not applicable	£67.00	None applicable	£102.75	120
	Resolution Chemicals 10mg	Not applicable	£56.63	None applicable	£87.90	3,270
	Resolution Chemicals 20mg	Not applicable	£55.25	None applicable	£102.75	80
Period 100 Apr 2016	Actavis UK Ltd 10mg	Allergan plc Hold Separate Regime	£68.65	None applicable	£84.57	64,660
	Actavis UK Ltd 20mg	Allergan plc	£64.94	None applicable	£100.67	2,875

		Hold Separate Regime				
	10mg Agreement sale	Not applicable	£71.77	Scheme M	£84.57	6,960
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	595
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	Nil
	Alissa Healthcare 10mg	Not applicable	£61.50	None applicable	£84.57	10,185
	Bristol Laboratories 10mg	Not applicable	£61.77	None applicable	£84.57	9,625
	Bristol Laboratories 20mg	Not applicable	£60.95	None applicable	£100.67	408
	Resolution Chemicals 10mg	Not applicable	£52.19	None applicable	£84.57	5,470
	Resolution Chemicals 20mg	Not applicable	£50.28	None applicable	£100.67	130
Period 101 May 2016	Actavis UK Ltd 10mg	Allergan plc Hold Separate Regime	£68.13	None applicable	£84.60	61,643
	Actavis UK Ltd 20mg	Allergan plc Hold Separate Regime	£60.87	None applicable	£101.36	3,346
	10mg Agreement sale	Not applicable	£63.05	Scheme M	£84.60	1,470
	Plenadren 5mg	Not applicable	£212.00	PPRS	£242.50	303
	Plenadren 20mg	Not applicable	£350.00	PPRS	£400.00	308
	Alissa Healthcare 10mg	Not applicable	£57.61	None applicable	£84.60	6,940
	Bristol Laboratories 10mg	Not applicable	£59.05	None applicable	£84.60	10,350
	Bristol Laboratories 20mg	Not applicable	£54.44	None applicable	£101.36	270
	Resolution Chemicals 10mg	Not applicable	£31.17	None applicable	£84.60	32,678
	Resolution Chemicals 20mg	Not applicable	£33.84	None applicable	£101.36	1,120
	AMCo (Aesica) 10mg	Not applicable	£59.32	Scheme M	£84.60	3,514
Period 102 Jun 2016	Actavis UK Ltd 10mg	Allergan plc Hold Separate Regime	£62.63	None applicable	£72.20	64,894
	Actavis UK Ltd 20mg	Allergan plc Hold Separate Regime	£54.30	None applicable	£100.69	3,152

	10mg Agreement sale	Not applicable	£55.52	Scheme M	£72.20	8,592
	Plenadren 5mg	Not applicable	£237.06	PPRS	£242.50	688
	Plenadren 20mg	Not applicable	£350.93	PPRS	£400.00	108
	Alissa Healthcare 10mg	Not applicable	£52.57	None applicable	£72.20	8,641
	Bristol Laboratories 10mg	Not applicable	£52.49	None applicable	£72.20	12,190
	Bristol Laboratories 20mg	Not applicable	£45.75	None applicable	£100.69	325
	Resolution Chemicals 10mg	Not applicable	£44.48	None applicable	£72.20	2,020
	Resolution Chemicals 20mg	Not applicable	£30.12	None applicable	£100.69	745
	AMCo (Aesica) 10mg	Not applicable	£50.69	Scheme M	£72.20	5,620
Period 103 Jul 2016	Actavis UK Ltd 10mg	Allergan plc Hold Separate Regime	£58.60	None applicable	£82.15	58,123\
	Actavis UK Ltd 20mg	Allergan plc Hold Separate Regime	£53.83	None applicable	£100.74	2,026
	10mg Agreement sale	Not applicable	£52.80	Scheme M	£82.15	3.360
	Plenadren 5mg	Not applicable	£239.05	PPRS	£242.50	622
	Plenadren 20mg	Not applicable	£393.02	PPRS	£400.00	242
	Alissa Healthcare 10mg	Not applicable	£42.10	None applicable	£82.15	6,578
	Bristol Laboratories 10mg	Not applicable	£44.95	None applicable	£82.15	16,221
	Bristol Laboratories 20mg	Not applicable	£41.73	None applicable	£100.74	230
	Resolution Chemicals 10mg	Not applicable	£42.31	None applicable	£82.15	2,590
	Resolution Chemicals 20mg	Not applicable	£48.62	None applicable	£100.74	10
	AMCo (Aesica) 10mg	Not applicable	£45.21	Scheme M	£82.15	1,880
2 Aug 2016	This is the date when Teva acquired Actavis UK Ltd, but subject to the Hold Separate Regime: see the Judgment at [126]*ff*.					
Period 104 Aug 2016	Actavis UK Ltd 10mg	Teva Hold Separate Regime	£62.73	None applicable	£82.05	51,977

	Actavis UK Ltd 20mg	Teva Hold Separate Regime	£53.45	None applicable	£100.46	2,750
	10mg Agreement sale	Not applicable	£55.40	Scheme M	£82.05	8,020
	Plenadren 5mg	Not applicable	£243.88	PPRS	£242.50	345
	Plenadren 20mg	Not applicable	£425.81	PPRS	£400.00	54
	Alissa Healthcare 10mg	Not applicable	£40.55	None applicable	£82.05	10,030
	Bristol Laboratories 10mg	Not applicable	£40.12	None applicable	£82.05	15,285
	Bristol Laboratories 20mg	Not applicable	£32.99	None applicable	£100.46	345
	Resolution Chemicals 10mg	Not applicable	£27.52	None applicable	£82.05	9,580
	Resolution Chemicals 20mg	Not applicable	£27.78	None applicable	£100.46	307
	AMCo (Aesica) 10mg	Not applicable	£44.63	Scheme M	£82.05	1,350
Period 105 Sep 2016	Actavis UK Ltd 10mg	Teva Hold Separate Regime	£63.01	None applicable	£82.22	44,227
	Actavis UK Ltd 20mg	Teva Hold Separate Regime	£43.04	None applicable	£100.40	2,623
	10mg Agreement sale	Not applicable	£50.37	Scheme M	£82.22	8,775
	Plenadren 5mg	Not applicable	£241.50	PPRS	£242.50	453
	Plenadren 20mg	Not applicable	£399.02	PPRS	£400.00	98
	Alissa Healthcare 10mg	Not applicable	£36.57	None applicable	£82.22	10,113
	Bristol Laboratories 10mg	Not applicable	£38.74	None applicable	£82.22	12,400
	Bristol Laboratories 20mg	Not applicable	£32.89	None applicable	£100.40	190
	Resolution Chemicals 10mg	Not applicable	£25.21	None applicable	£82.22	10,260
	Resolution Chemicals 20mg	Not applicable	£29.73	None applicable	£100.40	580
	AMCo (Aesica) 10mg	Not applicable	£36.03	Scheme M	£82.22	3,580
Period 106 Oct 2016	Actavis UK Ltd 10mg	Teva Hold Separate Regime	£59.08	None applicable	£74.58	35,708

	Actavis UK Ltd 20mg	Teva Hold Separate Regime	£51.76	None applicable	£100.26	2,798
	10mg Agreement sale	Not applicable	£50.00	Scheme M	£74.58	425
	Plenadren 5mg	Not applicable	£241.51	PPRS	£242.50	485
	Plenadren 20mg	Not applicable	£399.03	PPRS	£400.00	72
	Alissa Healthcare 10mg	Not applicable	£31.61	None applicable	£74.58	10,543
	Bristol Laboratories 10mg	Not applicable	£31.59	None applicable	£74.58	9,445
	Bristol Laboratories 20mg	Not applicable	£29.77	None applicable	£100.26	310
	Resolution Chemicals 10mg	Not applicable	£23.52	None applicable	£74.58	4,872
	Resolution Chemicals 20mg	Not applicable	£23.77	None applicable	£100.26	190
	AMCo (Aesica) 10mg	Not applicable	£28.23	Scheme M	£74.58	9,710
Period 107 Nov 2016	Actavis UK Ltd 10mg	Teva Hold Separate Regime	£59.74	None applicable	£74.55	48,385
	Actavis UK Ltd 20mg	Teva Hold Separate Regime	£68.74	None applicable	£100.18	2,089
	10mg Agreement sale	Not applicable	Nil	Scheme M	£74.55	Nil
	Plenadren 5mg	Not applicable	£241.50	PPRS	£242.50	513
	Plenadren 20mg	Not applicable	£399.00	PPRS	£400.00	110
	Alissa Healthcare 10mg	Not applicable	£27.35	None applicable	£74.55	8,161
	Bristol Laboratories 10mg	Not applicable	£26.64	None applicable	£74.55	10,868
	Bristol Laboratories 20mg	Not applicable	£23.59	None applicable	£100.18	450
	Resolution Chemicals 10mg	Not applicable	£24.14	None applicable	£74.55	11,748
	Resolution Chemicals 20mg	Not applicable	£30.22	None applicable	£100.18	280
	AMCo (Aesica) 10mg	Not applicable	£25.41	Scheme M	£74.55	4,900
Period 108 Dec 2016	Actavis UK Ltd 10mg	Teva Hold Separate Regime	£57.57	None applicable	£74.57	68,113

	Actavis UK Ltd 20mg	Teva Hold Separate Regime	£40.76	None applicable	£100.13	2,882
	10mg Agreement sale	Not applicable	£50.00	Scheme M	£74.57	398
	Plenadren 5mg	Not applicable	£241.50	PPRS	£242.50	725
	Plenadren 20mg	Not applicable	£399.01	PPRS	£400.00	129
	Alissa Healthcare 10mg	Not applicable	£25.49	None applicable	£74.57	8,618
	Bristol Laboratories 10mg	Not applicable	£24.83	None applicable	£74.57	15,090
	Bristol Laboratories 20mg	Not applicable	£24.87	None applicable	£100.13	140
	Resolution Chemicals 10mg	Not applicable	£21.00	None applicable	£74.57	20,982
	Resolution Chemicals 20mg	Not applicable	£26.71	None applicable	£100.13	334
	AMCo (Aesica) 10mg	Not applicable	£20.28	Scheme M	£74.57	5,957
9 Jan 2017	This is the date when Intas acquired Actavis UK Ltd: paragraph 117 of the Judgment. Actavis UK Ltd exited the Hold Separate Regime at this point in time.					
Period 109 Jan 2017	Actavis UK Ltd 10mg	Intas	£54.21	None applicable	£68.87	36,736
	Actavis UK Ltd 20mg	Intas	£51.28	None applicable	£100.02	2,448
	Plenadren 5mg	Not applicable	£241.50	PPRS	£242.50	370
	Plenadren 20mg	Not applicable	£399.00	PPRS	£400.00	78
	Alissa Healthcare 10mg	Not applicable	£22.08	None applicable	£68.87	7,912
	Bristol Laboratories 10mg	Not applicable	£22.03	None applicable	£68.87	10,780
	Bristol Laboratories 20mg	Not applicable	£22.42	None applicable	£100.02	530
	Resolution Chemicals 10mg	Not applicable	£18.32	None applicable	£68.87	5,262
	Resolution Chemicals 20mg	Not applicable	£25.00	None applicable	£100.02	230
	AMCo (Aesica) 10mg	Not applicable	£20.99	Scheme M	£68.87	4,950
Period 110 Feb 2017	Actavis UK Ltd 10mg	Intas	£50.78	None applicable	£68.76	55,718
	Actavis UK Ltd 20mg	Intas	£40.25	None applicable	£99.93	2,307

	Plenadren 5mg	Not applicable	£241.50	PPRS	£242.50	472
	Plenadren 20mg	Not applicable	£399.00	PPRS	£400.00	126
	Alissa Healthcare 10mg	Not applicable	£18.84	None applicable	£68.76	7,116
	Bristol Laboratories 10mg	Not applicable	£18.71	None applicable	£68.76	8,250
	Bristol Laboratories 20mg	Not applicable	£27.34	None applicable	£99.93	980
	Resolution Chemicals 10mg	Not applicable	£15.77	None applicable	£68.76	3,296
	Resolution Chemicals 20mg	Not applicable	£21.04	None applicable	£99.93	60
	AMCo (Aesica) 10mg	Not applicable	£18.00	Scheme M	£68.76	2,300
	Teva 10mg	Not applicable	£22.74	Scheme M	£68.76	6,714
	Teva 20mg	Not applicable	£27.29	Scheme M	£99.93	362
Period 111 Mar 2017	Actavis UK Ltd 10mg	Intas	£47.72	None applicable	£68.82	71,220
	Actavis UK Ltd 20mg	Intas	£32.38	None applicable	£99.86	3,014
	Plenadren 5mg	Not applicable	£241.50	PPRS	£242.50	565
	Plenadren 20mg	Not applicable	£399.00	PPRS	£400.00	238
	Alissa Healthcare 10mg	Not applicable	£15.77	None applicable	£68.82	11,566
	Bristol Laboratories 10mg	Not applicable	£16.68	None applicable	£68.82	9,070
	Bristol Laboratories 20mg	Not applicable	£22.66	None applicable	£99.86	557
	Resolution Chemicals 10mg	Not applicable	£13.78	None applicable	£68.82	5,140
	Resolution Chemicals 20mg	Not applicable	£17.43	None applicable	£99.86	60
	AMCo (Aesica) 10mg	Not applicable	£21.15	Scheme M	£68.82	7,790
	Teva 10mg	Not applicable	£21.52	Scheme M	£68.82	8,576
	Teva 20mg	Not applicable	£26.81	Scheme M	£99.86	535
Period 112 Apr 2017	Actavis UK Ltd 10mg	Intas	£46.70	None applicable	£62.13	23,165
	Actavis UK Ltd 20mg	Intas	£26.39	None applicable	£99.83	1,704
	Plenadren 5mg	Not applicable	£241.50	PPRS	£242.50	455

	Plenadren 20mg	Not applicable	£399.00	PPRS	£400.00	162
	Alissa Healthcare 10mg	Not applicable	£12.99	None applicable	£62.13	8,926
	Bristol Laboratories 10mg	Not applicable	£14.41	None applicable	£62.13	9,150
	Bristol Laboratories 20mg	Not applicable	£15.17	None applicable	£99.83	450
	Resolution Chemicals 10mg	Not applicable	£14.69	None applicable	£62.13	4,109
	Resolution Chemicals 20mg	Not applicable	£17.00	None applicable	£99.83	400
	AMCo (Aesica) 10mg	Not applicable	£24.54	Scheme M	£62.13	6,543
	Teva 10mg	Not applicable	£18.63	Scheme M	£62.13	3,922
	Teva 20mg	Not applicable	£19.90	Scheme M	£99.83	361
Period 113 May 2017	Actavis UK Ltd 10mg	Intas	£47.05	None applicable	£62.10	32,148
	Actavis UK Ltd 20mg	Intas	£29.09	None applicable	£92.21	1,919
	Plenadren 5mg	Not applicable	£241.97	PPRS	£242.50	435
	Plenadren 20mg	Not applicable	£399.45	PPRS	£400.00	215
	Alissa Healthcare 10mg	Not applicable	£12.05	None applicable	£62.10	11,816
	Bristol Laboratories 10mg	Not applicable	£12.38	None applicable	£62.10	13,890
	Bristol Laboratories 20mg	Not applicable	£22.36	None applicable	£92.21	930
	Resolution Chemicals 10mg	Not applicable	£10.37	None applicable	£62.10	3,182
	Resolution Chemicals 20mg	Not applicable	£15.83	None applicable	£92.21	540
	AMCo (Aesica) 10mg	Not applicable	£18.77	Scheme M	£62.10	8,490
	Teva 10mg	Not applicable	£18.44	Scheme M	£62.10	7,948
	Teva 20mg	Not applicable	£24.21	Scheme M	£92.21	228
Period 114 Jun 2017	Actavis UK Ltd 10mg	Intas	£45.41	None applicable	£62.08	30,787
	Actavis UK Ltd 20mg	Intas	£25.75	None applicable	£89.29	2,073
	Plenadren 5mg	Not applicable	£250.77	PPRS	£242.50	410
	Plenadren 20mg	Not applicable	£408.21	PPRS	£400.00	139

	Alissa Healthcare 10mg	Not applicable	£10.74	None applicable	£62.08	12,209
	Bristol Laboratories 10mg	Not applicable	£11.17	None applicable	£62.08	10,870
	Bristol Laboratories 20mg	Not applicable	£22.80	None applicable	£89.29	850
	Resolution Chemicals 10mg	Not applicable	£12.82	None applicable	£62.08	2,810
	Resolution Chemicals 20mg	Not applicable	£10.24	None applicable	£89.29	11
	AMCo (Aesica) 10mg	Not applicable	£16.69	Scheme M	£62.08	8,641
	Teva 10mg	Not applicable	£19.04	Scheme M	£62.08	7,825
	Teva 20mg	Not applicable	£15.54	Scheme M	£89.29	356
Period 115 Jul 2017	Actavis UK Ltd 10mg	Intas	£42.34	None applicable	£57.13	36,171
	Actavis UK Ltd 20mg	Intas	£27.13	None applicable	£87.95	2,335
	Plenadren 5mg	Not applicable	£252.48	PPRS	£242.50	465
	Plenadren 20mg	Not applicable	£499.73	PPRS	£400.00	247
	Alissa Healthcare 10mg	Not applicable	£9.11	None applicable	£57.13	10,602
	Bristol Laboratories 10mg	Not applicable	£9.59	None applicable	£57.13	12,145
	Bristol Laboratories 20mg	Not applicable	£28.49	None applicable	£87.95	555
	Resolution Chemicals 10mg	Not applicable	£10.28	None applicable	£57.13	3,882
	Resolution Chemicals 20mg	Not applicable	£11.34	None applicable	£87.95	944
	AMCo (Aesica) 10mg	Not applicable	£18.42	Scheme M	£57.13	7,157
	Teva 10mg	Not applicable	£16.89	Scheme M	£57.13	8,015
	Teva 20mg	Not applicable	£17.84	Scheme M	£87.95	506
Period 116 Aug 2017	Actavis UK Ltd 10mg	Intas	£38.78	None applicable	£51.18	41,314
	Actavis UK Ltd 20mg	Intas	£26.04	None applicable	£86.96	2,221
	Plenadren 5mg	Not applicable	£223.98	PPRS	£242.50	470
	Plenadren 20mg	Not applicable	£330.25	PPRS	£400.00	375

	Alissa Healthcare 10mg	Not applicable	£7.39	None applicable	£51.18	27,609
	Bristol Laboratories 10mg	Not applicable	£8.63	None applicable	£51.18	6,880
	Bristol Laboratories 20mg	Not applicable	£27.64	None applicable	£86.96	290
	Resolution Chemicals 10mg	Not applicable	£6.63	None applicable	£51.18	17,974
	Resolution Chemicals 20mg	Not applicable	£6.15	None applicable	£86.96	800
	AMCo (Aesica) 10mg	Not applicable	£11.35	Scheme M	£51.18	8,176
	AMCo (Focus) 10mg	Not applicable	Nil	Scheme M	£51.18	Nil
	AMCo (Focus) 20mg	Not applicable	£9.00	Scheme M	£86.96	260
	Teva 10mg	Not applicable	£15.16	Scheme M	£51.18	6,597
	Teva 20mg	Not applicable	£13.99	Scheme M	£86.96	514
Period 117 Sep 2017	Actavis UK Ltd 10mg	Intas	£37.42	None applicable	£51.14	42,188
	Actavis UK Ltd 20mg	Intas	£20.89	None applicable	£86.12	2,251
	Plenadren 5mg	Not applicable	£242.00	PPRS	£242.50	370
	Plenadren 20mg	Not applicable	£399.50	PPRS	£400.00	122
	Alissa Healthcare 10mg	Not applicable	£7.68	None applicable	£51.14	22,525
	Bristol Laboratories 10mg	Not applicable	£10.99	None applicable	£51.14	16,900
	Bristol Laboratories 20mg	Not applicable	£28.95	None applicable	£86.12	540
	Resolution Chemicals 10mg	Not applicable	£6.33	None applicable	£51.14	18,894
	Resolution Chemicals 20mg	Not applicable	£6.28	None applicable	£86.12	49
	AMCo (Aesica) 10mg	Not applicable	£14.66	Scheme M	£51.14	23,166
	AMCo (Focus) 10mg	Not applicable	Nil	Scheme M	£51.14	Nil
	AMCo (Focus) 20mg	Not applicable	£8.06	Scheme M	£86.12	1,276
	Teva 10mg	Not applicable	£12.13	Scheme M	£51.14	21,092
	Teva 20mg	Not applicable	£16.80	Scheme M	£86.12	519

Period 118 Oct 2017	Actavis UK Ltd 10mg	Intas	£32.30	None applicable	£41.35	47,378
	Actavis UK Ltd 20mg	Intas	£23.79	None applicable	£85.19	2,710
	Plenadren 5mg	Not applicable	£242.00	PPRS	£242.50	335
	Plenadren 20mg	Not applicable	£399.50	PPRS	£400.00	127
	Alissa Healthcare 10mg	Not applicable	£8.22	None applicable	£41.35	11,292
	Bristol Laboratories 10mg	Not applicable	£9.13	None applicable	£41.35	11,500
	Bristol Laboratories 20mg	Not applicable	£28.95	None applicable	£85.19	510
	Resolution Chemicals 10mg	Not applicable	£6.04	None applicable	£41.35	4,270
	Resolution Chemicals 20mg	Not applicable	Nil	None applicable	£85.19	Nil
	AMCo (Aesica) 10mg	Not applicable	£25.63	Scheme M	£41.35	3,336
	AMCo (Focus) 10mg	Not applicable	£7.00	Scheme M	£41.35	3,020
	AMCo (Focus) 20mg	Not applicable	£8.75	Scheme M	£85.19	486
	Teva 10mg	Not applicable	£11.49	Scheme M	£41.35	11,175
	Teva 20mg	Not applicable	£14.26	Scheme M	£85.19	281
Period 119 Nov 2017	Actavis UK Ltd 10mg	Intas	£31.05	None applicable	£41.37	46,434
	Actavis UK Ltd 20mg	Intas	£21.90	None applicable	£84.90	2,230
	Plenadren 5mg	Not applicable	£242.00	PPRS	£242.50	335
	Plenadren 20mg	Not applicable	£399.50	PPRS	£400.00	127
	Alissa Healthcare 10mg	Not applicable	£7.80	None applicable	£41.37	11,559
	Bristol Laboratories 10mg	Not applicable	£8.22	None applicable	£41.37	4,630
	Bristol Laboratories 20mg	Not applicable	Nil	None applicable	£84.90	Nil
	Resolution Chemicals 10mg	Not applicable	£6.37	None applicable	£41.37	1,250
	Resolution Chemicals 20mg	Not applicable	Nil	None applicable	£84.90	Nil
	AMCo (Aesica) 10mg	Not applicable	£19.13	Scheme M	£41.37	6,607

	AMCo (Focus) 10mg	Not applicable	Nil	Scheme M	£41.37	Nil
	AMCo (Focus) 20mg	Not applicable	£8.37	Scheme M	£84.90	672
	Teva 10mg	Not applicable	£12.61	Scheme M	£41.37	8,318
	Teva 20mg	Not applicable	£15.36	Scheme M	£84.90	408
	Genesis 10mg	Not applicable	£7.92	Scheme M	£41.37	1,936
	Genesis 20mg	Not applicable	£9.00	Scheme M	£84.90	20
Period 120 Dec 2017	Actavis UK Ltd 10mg	Intas	£29.33	None applicable	£41.32	46,879
	Actavis UK Ltd 20mg	Intas	£15.66	None applicable	£84.28	2,309
	Plenadren 5mg	Not applicable	£242.00	PPRS	£242.50	210
	Plenadren 20mg	Not applicable	£399.50	PPRS	£400.00	163
	Alissa Healthcare 10mg	Not applicable	£7.49	None applicable	£41.32	9,195
	Bristol Laboratories 10mg	Not applicable	£6.46	None applicable	£41.32	3,568
	Bristol Laboratories 20mg	Not applicable	Nil	None applicable	£84.38	Nil
	Resolution Chemicals 10mg	Not applicable	£5.53	None applicable	£41.32	30,194
	Resolution Chemicals 20mg	Not applicable	£6.49	None applicable	£84.38	2,208
	AMCo (Aesica) 10mg	Not applicable	£24.35	Scheme M	£41.32	1,098[12]
	AMCo (Focus) 10mg	Not applicable	Nil	Scheme M	£41.32	Nil
	AMCo (Focus) 20mg	Not applicable	£8.66	Scheme M	£84.38	160
	Teva 10mg	Not applicable	£13.25	Scheme M	£41.32	8,904
	Teva 20mg	Not applicable	£11.53	Scheme M	£84.38	610
	Genesis 10mg	Not applicable	£6.52	Scheme M	£41.32	3,700
	Genesis 20mg	Not applicable	£7.47	Scheme M	£84.38	385
Jan 2018	This is the month (date unknown) on which the Teva-Allergan-Intas agreement was entered into: Judgment at [130].					
Period 121 Jan 2018	Actavis UK Ltd 10mg	Intas	£26.91	None applicable	£34.26	51,427

[12] AMCo ceased supplying the market via Aesica from this point on, and the AMCo (Aesica) supply does not feature any further in this table.

	Actavis UK Ltd 20mg	Intas	£22.46	None applicable	£84.09	2,425
	Plenadren 5mg	Not applicable	£242.00	PPRS	£242.50	170
	Plenadren 20mg	Not applicable	£399.50	PPRS	£400.00	254
	Alissa Healthcare 10mg	Not applicable	£6.51	None applicable	£34.26	10,497
	Bristol Laboratories 10mg	Not applicable	£5.93	None applicable	£34.26	7,257
	Bristol Laboratories 20mg	Not applicable	Nil	None applicable	£84.09	Nil
	Resolution Chemicals 10mg	Not applicable	£5.50	None applicable	£34.26	15,757
	Resolution Chemicals 20mg	Not applicable	£16.15	None applicable	£84.09	500
	AMCo (Focus) 10mg	Not applicable	Nil	Scheme M	£34.26	Nil
	AMCo (Focus) 20mg	Not applicable	£6.91	Scheme M	£84.09	90
	Teva 10mg	Not applicable	£12.68	Scheme M	£34.26	14,683
	Teva 20mg	Not applicable	£12.68	Scheme M	£84.09	1,151
	Genesis 10mg	Not applicable	£5.89	Scheme M	£34.26	2,177
	Genesis 20mg	Not applicable	£8.44	Scheme M	£84.09	102
Period 122 Feb 2018	Actavis UK Ltd 10mg	Intas	£26.07	None applicable	£34.18	40,806
	Actavis UK Ltd 20mg	Intas	£8.54	None applicable	£83.67	1,929
	Plenadren 5mg	Not applicable	£242.00	PPRS	£242.50	172
	Plenadren 20mg	Not applicable	£399.50	PPRS	£400.00	275
	Alissa Healthcare 10mg	Not applicable	£5.48	None applicable	£34.18	10,774
	Bristol Laboratories 10mg	Not applicable	£5.23	None applicable	£34.18	8,600
	Bristol Laboratories 20mg	Not applicable	Nil	None applicable	£83.67	Nil
	Resolution Chemicals 10mg	Not applicable	£5.50	None applicable	£34.18	4,490
	Resolution Chemicals 20mg	Not applicable	£6.00	None applicable	£83.67	220
	AMCo (Focus) 10mg	Not applicable	Nil	Scheme M	£34.18	Nil

	AMCo (Focus) 20mg	Not applicable	£7.00	Scheme M	£83.67	30
	Teva 10mg	Not applicable	£10.00	Scheme M	£34.18	9,096
	Teva 20mg	Not applicable	£12.63	Scheme M	£83.67	467
	Genesis 10mg	Not applicable	£5.06	Scheme M	£34.18	3,330
	Genesis 20mg	Not applicable	£5.54	Scheme M	£83.67	186
Period 123 Mar 2018[13]	Accord-UK Ltd 10mg	Intas	£26.62	None applicable	£34.22	58,565
	Accord-UK Ltd 20mg	Intas	£14.87	None applicable	£83.48	2,111
	Plenadren 5mg	Not applicable	£242.00	PPRS	£242.50	140
	Plenadren 20mg	Not applicable	£399.50	PPRS	£400.00	583
	Alissa Healthcare 10mg	Not applicable	£4.86	None applicable	£34.22	13,614
	Bristol Laboratories 10mg	Not applicable	£4.83	None applicable	£34.22	22,460
	Bristol Laboratories 20mg	Not applicable	Nil	None applicable	£83.48	Nil
	Resolution Chemicals 10mg	Not applicable	£5.50	None applicable	£34.22	1,210
	Resolution Chemicals 20mg	Not applicable	£6.00	None applicable	£83.48	420
	AMCo (Focus) 10mg	Not applicable	Nil	Scheme M	£34.22	Nil
	AMCo (Focus) 20mg	Not applicable	£7.43	Scheme M	£83.48	7
	Teva 10mg	Not applicable	£12.70	Scheme M	£34.22	13,355
	Teva 20mg	Not applicable	£16.02	Scheme M	£83.48	646
	Genesis 10mg	Not applicable	£4.29	Scheme M	£34.22	14,415
	Genesis 20mg	Not applicable	£5.01	Scheme M	£83.48	341
Period 124 Apr 2018	Accord-UK Ltd 10mg	Intas	£25.30	None applicable	£32.90	37,193
	Accord-UK Ltd 20mg	Intas	£7.98	None applicable	£83.24	1,872
	Plenadren 5mg	Not applicable	£242.00	PPRS	£242.50	151
	Plenadren 20mg	Not applicable	£399.50	PPRS	£400.00	1,104

[13] On 5 March 2018, Actavis UK Ltd was renamed Accord-UK Ltd: Judgment at [126], [131].

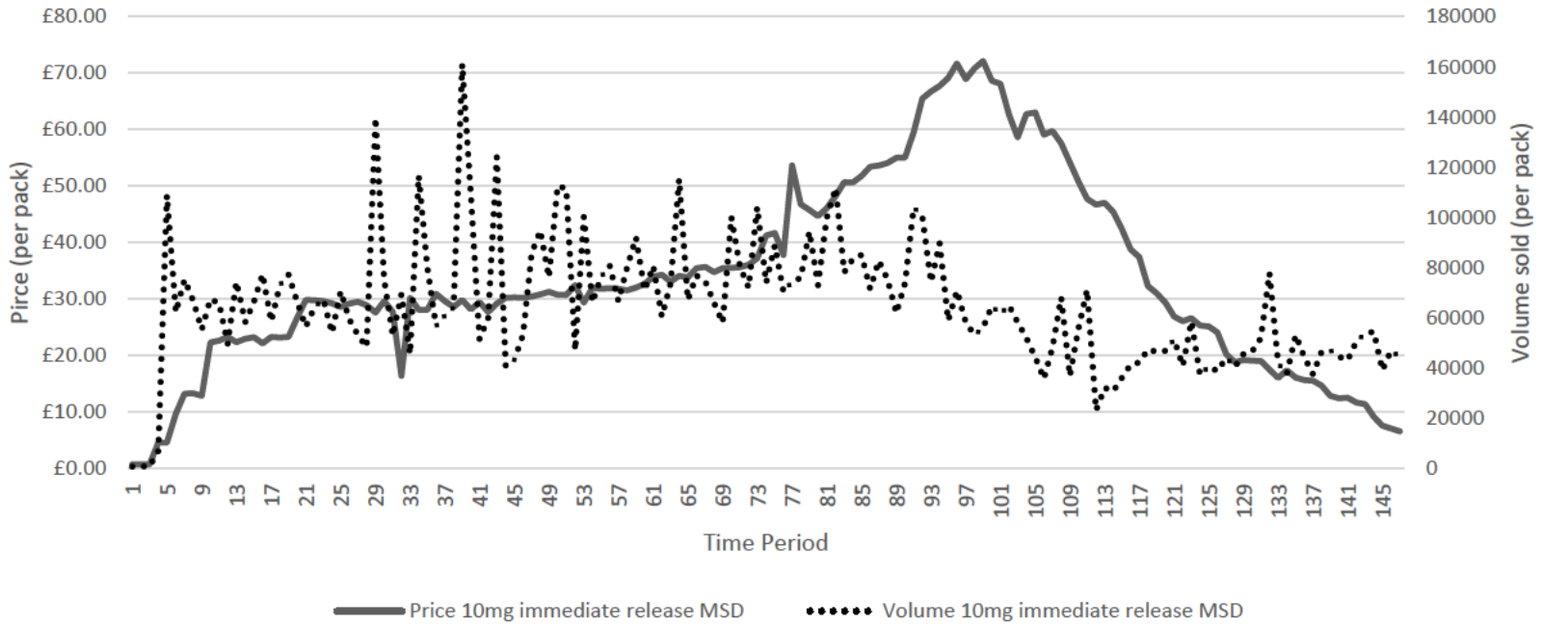
	Alissa Healthcare 10mg	Not applicable	£4.70	None applicable	£32.90	12,187
	Bristol Laboratories 10mg	Not applicable	£4.55	None applicable	£32.90	2,270
	Bristol Laboratories 20mg	Not applicable	Nil	None applicable	£83.24	Nil
	Resolution Chemicals 10mg	Not applicable	£3.99	None applicable	£32.90	5,169
	Resolution Chemicals 20mg	Not applicable	£16.15	None applicable	£83.24	800
	AMCo (Focus) 10mg	Not applicable	£26.08	Scheme M	£32.90	4,500
	AMCo (Focus) 20mg	Not applicable	£5.00	Scheme M	£83,24	18
	Teva 10mg	Not applicable	£12.53	Scheme M	£32.90	9,602
	Teva 20mg	Not applicable	£17.76	Scheme M	£83.24	346
	Genesis 10mg	Not applicable	£4.18	Scheme M	£32.90	11,917
	Genesis 20mg	Not applicable	£5.43	Scheme M	£83.24	472
Period 125 May 2018	Accord-UK Ltd 10mg	Intas	£25.16	None applicable	£32.92	40,677
	Accord-UK Ltd 20mg	Intas	£9.31	None applicable	£83.16	1,720
	Plenadren 5mg	Not applicable	£242.00	PPRS	£242.50	325
	Plenadren 20mg	Not applicable	£399.50	PPRS	£400.00	324
	Alissa Healthcare 10mg	Not applicable	£4.11	None applicable	£32.92	16,349
	Bristol Laboratories 10mg	Not applicable	Nil	None applicable	£32.92	Nil[14]
	Bristol Laboratories 20mg	Not applicable	Nil	None applicable	£83.16	Nil
	Resolution Chemicals 10mg	Not applicable	£3.81	None applicable	£32.92	4,439
	Resolution Chemicals 20mg	Not applicable	£3.74	None applicable	£83.16	250
	AMCo (Focus) 10mg	Not applicable	Nil	Scheme M	£32.92	Nil
	AMCo (Focus) 20mg	Not applicable	Nil	Scheme M	£83.16	Nil

[14] It is not clear what happened to Bristol Laboratories at this point. Supplies of 20mg "immediate release" hydrocortisone tablets had stopped in November 2017, and for the next few months all supplies stopped. However, in December 2018, sales of both 10mg and 20mg "immediate release" hydrocortisone tables resumed. This was not, therefore, a case of insolvency.

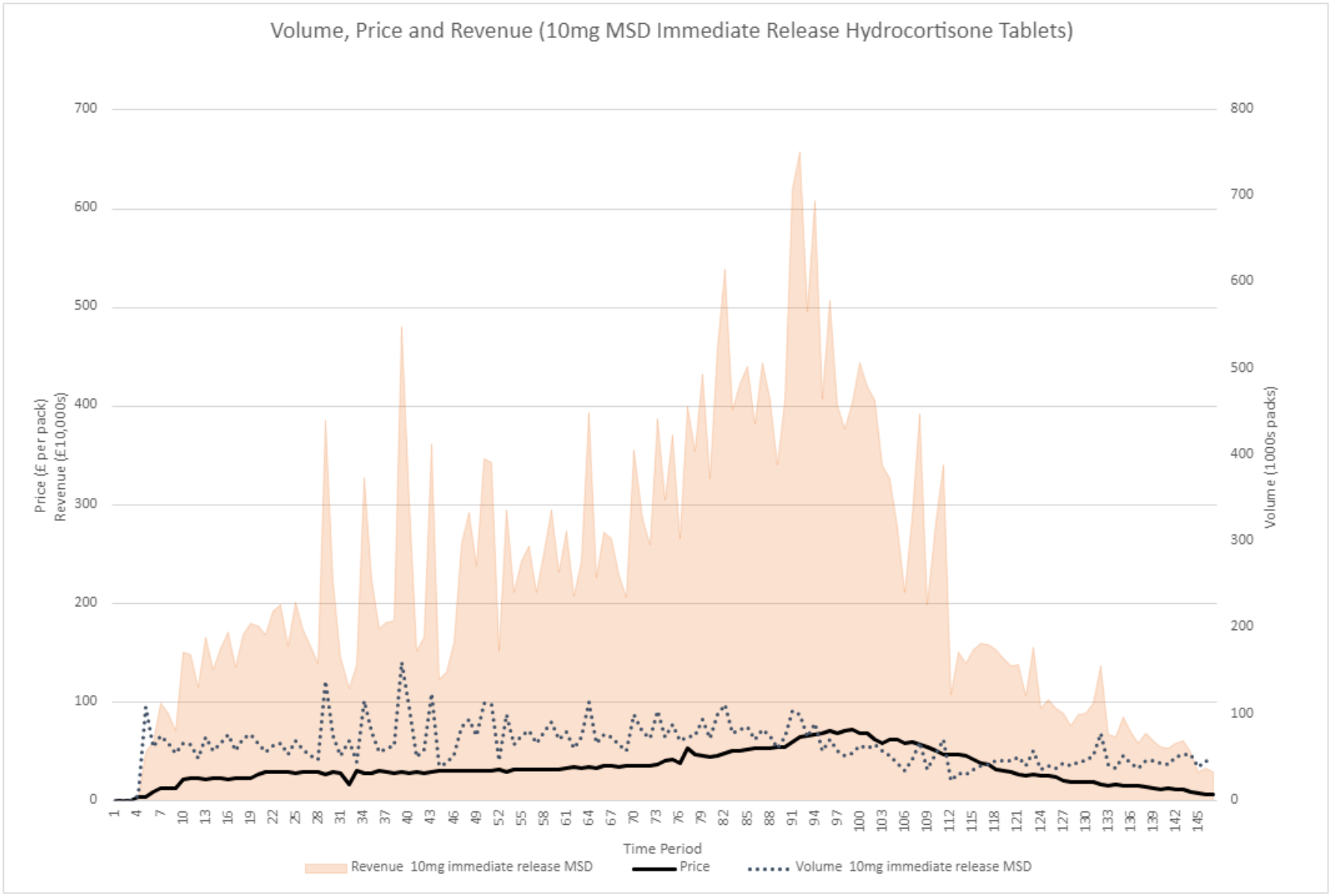
	Teva 10mg	Not applicable	£13.10	Scheme M	£32.92	9,173
	Teva 20mg	Not applicable	£13.53	Scheme M	£83.16	440
	Genesis 10mg	Not applicable	£3.88	Scheme M	£32.92	11,735
	Genesis 20mg	Not applicable	£4.96	Scheme M	£83.16	£173
Period 126 Jun 2018	Accord-UK Ltd 10mg	Intas	£24.10	None applicable	£32.91	38,799
	Accord-UK Ltd 20mg	Intas	£9.51	None applicable	£82.97	1,659
	Plenadren 5mg	Not applicable	£242.00	PPRS	£242.50	410
	Plenadren 20mg	Not applicable	£399.50	PPRS	£400.00	316
	Alissa Healthcare 10mg	Not applicable	£4.02	None applicable	£32.91	11,585
	Bristol Laboratories 10mg	Not applicable	Nil	None applicable	£32.91	Nil
	Bristol Laboratories 20mg	Not applicable	Nil	None applicable	£82.97	Nil
	Resolution Chemicals 10mg	Not applicable	£3.80	None applicable	£32.91	4,490
	Resolution Chemicals 20mg	Not applicable	£3.87	None applicable	£82.87	399
	AMCo (Focus) 10mg	Not applicable	£4.08	Scheme M	£32.91	6,600
	AMCo (Focus) 20mg	Not applicable	Nil	Scheme M	£82.97	Nil
	Teva 10mg	Not applicable	£2.51	Scheme M	£32.91	9,846
	Teva 20mg	Not applicable	£4.24	Scheme M	£82.97	414
	Genesis 10mg	Not applicable	£4.06	Scheme M	£32.91	4,399
	Genesis 20mg	Not applicable	£4.08	Scheme M	£82.97	1,102
Period 127 Jul 2018	Accord-UK Ltd 10mg	Intas	£20.23	None applicable	£25.08	44,031
	Accord-UK Ltd 20mg	Intas	£7.78	None applicable	£82.78	1,852
	Plenadren 5mg	Not applicable	£242.00	PPRS	£242.50	330
	Plenadren 20mg	Not applicable	£399.50	PPRS	£400.00	615
	Alissa Healthcare 10mg	Not applicable	£3.74	None applicable	£25.08	15,054
	Bristol Laboratories 10mg	Not applicable	Nil	None applicable	£25.08	Nil

	Bristol Laboratories 20mg	Not applicable	Nil	None applicable	£82.78	Nil
	Resolution Chemicals 10mg	Not applicable	£3.77	None applicable	£25.08	3,105
	Resolution Chemicals 20mg	Not applicable	£3.94	None applicable	£82.78	1,117
	AMCo (Focus) 10mg	Not applicable	£3.60	Scheme M	£25.08	300
	AMCo (Focus) 20mg	Not applicable	£3.92	Scheme M	£82.78	156
	Teva 10mg	Not applicable	£3.42	Scheme M	£25.08	12,814
	Teva 20mg	Not applicable	£3.75	Scheme M	£82.78	421
	Genesis 10mg	Not applicable	£3.70	Scheme M	£25.08	7,654
	Genesis 20mg	Not applicable	£4.25	Scheme M	£82.78	297

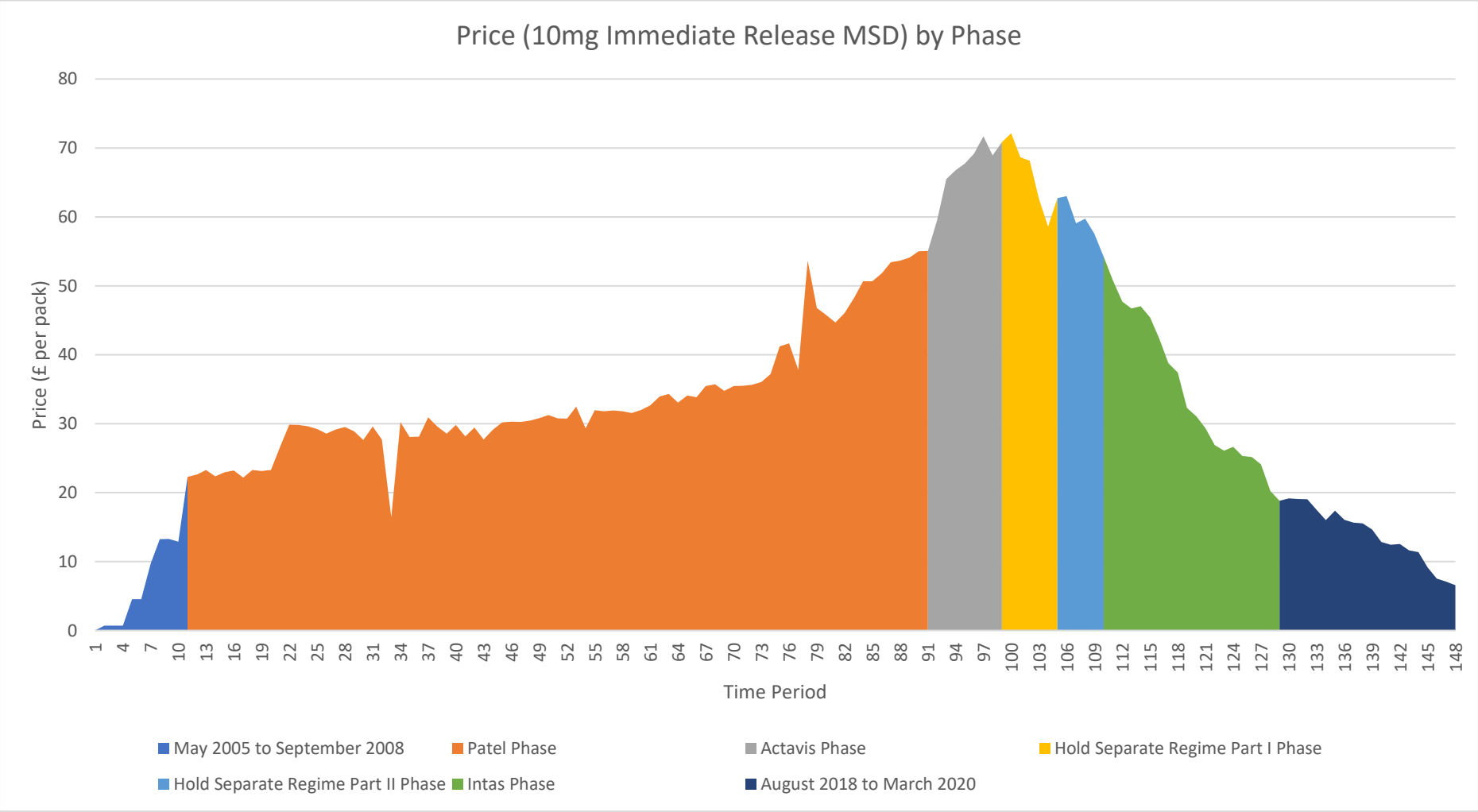
ANNEX 4A (Judgment at [114(7)(i)]
Prices and volumes for 10mg immediate release hydrocortisone tablets sold under the Merck, Sharpe and Dohme MA

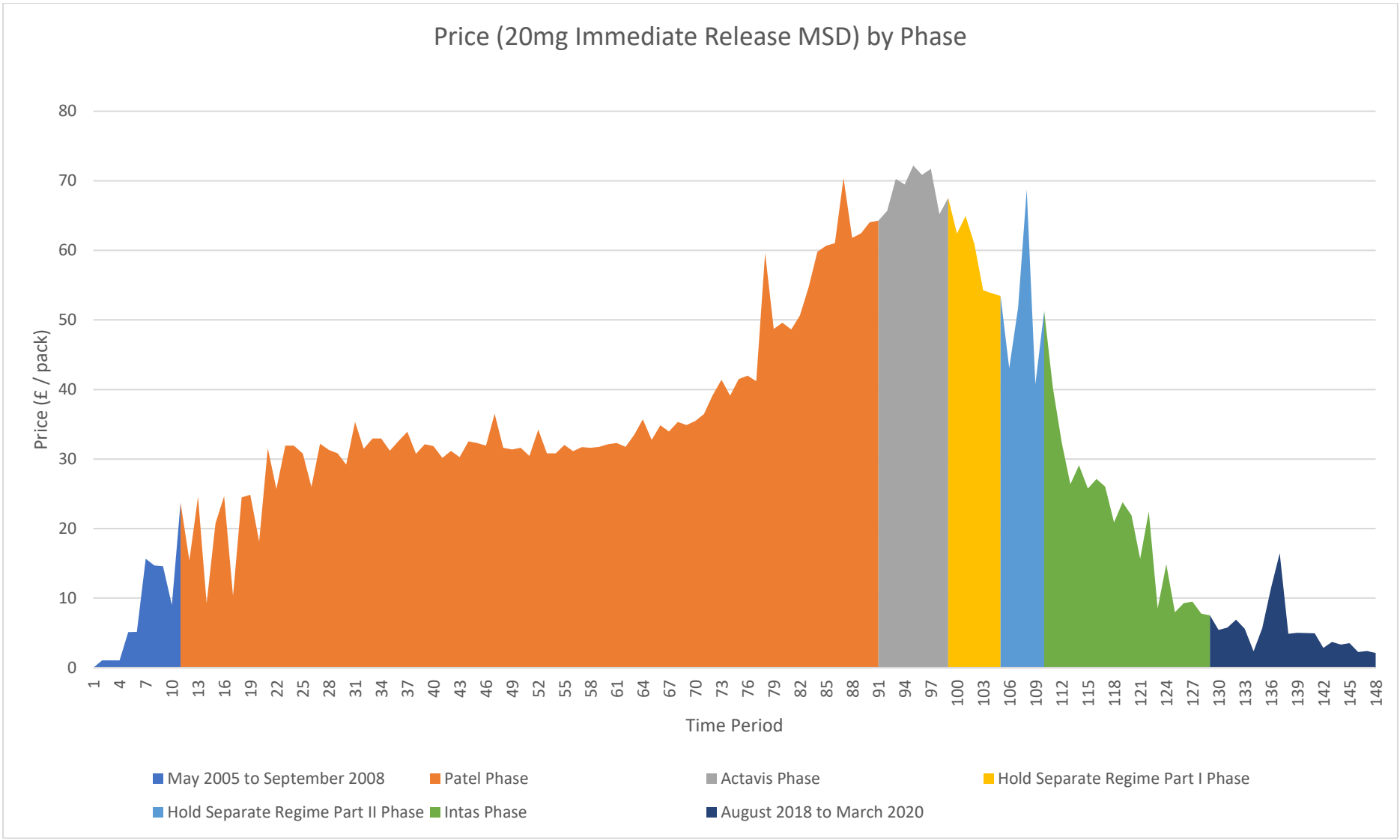


ANNEX 4B (Judgment at [114(7)(ii)])

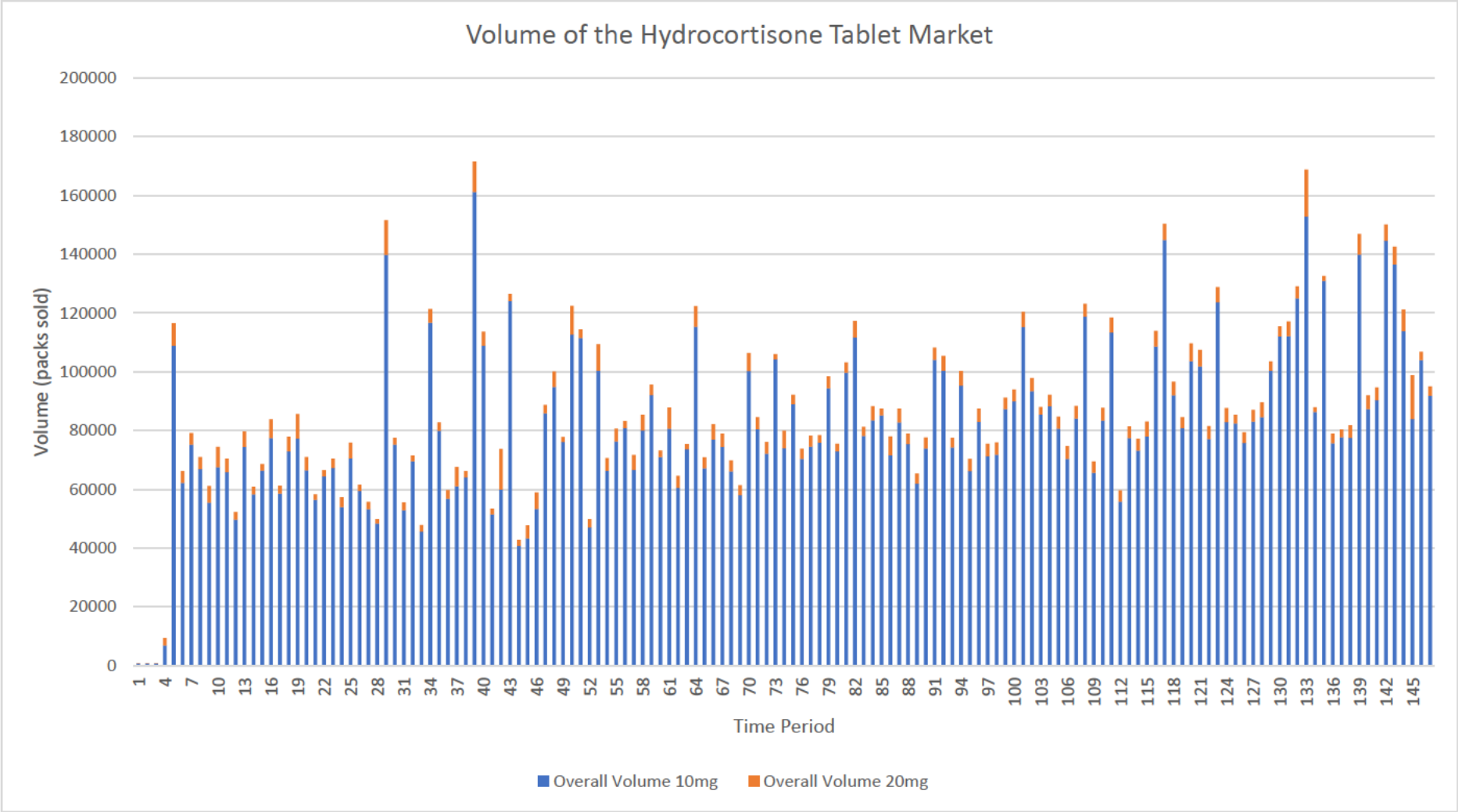


ANNEX 4C (Judgment at [180])




Price (20mg Immediate Release MSD) by Phase
Price (£ / pack)
0
10
20
30
40
50
60
70
80
1 4 7 10 13 16 19 22 25 28 31 34 37 40 43 46 49 52 55 58 61 64 67 70 73 76 79 82 85 88 91 94 97 100 103 106 109 112 115 118 121 124 127 130 133 136 139 142 145 148
Time Period
May 2005 to September 2008
Patel Phase
Actavis Phase
Hold Separate Regime Part I Phase
Hold Separate Regime Part II Phase
Intas Phase
August 2018 to March 2020

ANNEX 5 (Judgment at [116(2)]



ANNEX 6 (Judgment at [214(4)(iv)(c)]