

**This judgment must be read in light of the Tribunal's later judgment at [2024] CAT 17. That is because the provisional findings made against witnesses called are unsafe and are repudiated by the Tribunal. They were made because of a failure, on the part of the CMA, to observe fundamental principles of due process, and for that reason they cannot stand.**



Neutral citation [2023] CAT 57

Case Nos: 1407/1/12/21, 1411/1/12/21, 1412/1/12/21, 1413/1/12/21, 1414/1/12/21

**IN THE COMPETITION**  
**APPEAL TRIBUNAL**

Salisbury Square House  
8 Salisbury Square  
London EC4Y 8AP

29 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**

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**(The Intas Appellant)**

**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 on 27 April 2023 and 15 May 2023.

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**JUDGMENT**

**(CARTEL INFRINGEMENTS)**

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#### **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 Appellant

**Mr Mark Brealey, KC** (instructed by **Morgan Lewis 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

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## **A. INTRODUCTION**

### **(1) The Judgment (Abuse of Dominance Infringements)**

1. The Judgment (Abuse of Dominance Infringements) was handed down on 18 September 2023 under Neutral Citation Number [2023] CAT 56. This Judgment – the Judgment (Cartel Infringements) – follows on from the Judgment (Abuse of Dominance Infringements). The terms, abbreviations and descriptions used in the Judgment (Abuse of Dominance Infringements), as set out in Annexes 1 and 2 thereto are adopted.
2. The Judgment (Abuse of Dominance Infringements) determined (finally, so far as this Tribunal is concerned) the appeals in regard to the Abuse of Dominance Infringements. It did not determine the appeals in regard to the Cartel Infringements, for the reasons given (necessarily, somewhat opaquely) in Judgment (Abuse of Dominance Infringements)/[16]. Those appeals are determined in this Judgment (Cartel Infringements). The reasons for dealing with the Cartel Infringements separately from the Abuse of Dominance Infringements are set out, much more fully than in the Judgment (Abuse of Dominance Infringements), in this judgment.
3. All of the facts and matters decided in the Judgment (Abuse of Dominance Infringements) are adopted herein without reservation and referred to as necessary. They are not repeated.

### **(2) The Cartel Infringements**

4. The Hydrocortisone Decision found two Cartel Infringements arising out of the 20mg Agreement and the 10mg Agreement. It is only the finding of liability in relation to the latter agreement (i.e. the 10mg Agreement) that is under appeal. However, for reasons articulated later on in this Judgment (Cartel Infringements), it is important at least to understand the factual findings that the CMA made in respect of both the 20mg and the 10mg Agreements: although we are conscious that some of the Appellants disputed the relevance of the 20mg Agreement to the findings of infringement in relation to the 10mg Agreement, and we bear that in mind.
5. It is obvious that for the purposes of this Judgment (Cartel Infringements), the factual findings made in respect of the 10mg Agreement are the most important, because it is these findings that are under appeal.
6. Annex 3 described the chronology of relevant events (amongst a mass of price information), and (so far) the terminology in Annex 3 has been used to describe relevant persons. The Hydrocortisone Decision refers to the three parties involved in the 10mg and 20mg Agreements as (respectively) “Auden”, “Waymade” and “AMCo”. The latter

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two terms correspond to terms we use. “Auden” refers to AM Pharma and the companies associated with it. Because it is so frequently used in the Hydrocortisone Decision, we (to this extent) abandon the Annex 3 terminology, and also refer to “Auden”.<sup>1</sup>

**(3) The findings in the Hydrocortisone Decision**

7. As regards the 10mg Agreement, the Hydrocortisone Decision found that:

- (1) From 23 October 2012 to 24 June 2016, Auden entered into an agreement that had as its object the prevention, restriction or distortion of competition (so infringing the Chapter I prohibition).<sup>2</sup> This is what the Hydrocortisone Decision and we refer to as the “10mg Agreement”.
- (2) The 10mg Agreement was, initially, between Auden and Waymade (from 23 October 2012 to 30 October 2012).<sup>3</sup> On 31 October 2012, AMCo replaced Waymade as party to the 10mg Agreement, and the agreement continued between Auden and AMCo until 24 June 2016.<sup>4</sup> We should be clear that so far as the Cartel Infringements were concerned, there was no dispute between the parties as to the existence of the agreements between Auden, Waymade and AMCo said by the CMA to be infringing. What was in dispute was the nature of those agreements (i.e. what in fact was agreed) and what the implications, in terms of infringement of the Chapter I prohibition, were.<sup>5</sup> For this reason, the distinction we drew in the Judgment (Abuse of Dominance Infringements)<sup>6</sup> between affirmed findings of fact and cross-references in the Hydrocortisone Decision becomes impossible to maintain, because many references are uncontroversial in part (i.e. there was an agreement) and controversial in part (i.e. there was a dispute as to whether the agreement was or was not an infringing agreement). This Judgment (Cartel Infringements) therefore necessarily abandons the distinction we draw in the Judgment (Abuse of Dominance Infringements) between findings of fact which we accept, and mere cross-references. We trust, however, that the findings in the Hydrocortisone Decision

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<sup>1</sup> Given the nature of the 10mg Agreement – which we come to describe – we consider that a certain absence of precision is preferable to the spurious precision of “AM Pharma”.

<sup>2</sup> Hydrocortisone Decision/1.4(d).

<sup>3</sup> Hydrocortisone Decision/1.4(d)(i).

<sup>4</sup> Hydrocortisone Decision/1.4(d)(ii).

<sup>5</sup> In other words, it was denied by the Appellants that the 10mg Agreement did infringe the Chapter I prohibition.

<sup>6</sup> Judgment (Abuse of Dominance Infringements)/[19].

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that we accept, and those that we do not accept, emerge with clarity from this judgment.

- (3) The 10mg Agreement involved the supply, by Auden, to Waymade and then AMCo, of 10mg immediate release hydrocortisone tablets at a significant discount to the market price of that product. The sales of this product by Waymade/AMCo into the market are described in Judgment (Abuse of Dominance)/[149] to [150] and in the **white on dark red** entries in Annex 3. The Annex 3 entries disclose only the sale price achieved by Waymade/AMCo (which was at around, and usually a little above, the price level that AM Pharma charged when selling the same product).
- (4) The discount on the sale of 10mg immediate release hydrocortisone was a payment by Auden to Waymade/AMCo to stay off the market. The Hydrocortisone Decision expressly records:<sup>7</sup>

“In that agreement, Auden/Actavis agreed to make substantial monthly payments to Waymade and AMCo in exchange for each of Waymade and AMCo agreeing not to enter the market independently with its own 10mg hydrocortisone tablets.”

It is important to appreciate that the Hydrocortisone Decision finds that the “substantial monthly payments” manifested themselves by way of the difference between what Waymade/AMCo paid for the supply (which price varied, but which never exceeded £1.78/pack) and the price they achieved on sale to the market (which Annex 3 shows was never less than £30/pack and generally far more than this). The maximum supply of product by Auden to AMCo was 12,000 packs/month. On this basis, the “substantial monthly payments” can conservatively be reckoned at £338,640.<sup>8</sup>

- (5) Two matters emerge (at the very least by implication) out of these passages in the Hydrocortisone Decision:
- (i) First, that the “substantial monthly payments” were disguised.<sup>9</sup> The 10mg immediate release hydrocortisone tablets were provided to

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<sup>7</sup> Hydrocortisone Decision/1.4(d).

<sup>8</sup> I.e.  $12,000 \times £30 = £360,000$  minus  $12,000 \times £1.78 = £21,360$ , which gives £338,640. The figure is conservative because the per pack price of £30 is low.

<sup>9</sup> In comments on a draft of this Judgment, the CMA suggested that this was not a finding that the Hydrocortisone Decision made. We disagree. The Hydrocortisone Decision finds that there were inflated payments for product to which it attributed a purpose other than simply payment for the product, which was nowhere expressed.



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Waymade/AMCo at so low a price as to enable Waymade/AMCo to generate considerable profits simply by on-selling this product into the market. There was never any direct payment by Auden to Waymade/AMCo.

- (ii) Secondly, and relatedly, because of the manner in which these payments were made (effectively disguised as supply agreements) the promise not to enter the market independently is not express. On its face, the 10mg Agreement is for the supply of product by Auden to Waymade/AMCo at what could be characterised<sup>10</sup> an undervalue.

- (6) The Hydrocortisone Decision made these implications express later on in the Hydrocortisone Decision:<sup>11</sup>

“In October 2012 – at the latest by 23 October 2012 – Auden and Waymade entered into a further agreement, relating to 10mg hydrocortisone tablets, on essentially the same common understanding as the 20mg Agreement (and through some of the same individuals, especially Amit (Auden) Patel and Brian McEwan). Auden paid Waymade through the monthly transfer of margin on a specified volume of 10mg hydrocortisone tablets, which it supplied to Waymade at £1 per pack: a 97% discount to its price to Waymade prior to October 2012 and to its price to all other customers.

No party or individual has given a credible explanation for this discount, other than that it was to buy off Waymade’s entry. The CMA finds that in exchange Waymade agreed that it would not enter the market independently with its own 10mg hydrocortisone tablets.”

- (7) The Hydrocortisone Decision found that this arrangement continued with AMCo:<sup>12</sup>

“From 31 October 2012 until 24 June 2016, the agreement continued, with AMCo replacing Waymade as Auden’s counterparty. Mr McEwan continued to administer the agreement for AMCo, negotiating with Auden a threefold increase in monthly volumes at the £1 supply price with effect from January 2013 onwards under the supervision of John Beighton, who subsequently took over negotiating further increases with Auden in 2014.”

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<sup>10</sup> Although this was disputed.

<sup>11</sup> Hydrocortisone Decision/6.11 – 6.12.

<sup>12</sup> Hydrocortisone Decision/6.14.

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The substance of Hydrocortisone Decision/6.12 was then repeated at Hydrocortisone Decision/6.16, namely that there was no credible explanation for this discount, “other than that it was to buy off AMCo’s entry. The CMA found that in exchange AMCo agreed not to enter the market independently with its own 10mg hydrocortisone tablets.”

- (8) The CMA then made the following express finding as to common understanding:<sup>13</sup>

“The CMA therefore concludes that between 23 October 2012 and 24 June 2016, Auden/Actavis shared a common understanding first with Waymade, and then with AMCo, that:

- a. Auden/Actavis would supply first Waymade, and then AMCo, with 10mg hydrocortisone tablets on terms that amounted to monthly payments (or “value transfers”) to them; and
- b. In exchange for these payments, each of Waymade and AMCo would not enter the market independently with its own 10mg hydrocortisone tablets.”

- (9) The 10mg Agreement was initially oral. It was later put into written form in what we refer to as the “First Written Agreement” and the “Second Written Agreement”. The CMA did not go so far as to contend that these written forms in themselves infringed the Chapter I prohibition.<sup>14</sup> Rather, the Hydrocortisone Decision finds that these written agreements were incomplete statements of the true arrangement between the parties. Thus, the Hydrocortisone Decision records:<sup>15</sup>

“6.831 The CMA has found that throughout the period from 31 October 2012 to 24 June 2016, Auden made monthly payments to AMCo in exchange for AMCo agreeing not to independently enter the market with its own 10mg hydrocortisone tablets. This common understanding is the 10mg Agreement.

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<sup>13</sup> Hydrocortisone Decision/6.17. Some form of common understanding is, of course, required in order to establish an infringement of the Chapter I prohibition.

<sup>14</sup> Hydrocortisone Decision/2.27(c). The CMA was able to reconcile this finding with the finding of the Cartel Infringements by finding that the First and Second Written Agreements were shams, “meaning that their true purpose was for Auden/Actavis to pay Waymade and AMCo, rather than simply to give them product to sell as a genuine bona fide distribution deal.” See also Hydrocortisone Decision/6.889.

<sup>15</sup> Emphasis in **bold** added. Underlining as in the original.

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6.832 As explained in paragraph 6.714 above, **the Second Written Agreement is not in itself the 10mg Agreement**. It represented continued and increasing payments from Auden to AMCo. In exchange for these continued and increasing payments **AMCo renewed its commitment not to enter**, as is clear in particular from the evidence documenting the negotiations leading up to the conclusion of the Second Written Agreement and AMCo’s conduct after entering into the Second Written Agreement. These two elements together – payment in exchange for non-entry – constitute the common understanding defined as the 10mg Agreement. The Second Written Agreement must be read in the context of that common understanding.”

- (10) The Hydrocortisone Decision expressly records that the “10mg supply agreements were a sham: their true purpose was for Auden/Actavis to make substantial monthly payments to Waymade and AMCo”.<sup>16</sup> The Hydrocortisone Decision recognises that this finding raised a question of *bona fides* when rebutting contentions made by AMCo and Cinven:<sup>17</sup>

“AMCo and Cinven made extensive representations to the effect that the supply deals were bona fide and not a sham, dealing with the actual terms of the 10mg Agreement only as a secondary point. They submitted that the CMA had not established, as it must to sustain the allegation that the supply deals were a sham, that everyone involved in the negotiation of the First and Second Written Agreements, including external counsel, was engaged in an elaborate deception to cloak their true intentions.

The description of the supply deals as a sham simply means that the CMA has found their true purpose to be for Auden/Actavis to pay AMCo, rather than simply to give it product to sell as in a genuine bona fide distribution deal. The supply agreements, under which Auden/Actavis supplied AMCo at a 97% discount to its other customers, would not have existed on these terms in the absence of counter-performance from AMCo. The CMA has found that the counter-performance was AMCo’s agreement not to enter the market independently. The parties have not proposed any legitimate counter-performance.

The CMA has not found or alleged an elaborate conspiracy beyond the terms of the 10mg Agreement.”

The “elaborate conspiracy” argument run on behalf of AMCo and Cinven is a common forensic argument in cases of dishonesty and fraud, whereby the respondents to the accusation seek to cause the evidential bar to be raised by

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<sup>16</sup> Hydrocortisone Decision/6.884.

<sup>17</sup> Hydrocortisone Decision/6.921 to 6.923.

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suggesting that the dishonesty or fraud can only have involved a vast array of (generally clearly innocent) characters. For traction, such points rely on improbability through overstatement, for it is perfectly possible to have a case of dishonesty or fraud involving only a few characters at its heart, with the rest of the world innocent of any dishonesty. Hydrocortisone Decision/6.923 represents a straightforward rejection of this forensic argument, and we quite accept that the Hydrocortisone Decision at no point even comes close to suggesting any kind of “elaborate conspiracy”. The establishment of the Cartel Infringements does not require any such finding. But this is not sufficient to enable the CMA to escape the consequences of the findings that they did make, namely that some (perhaps a very limited number of) human actors must have had the common understanding that:

- (i) The First and Second Written Agreements said less than what had been promised, agreed or arranged.
- (ii) The agreements hid the true purpose of the arrangement which, so the CMA found, was “for Auden/Actavis to pay AMCo, rather than simply to give it product to sell as in a genuine bona fide distribution deal”.<sup>18</sup>

Put another way: the Hydrocortisone Decision found a “common understanding” going beyond the written agreements.<sup>19</sup> That common understanding must reside somewhere.

#### **(4) The grounds of appeal**

8. As we have noted, there were multiple notices of appeal raising similar grounds. Those grounds were as follows:

- (1) *The Hydrocortisone Decision erred in finding that the 10mg Agreement constituted a “by object” Chapter I prohibition infringement.* The point was that the 10mg Agreement was no more than the First and Second Written Agreements, which were not infringing agreements. The preceding oral agreement was no wider than the written agreements (which did no more than document a pre-existing arrangement). In short, the agreements were simple supply agreements, under which Auden took the place of a Contract Manufacturing Organisation. In short, the CMA erred in finding a by object

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<sup>18</sup> Quoting from Hydrocortisone Decision/6.922.

<sup>19</sup> See [7(7)] above.

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infringement in circumstances where the written contracts represented the true agreements and were not on their face anticompetitive.

- (2) *No 10mg Agreement existed.* The CMA’s inferred 10mg Agreement did not exist. Specifically:
- (i) The CMA needed to and had failed to establish that both Auden and AMCo had the necessary subjective element that AMCo was being paid not to enter the market. This was to be distinguished from unilateral conduct. There was no evidence of consensus on the part of AMCo that it was being paid by Auden to stay out of the market. There was no express provision in the written agreements preventing AMCo from developing and selling its own products – this was expressly envisaged in their terms. There was no contemporaneous documentary evidence that directly supported the alleged unwritten 10mg Agreement.
  - (ii) Contemporaneous documents evidenced AMCo’s genuine desire to develop its own 10mg product – rather than being paid to stay out of the market. The CMA also ignored issues regarding the contestability of the market for skinny label product, and the need for AMCo to secure saleable stock, as a legitimate reason to conclude the Second Written Agreement.
- (3) *There was no anti-competitive object.* The CMA’s decision relied on a flawed presumption that single generic entry (here: by Waymade/AMCo) would lead to a precipitous decline in prices. Aggressive pricing behaviour would not be expected in the generic pharmaceutical market until several generic competitors had launched competing products. In the absence of the 10mg Agreement, competitive entry by AMCo was unlikely to have prompted material falls in prices, and so it could not be said that the 10mg Agreement amounted to a “by object” infringement.
- (4) *No common understanding as found by the CMA.* The CMA’s inference as to the existence of a common understanding was unsupported by a proper examination of the real conditions of the functioning and structure of the market. The CMA failed to adduce sufficiently precise and consistent evidence of the allegedly infringing agreement. It failed to have regard to the fact that it was commonplace for generic companies to enter the market by seeking supply from CMOs rather than entering with their own manufactured supply. It also failed to appreciate the need for generic companies to have a reliable, consistent and high-quality supply of product. Finally, the explanation for the fall in price for 10mg hydrocortisone release tablets once Waymade obtained its 10mg MA was that Waymade now had a choice to supply the skinny label product from Aesica or

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the full label product from Auden. Auden was obliged to drop its price as a competing CMO with Aesica.

- (5) *No volume caps.* The 10mg Agreement contained no volume caps and so was not a “pay for delay” agreement.
  - (6) *Duration of the 10mg Agreement given the changes of ownership over time.* Annex 3 details the changes in corporate structure and ownership over time. It was contended that the CMA could not infer that any anticompetitive common understanding in the alleged 10mg Agreement extended beyond 29 May 2015, upon the sale of Auden to Actavis, following the change of ownership and personnel driving the 10mg Agreement. In the alternative, any alleged common understanding must have ended after independent generic entry: in March 2016 AMCo had formed the view that it could delay its independent launch no longer and entered in April 2016 with its first order and made its first sales in May 2016. Any common understanding that AMCo would refrain from entry with its own product must have been over by the end of March (or, alternatively, April or May).
  - (7) *Reliance on the 20mg Agreement.* It was contended that it was not appropriate for the CMA to refer to its findings in respect of the 20mg Agreement as context for its findings of the 10mg Agreement, because the Agreements were separate and significantly different. The 20mg Agreement was not recorded in writing and did not involve AMCo.
  - (8) *The alleged Agreements could not be a by object infringement as a large proportion of the market was not contestable.* Even if there was an agreement by AMCo not to enter, the CMA had not identified for how long AMCo agreed not to enter, or under what terms. The alleged Agreement would not have as its object a significant loss of competition, because in the alleged Infringement Period the mainline wholesalers were not interested in the skinny label product – at least 50% of the market was not contestable. The remainder of the market was restricted because of the legal constraints on marketing. AMCo was not obliged to take these risks by entering with its own product.
9. To a very considerable extent, these grounds of appeal overlap, and our treatment of them reflects this. The critical questions on the appeal turn on precisely what was agreed, the extent to which those agreements affected “successors in title” and the extent to which those agreements had either an anti-competitive object and/or an anti-competitive effect.

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**(5) A question of due process**

**(a) *Introduction: the nature of the inquiry into Covert Chapter I Infringements***

10. No-one before us expressly suggested that any kind of contractual agreement or express understanding between cartelists needed to be established in order for there to be an infringement of the Chapter I prohibition.<sup>20</sup> For analytical purposes, it assists to differentiate between two different types of infringement of the Chapter I prohibition, which we shall label “Covert Chapter I Infringements” and “Overt Chapter I Infringements”:
- (1) In the case of Overt Chapter I Infringements, the alleged infringement is plain to see; and the argument is whether the evident arrangement does, as a matter of law, infringe. In other words, the alleged infringer does not deny the arrangement – indeed, positively avers it – but does deny that it is either a by object or by effect infringement. This is the case as regards the multilateral interchange fee litigation that has been before this Tribunal on a number of occasions;<sup>21</sup> and also as regards most favoured nation clauses.<sup>22</sup> Overt Chapter I Infringements usually give rise to difficult and technical legal and economic argument, but they do not tend to involve the Tribunal in ascertaining the scope of the arrangement said to constitute the infringement.
  - (2) By contrast, Covert Chapter I Infringements generally involve a high degree of careful factual inquiry and inference from established fact. That is because the very nature of the agreement – and so, the nature of the infringement – is controversial. It may very well be the case that even when the true nature of the arrangement has been found, difficult questions of characterisation remain – does the arrangement, as found, infringe or does it not? But it is difficult to

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<sup>20</sup> Whish and Bailey, *Competition Law*, 10<sup>th</sup> ed (2021) at 356: “An agreement [in the context of the Chapter I prohibition] is not confined to legally binding contracts but covers any morally binding commitment: it is sufficient if the undertakings have expressed their joint intention to conduct themselves in the market in a particular way. An agreement may be written or spoken or inferred from the circumstances and can consist in a continuing course of business dealings between the parties.”

<sup>21</sup> See, for example, *Sainsbury’s Supermarkets Ltd v. Visa Europe Services LLC*, [2020] UKSC 24 at [100]: “That [i.e. the MIF] minimum price is non-negotiable...It is a known common cost which acquirers know they can pass on in full and do so. Merchants have no ability to negotiate it down”; *Sainsbury’s Supermarkets Ltd v. Mastercard Incorporated*, [2016] CAT 11 at [102(2)]: “It is also worth bearing in mind that price-fixing cartels (the classic “by object” restriction) are almost invariably secret. The MasterCard Scheme Rules, including the provisions regarding the MIF, are not secret. They are extant in every relevant licence agreement and the MIFs (as well as the Scheme Rules) are published by MasterCard on its website.”

<sup>22</sup> [2022] CAT 36 *BGL (Holdings) Limited v. Competition and Markets Authority* (referred to in Annex 1 as “BGL”).

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underestimate the importance of the factual inquiry that must be undertaken when seeking to ascertain precisely what the nature of the allegedly unlawful arrangement actually was.

11. Covert Chapter I Infringements require the decision-maker (here: the CMA) and any reviewing court (here: the Tribunal) to exercise an extraordinarily high degree of care in finding the facts. We expand upon the implications of this below. Before we do so, however, we consider more specifically the issues arising in this case.

**(b) This case**

**(i) The issues on this appeal**

12. Whatever its other complexities, there was a clear dispute on the facts as between the CMA and the undertakings found to have been party to the 10mg Agreement as to the terms of that agreement. Whilst there was no dispute as to the existence of the 10mg Agreement between Auden, Waymade and AMCo, there was clear dispute as to its terms. We have already set out what the CMA found in the Hydrocortisone Decision. It is obvious that the following questions of (related) controverted fact arise on these appeals:
  - (1) The question of whether there were any payments to Waymade/AMCo by Auden at all. The Appellants’ position<sup>23</sup> was that Waymade/AMCo were paying a market price for the 10mg immediate release hydrocortisone tablets, and that the market price was determined by competition between CMOs. The Hydrocortisone Decision, by contrast, found that the supply agreements were “shams” and in effect a device whereby significant value could be transferred from Auden to Waymade/AMCo.
  - (2) The question why this significant value was transferred does not arise on the Appellants’ case: their case was that there was no such transfer of value at all. The Hydrocortisone Decision, by contrast, finds not only the existence of a value transfer, but that the only purpose underlying this value transfer was because Waymade and AMCo agreed in return not to enter the market independently.
  - (3) The First and Second Written Agreements are, on the Appellants’ case, a complete statement of the commercial relations between Auden and AMCo. Since, as the CMA has accepted, the agreements as they stand do not infringe competition law, it was a necessary part of the Hydrocortisone Decision that

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<sup>23</sup> Of course, only some Appellants appealed the Cartel Infringements. Our reference to “Appellants” is so limited.



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these agreements were not what they appeared to be. They were – in the words of the Hydrocortisone Decision – shams.

Clearly, this is a case of a Covert Chapter I Infringement, whatever other complexities may arise. We next set out the implications of this.

(ii) Implications

13. Self-evidently, the CMA cannot successfully defend the Hydrocortisone Decision by reference only to the terms of the First and Second Written Agreements. The CMA has found that these agreements did not infringe the Chapter I prohibition. That is the starting point for these appeals – and is not a finding we are going to look behind or second guess. The CMA has made a decision, and it is not appealed to us.
14. The critical question, therefore, is what arrangement – if any – subsisted that went beyond the terms of the First and Second Written Agreements. The Appellants denied any such arrangement existed at all: the burden therefore was on the CMA to show not only that such an arrangement existed, but that it was as had been found in the Hydrocortisone Decision itself.<sup>24</sup>
15. Unpacking this still further:
  - (1) It is fundamental to the Chapter I prohibition that unilateral conduct does not constitute an infringement of that prohibition. What needs to be demonstrated is some form of (not necessarily contractual) common understanding. In closing, the Tribunal suggested that it was important to focus on communications “crossing the line”. This is a phrase used by the Court of Appeal in *K Lokumal & Sons (London) Ltd v. Lotte Shipping Company Pte Ltd, The “August Leonhardt”* in the context of estoppel:<sup>25</sup>

“All estoppels must involve some statement or conduct by the party alleged to be estopped on which the alleged representee was entitled to rely and did rely. In this sense all estoppels may be regarded as requiring some manifest representation which crosses the line between representor and representee, either by statement or conduct. It may be an express statement or it may be implied from conduct, e.g. a failure by the alleged representor to react to something said or done by the alleged representee so as to imply a manifestation of assent which leads to an estoppel by silence or acquiescence.

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<sup>24</sup> It is trite that the CMA is defending the decision it has made, not advancing a new case to be affirmed on appeal.

<sup>25</sup> [1985] 2 Lloyd’s Rep 28 at 34.

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Similarly, in cases of so-called estoppels by convention, there must be some mutually manifest conduct by the parties which is based on a common but mistaken assumption.”

We accept that the Chapter I prohibition is very different in nature from either contract or estoppel. Nevertheless, this is a helpful passage, because it articulates very well the need for the arrangement said to constitute the infringement of the Chapter I prohibition to “cross the line” between the parties to it.

- (2) How that arrangement was reached, how it manifested itself, and how it is established on what may be limited and exiguous evidence will depend on the specific facts of any case. But some arrangement crossing the line must be shown. Unilateral conduct will not suffice.
- (3) In this case, whilst the First and Second Written Agreements are obviously enormously important background facts, and undoubtedly do cross the line, they remain background facts insufficient in themselves to establish the Cartel Infringements found in the Hydrocortisone Decision. Of course, taken into account with other facts, the First and Second Written Agreements may be (and, indeed, in this case are) highly significant.
- (4) It is obvious that this kind of arrangement can only arise through some form of intentional conduct. There will have to be conduct of some sort resulting in the arrangement augmenting the terms of the First and Second Written Agreements. That, as it seems to us, is the unavoidable consequence of the Hydrocortisone Decision. The arrangement augmenting the terms of the First and Second Written Agreements cannot have been immaterial. In order to give rise to an infringement, the First and Second Written Agreements must have been materially added to or augmented.
- (5) The Hydrocortisone Decision does not shrink from this. The First and Second Written Agreements are expressly labelled “shams” and that label cannot be disavowed on appeal by the CMA, because it represents the conclusion reached (in this regard) by the Hydrocortisone Decision.
- (6) Although not without definitional complexity at its fringes, the term “sham” has a core meaning that is well-understood. The best case articulating it is *Snook v. West London Riding Investments*, where Diplock LJ said this:<sup>26</sup>

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<sup>26</sup> [1967] 2 QB 786 at 802.

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“As regards the contentions of the plaintiff that the transactions between himself, Auto Finance and the defendants were a “sham”, it is, I think, necessary to consider what, if any, legal concept is involved in the use of this popular and pejorative word. I apprehend that, if it has any meaning in law, it means acts done or documents executed by the parties to the “sham” which are intended by them to give to third parties or to the court the appearance of creating between the parties legal rights and obligations different from the actual legal rights and obligations (if any) which the parties intend to create. But one thing, I think, is clear in legal principle, morality and the authorities..., that for acts or documents to be a “sham”, with whatever legal consequences follow from this, all the parties thereto must have a common intention that the acts or documents are not to create the legal rights and obligations which they give the appearance of creating. No unexpressed intentions of a “shammer” affect the rights of a party whom he deceived...”

- (7) Although the Hydrocortisone Decision did not find that the supplemental agreement so “overwrote” the First and Second Written Agreements as to render their terms entirely irrelevant, the Hydrocortisone Decision did find that the First and Second Written Agreements were supplemented or augmented by an additional arrangement so as to render those agreements materially different from their written terms. The label “sham”, used in the Hydrocortisone Decision, was entirely appropriate as a sound conclusory statement encapsulating the factual basis for the Cartel Infringements.

16. We appreciate that the Chapter I prohibition is a strict liability tort, and that it is not necessary to show any intention to infringe. However, in this case, the CMA were – rightly, and inevitably, given the findings in the Hydrocortisone Decision – alleging and finding an intentional infringement. The point that we make is that the nature of the CMA’s findings – given that they were, in this regard, denied in their entirety by the Appellants – might come very close to or in fact amount to an allegation of dishonesty against someone. We have no desire to run ahead of ourselves, but this was, we consider, an obvious risk from the outset of these appeals: indeed, it was obvious from the moment the Hydrocortisone Decision was published. That would be the case whether or not the term “sham” was used: but its use, with all the pejorative connotations the term has, makes the point very well.

(iii) Questions of proof

17. Prior to the publication of the Hydrocortisone Decision, and as is recorded therein, the Cinven Appellants contended that the CMA had placed inappropriate weight on *ex post* interview evidence.<sup>27</sup> The CMA rejected this criticism in the following terms:<sup>28</sup>

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<sup>27</sup> Hydrocortisone Decision/6.48.

<sup>28</sup> Hydrocortisone Decision/6.49.

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“The CMA does not accept Cinven’s representations, which in any event are inaccurate. The primary source of evidence that the CMA has relied upon in this case is contemporaneous documents. It has sought to highlight where interview evidence is corroborative of the contents of those documents. In particular, the interviews with the key witnesses involved in negotiating and implementing the Agreements (all of which were conducted under section 26A of the Act) had common characteristics...”

18. We accept that, where a Covert Chapter I Infringement is in issue, both at the investigation stage by the CMA, and when a decision of the CMA is appealed to this Tribunal, the most probative evidence is likely to be the contemporary documentation and the contemporary events. Much will turn on what can properly be inferred from such evidence, and what ultimate conclusions can properly be drawn. Furthermore, both the CMA and the Tribunal must appreciate the sensitive and important nature of the decisions made by the CMA.
19. Where relevant witness evidence can be obtained, its value is enormous. In *AH Willis and Sons Ltd v. Office of Fair Trading*,<sup>29</sup> the OFT failed to call witness evidence that it might have called, preferring instead to rely on transcripts of evidence previously obtained. The Tribunal commented as follows:
  - “66. As we stated in paragraph 19(3) above, difficult and important questions arise in relation to the “evidence” adduced by the OFT. We have already noted that the transcript of Mr Russ’ interview with the OFT does not appear to have been satisfactorily reviewed by and attested to by Mr Russ (see paragraph 54 above). Certainly he has not endorsed the transcript with a statement of truth or even signed it.
  67. More fundamentally, we have considerable doubts as to whether material contained in transcripts of interview – even if reviewed and attested – is a satisfactory means of evidencing alleged infringements in cases of this kind. It is one thing to use a transcript of interview as evidence of relevant admissions by the interviewee; it is quite another thing to attempt to use it as evidence against a third party. In paragraph 81 of the Tribunal’s decision in *Argos Limited v. The Office of Fair Trading*, [2003] CAT 16, the Tribunal observed that “notes of interview are not, in our view, satisfactory substitutes for witness statements”. We agree. A witness statement will set out the relevant facts, will be attested to by the witness by way of a statement of truth, and will enable the witness to be exposed to cross-examination should the accuracy and/or truth of those facts be disputed. This is not to say that relevant interview transcripts cannot or should not be put before the Tribunal in support of a witness statement. It is simply that they are not a substitute for it.
  68. We do not therefore agree with the suggestion in numbered paragraph 2 of the OFT’s letter to the Tribunal dated 6 August 2010, and referenced to inter alia this appeal, that

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<sup>29</sup> [2011] CAT 13. See also *BGL* at [234].

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the preparation of a witness statement in circumstances such as the present would be “a complete triumph of form over substance”. Where crucial facts are disputed it may in certain cases, and depending upon what if any other evidence is available, be very difficult to resolve the issues in the absence of evidence from a witness who has been deposed in the ordinary way and whose assertions are available to be tested in cross-examination by those who dispute them. Where central issues of fact cannot be resolved, the outcome may have to turn on the burden of proof. It is therefore all the more important from the OFT's perspective that there should be probative evidence before the Tribunal. Thus, even if the OFT has not obtained witness statements in order to fortify its own decision-making process, once it becomes clear that there is a material dispute as to the facts on which its decision was based, the OFT should consider to what extent such statements are necessary or desirable in order to support those facts in an appeal, subject always to the provisions of rule 22 of the Competition Appeal Tribunal Rules 2003 (SI 2003 No. 1372). It is, of course, not normally the role of the Tribunal to decide whether and if so which witnesses should be deposed or called to give evidence by any party. We should add in regard to these matters that we are in entire agreement with the comments of the Tribunal at paragraphs 108 to 110 of its judgment in *Durkan Holdings Limited and others v. OFT*, [2011] CAT 6.”

20. By this, we do not mean to say that it is necessarily incumbent upon the CMA to call witness evidence in order to make good the findings it has made. Of course, where such evidence can feasibly be called, it would be helpful were it to be adduced. But that is not this case, and we say no more about what the CMA can and should do about witness evidence.
21. The reason we have cited *Willis* at such length, and the reason we are stressing the significance of witness evidence and cross-examination, is because the Advanz Appellants, in support of their appeal, adduced witness evidence from Mr Sully and Mr Beighton, and presented them for cross-examination. This, as it seems to us, obliges the CMA to put its case to those witnesses to the extent that they can properly answer it. That serves two, quite fundamental, yet quite distinct, purposes:
  - (1) First, it enables a far better understanding of the evidence to be obtained. Whilst hyperbolic in tone, Professor Wigmore was right when he said that cross-examination was the greatest engine ever invented for the discovery of truth.
  - (2) Secondly, it enables the witness to answer back, to make good the version of events that the witness has advanced. This is particularly important in cases where issues of honesty may arise. In such cases, absent exceptional

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circumstances, a witness positively ought to be confronted with the case against them.<sup>30</sup>

22. Since the undertakings in these appeals are legal and not natural persons, who therefore have to conduct themselves through human actors, it would be perverse not to ask the relevant questions of those actors who have been called by an Appellant to give evidence on the very point in controversy. In this case, Mr Sully and Mr Beighton were centrally involved in the Cartel Infringements, and gave substantial witness statements setting out their versions of the history.
23. We stress that we are not saying that the CMA were themselves obliged to call Mr Sully or Mr Beighton or (indeed) any other factual witness on this point. It is perfectly proper for the CMA – if so advised – to make good its defence of a decision by reference to the contemporaneous material. That is how the CMA sought to defend the Hydrocortisone Decision in this case.<sup>31</sup> What we are, however, saying, is that where relevant witnesses are called by an Appellant, it is incumbent upon the CMA to put its case.

(iv) What was the CMA’s case – and was it put?

24. It is not for the Tribunal to conduct the CMA’s defence of an appeal, but to determine the appeal having heard the evidence and submissions. At the conclusion of the hearing, during closing submissions, the Tribunal raised a concern with Ms Demetriou, KC (leading counsel for the CMA in relation to the Cartel Infringements) as to what the CMA’s case was. It is necessary to set out some of these exchanges at some length:
- (1) During the course of the hearing, the Tribunal had identified that the burden of proving a “sham” might trigger the “heightened” civil standard of proof on the CMA.<sup>32</sup> Ms Demetriou, KC began her closing submissions by asserting that this was not a true case of “sham”, because:<sup>33</sup>

“It is of the essence of this type of sham transaction that the parties to a transaction intend to create one set of rights and obligations, but do acts or enter into documents which they intend should give third parties...the appearance of creating different rights and obligations.”

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<sup>30</sup> *Bhaur v. Equity First Trustees (Nevis) Limited and others* [2023] EWCA Civ 534 at [107] to [122]. See also, for example, *Arroyo and Other v. Equion Energia Limited*, [2016] EWHC 1699 (TC) at [1413] and *NGM Sustainable Developments v. Phillip Wallis*, [2015] EWHC 2089 (Ch) at [50] to [59].

<sup>31</sup> See [17].

<sup>32</sup> This heightened standard is described in Judgment (Abuse of Dominance Infringements)/[34].

<sup>33</sup> Transcript Day 16/p.8.

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We have some difficulty in understanding this point, and we do not consider that it was open to the CMA to resile from what (as we have stated) the Hydrocortisone Decision actually found.

- (2) This lead directly to the President making clear that he regarded the case as a case of dishonesty, and that this affected the level of the burden of proof on the CMA. Surprisingly, to the Tribunal, Ms Demetriou, KC pushed back to say “it is not a dishonesty case”.<sup>34</sup> Ms Demetriou, KC continued:<sup>35</sup>

“...So we do not have to show dishonesty. Our case, just to be clear, is that we are not alleging a separate dishonest rider or a separate dishonest side agreement. What we are saying is that the premise, the commonly understood premise for this supply agreement was that it was happening, supply was being given on these terms, on the basis that it was an alternative to AMCo coming on the market and that was understood by both parties.

...

...Our case is that the supply agreement was a supply agreement. Those were the terms, the essential terms that were agreed, but both sides understood that the premise for that was that AMCo would not enter the market with its own product. That is the CMA’s case.

We do not need to show that that is dishonest. We do not need to show that it is a hidden term. We do not need to show that it is a side agreement or a rider.”

- (3) We have some difficulty in reconciling these statements with the findings of the Hydrocortisone Decision set out above. We accept, of course, that dishonesty is not a requirement to find an infringement: nor is intention or negligence. But the latter two elements are necessary to invoke the penalty jurisdiction, and the CMA’s case here was one of intentional infringement of the Chapter I prohibition. The concern being articulated by the President was that in making good this case, issues of honesty might inevitably arise and – if they did – needed to be appropriately put.

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<sup>34</sup> Transcript Day 16/p.11.

<sup>35</sup> Transcript Day 16/pp.12 to 14.

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- (4) Ms Demetriou, KC repeated the point made in Hydrocortisone Decision/6.923 above,<sup>36</sup> namely that the CMA was not asserting “an elaborate conspiracy”.<sup>37</sup> We accept this: but, as we said in [7(9)] above, this was not sufficient to enable the CMA to escape the consequences of its findings, namely that some (perhaps a very limited number) of human actors must have had the common understanding that the First and Second Written Agreements said less than what had been arranged and hid the true purpose of the arrangement which, so the CMA found, was “for Auden/Actavis to pay AMCo, rather than simply to give it product to sell as in a genuine bona fide distribution deal”.<sup>38</sup>
- (5) In their closing submissions, the Appellants made the point that the Cartel Infringements involved “career ending findings of dishonesty”.<sup>39</sup> In response to this, Ms Demetriou, KC submitted (correctly) that dishonesty was not a necessary ingredient of the Chapter I prohibition. More controversially, she contended that the Hydrocortisone Decision did not involve any such assertion. On the face of the Hydrocortisone Decision, that is right: no express finding of dishonesty is made. But that does not answer the substance of the concern that we have, which is that issues of honesty or dishonesty are so inextricably linked to the findings that were made in the Hydrocortisone Decision that the CMA’s case on infringement would need to be put with some clarity to any witness called by the Appellants who were able to assist on the point.

(v) Our approach

25. We are concerned that the CMA’s case was not fully put to Mr Sully or Mr Beighton. We express no concluded view, not least because the parties have not had the opportunity to address us on this point – nor on the implications of it, if it is well-founded.
26. We propose to decide the issues arising out of the appeals in relation to the Cartel Infringements on the basis of the evidence before us. This is – self-evidently – a question of carefully reviewing the factual material before us and of making findings in relation to that material. That exercise is carried out in Section B below. In Section C, we set out our conclusions in relation to the various grounds of appeal, based upon the findings made in Section B. In Section D, we return to the concern just articulated: the question

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<sup>36</sup> Quoted in paragraph 7(9) above.

<sup>37</sup> Transcript Day 16/p.18.

<sup>38</sup> Quoting from Hydrocortisone Decision/6.922.

<sup>39</sup> Ms Demetriou, KC was quoting Mr O’Donoghue, KC’s closing at Transcript Day 16/pp.34 to 35.



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of whether (in light of our consideration of the evidence, and the findings we have made) the CMA put its case and (if they did not) what the implications of this are.

## **B. FINDINGS OF FACT IN RELATION TO THE CARTEL INFRINGEMENTS**

### **(1) Introduction**

27. This section is confined to making findings of fact in relation to the Cartel Infringements. Our approach is first to set out the basic facts, first in relation to the 20mg Agreement (because it is chronologically first: Section B(2)) and then in relation to the 10mg Agreement (because it is second in time, Section B(3)). The following Sections consider what can properly be inferred from these facts.

### **(2) The 20mg Agreement**

#### ***(a) The Marketing Authorisation***

28. Waymade acquired a Marketing Authorisation for the sale of 20mg “immediate release” hydrocortisone tablets in 1998. This Marketing Authorisation had been granted to another supplier in May 1987, and was subsequently acquired by Waymade.<sup>40</sup> Given the date of the Marketing Authorisation, this was a “full label” Marketing Authorisation.

#### ***(b) Readiness to sell 20mg tablets***

29. Between 2008 and early 2011, Waymade developed its own 20mg hydrocortisone tablets<sup>41</sup> and had by 28 March 2011 cleared all regulatory requirements.<sup>42</sup> Waymade received commercial stock ready for sale on 9 May 2011.<sup>43</sup>

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<sup>40</sup> Hydrocortisone Decision/3.204 (Table 3.5), and Hydrocortisone Decision/3.345.

<sup>41</sup> Hydrocortisone Decision/6.1(a).

<sup>42</sup> Hydrocortisone Decision/6.1(b).

<sup>43</sup> Hydrocortisone Decision/6.1(c).

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**(c) *The 20mg Agreement***

**(i) Supply**

30. We have set out what the CMA found occurred pursuant to the 20mg Agreement at Judgment (Abuse of Dominance Infringements)/[146] to [148]. Essentially, 1,000 packs were supplied to Waymade by Auden:

- (1) Some of these Waymade sold on its own account. The agreement was for Auden not to sell to Waymade more than 200 packs per month for Waymade to sell for its own account. These are included in Annex 3, coloured red.
- (2) The remainder were bought back at a far higher price than they were sold to Waymade in the first place. The annualised payments that Waymade thereby received are set out in Judgment (Abuse of Dominance Infringements)/[148], and were substantial.<sup>44</sup>

**(ii) The written agreement**

31. The agreement between the parties was, according to the Hydrocortisone Decision, “documented in emails”.<sup>45</sup> Considering the emails in question, that is an overstatement: we would suggest that there are emails which evidence an agreement. The emails were as follows:

- (1) In an email dated 11 July 2011 from Mr Brian McEwan (Waymade’s director of operations) to Mr Alan Barnard (head of sales and marketing at Auden Mckenzie), headed “Hydro 20mg”, Mr McEwan stated:

“Managed to get both Brian<sup>46</sup> and David<sup>47</sup> [on] Friday evening to discuss the amended offer and, yes, we are ok with the idea to invoice us the stock at the special price and we immediately sell back 800 of them to you at £34.50. The problem we have, as I suspected, is the other 200, where we are not willing to compromise on the agreed terms of these coming to us also at the special price. Basically, yes, if and when we see another

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<sup>44</sup> Hydrocortisone Decision/6.6 records that these payments amounted to at least £1.8 million between 11 July 2011 and 30 April 2015.

<sup>45</sup> Hydrocortisone Decision/6.46.

<sup>46</sup> This would appear to be a reference to Mr Brian Wyatt (director of operations at Waymade).

<sup>47</sup> This would appear to be a reference to Mr David Day (finance director of Waymade).

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20mg licence granted on RAMA (Amit’s terms to us) then we will have to come to discuss, but until that happens, the deal is sound.<sup>48</sup>

Can you please confirm that the 3000 x 10mg has been dispatched to us as I am surprised it was not received at the back end of last week.”

(2) On 11 July 2011, Mr Barnard replied:

“Thanks for your email, understand your situation and agree that we will go with the terms below and reassess the situation as and when there are any licensing updates.

Suggest you place an order for the 1,000 packs and we will despatch the 200 to you.

With regards to the 10mg apologies for the delay, however the stock should be with you today.”

(iii) Interview evidence

32. The CMA – quite rightly – conducted interviews with the persons who had been involved in the 20mg Agreement. We were not referred to any material evidence taking the matter forward by any party, and need say no more about it.

*(d) Conclusion*

33. Apart from context – which is, clearly, important, and to which we will come – we can discern no further material evidence regarding the 20mg Agreement.

**(3) The 10mg Agreement**

*(a) The Marketing Authorisation*

34. Between 2008 and 2012, Waymade worked to obtain a marketing authorisation for 10mg “immediate release” hydrocortisone tablets.<sup>49</sup> Waymade obtained a marketing authorisation on 27 September 2012.<sup>50</sup>

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<sup>48</sup> RAMA refers to “RAMA XL” – an external resource provided by the UK Government that would allow the parties to know when a third party obtained a 20mg MA: Hydrocortisone Decision/6.470).

<sup>49</sup> Hydrocortisone Decision/6.8.

<sup>50</sup> Hydrocortisone Decision/6.10.

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***(b) Supply of 10mg “immediate release” prior to the conclusion of the 10mg Agreement***

35. Between July 2011 and September 2012, Auden supplied Waymade with 10mg “immediate release” hydrocortisone tablets at the market rate: between £31.50 and £34.50 per pack.<sup>51</sup> We do not know how Waymade itself supplied the market. Given that at this time there was no Waymade marketing authorisation, Waymade could not have sold this product save as Auden’s product.

***(c) The original agreement between Auden and Waymade***

36. We will begin with the finding in the Hydrocortisone Decision:<sup>52</sup>

“In October 2012 – at the latest by 23 October 2012 – Auden and Waymade entered into a further agreement, relating to 10mg hydrocortisone tablets, on essentially the same common understanding as the 20mg Agreement (and through some of the same individuals, especially Amit (Auden) Patel and Brian McEwan). Auden paid Waymade through the monthly transfer of margin on a specified volume of 10mg hydrocortisone tablets, which it supplied to Waymade at £1 per pack: a 97% discount to its price to Waymade prior to October 2012 and to its price to all other customers.”

***(d) Exit Waymade, enter AMCo***

37. On 31 October 2012, Waymade’s 10mg Marketing Authorisation, 10mg product development and relevant staff – including Mr McEwan – became part of AMCo.<sup>53</sup>

***(e) The continued agreement between Auden and AMCo and AMCo’s legal review***

38. Again, we begin with the finding in the Hydrocortisone Decision:<sup>54</sup>

“From 31 October 2012 until 24 June 2016, the agreement continued, with AMCo replacing Waymade as Auden’s counterparty. Mr McEwan continued to administer the agreement for AMCo, negotiating with Auden a threefold increase in monthly volumes at the £1 supply price

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<sup>51</sup> Hydrocortisone Decision/6.9.

<sup>52</sup> Hydrocortisone Decision/6.11.

<sup>53</sup> Hydrocortisone Decision/6.13.

<sup>54</sup> Hydrocortisone Decision/6.14.

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with effect from January 2013 onwards under the supervision of John Beighton, who subsequently took over negotiating further increases with Auden in 2014.”

39. We will describe the performance of the 10mg Agreement in greater detail below. This section is concerned with the bare bones of what was agreed over time.
40. Mr Sully describes the creation and organisation of AMCo in Sully 1, which occurred after the Amdipharm business was acquired from Waymade in October 2012.<sup>55</sup> He describes a period of exceptional busyness between October 2012 and March 2013.<sup>56</sup> He also describes the “rolling annual compliance programme, specifically including in relation to competition law”, which he instituted in 2011, and which came to be applied to the business acquired from Waymade.<sup>57</sup> As to this:

“When AMCo was formed in March 2013, I was instructed by the new AMCo Board to ensure that AMCo continued these endeavours and implemented a “best in class” compliance culture. I did this and, for example, AMCo became the first pharma company in the world to be credited with British Standard BS 10500...”

41. Mr Sully attended all board meetings in his capacity as AMCo general counsel and a “legal and compliance” section became the norm on the agenda for each board meeting.<sup>58</sup> Compliance workshops, involving mandatory training, including in relation to competition issues, were instituted.<sup>59</sup> These resulted in a number of compliance issues, in relation to which Mr Sully engaged the law firm Pinsent Masons LLP.<sup>60</sup> As part of this review, the 10mg Agreement became a topic of consideration.<sup>61</sup>
42. Mr Sully said this about the 10mg Agreement, and Pinsent Masons’ advice in this regard:<sup>62</sup>

“...as regards the unwritten agreement with Auden for the supply of Auden’s 10mg HT, Pinsent Masons advised in August 2013 that it might be misinterpreted as involving resale price maintenance and recommended that any scope for misinterpretation should be removed by the

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<sup>55</sup> Sully 1/11.

<sup>56</sup> Sully 1/13.

<sup>57</sup> Sully 1/15 to 16.

<sup>58</sup> Sully 1/18.

<sup>59</sup> Sully 1/19.

<sup>60</sup> Sully 1/20.

<sup>61</sup> Sully 1/21.

<sup>62</sup> Sully 1/21.

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agreement being formalised in writing so that the “basis of the relationship [with Auden] was clear and there was no ambiguity”. Pinsent Masons advised that if AMCo did this “we consider that the competition risk [of the unwritten supply agreement being misconstrued as resale price maintenance] would be low”. I recall checking whether “low” was the lowest rating that they gave, or whether they would ever say “nil”, and I was informed that “low” was their lowest rating. Pinsent Masons did not identify any other potential competition law risk from the 10mg HT supply arrangement with Auden.”

43. The fact that Pinsent Masons had given this clean bill of health was relied upon by AMCo to suggest that the CMA’s findings in the Hydrocortisone Decision were wide of the mark. It is therefore necessary to consider the Pinsent Masons review in some detail:

- (1) It should first be noted that Mr Sully does not say what he or Pinsent Masons understood the 10mg Agreement to comprise. Obviously, Mr Sully rejected any suggestion that AMCo were being paid to stay out of the 10mg hydrocortisone market; but we do not understand the essential terms of the 10mg Agreement – that is, the supply of a given quantity of 10mg “immediate release” hydrocortisone tablets for sale by AMCo at a 97% discount to Auden’s normal price to be controverted. The obvious question which arises is not whether these terms were anti-competitive, but why Auden were being so uncommercial in their supply to a competitor.<sup>63</sup>
- (2) We note the reference to the concern that such an arrangement might give rise to a risk of “resale price maintenance”. Resale price maintenance is an arrangement where a supplier requests a retailer not to sell below a specified price. Clearly, there was no such express term in the oral agreement we have described. Looking at the figures in Annex 3, however, it is clear that AMCo priced the identical product it was selling at about the same price as Auden or a little bit higher than Auden.
- (3) A more fundamental question is why Pinsent Masons did not at least ask about the “elephant in the room”, namely what was Auden getting in return for selling 10mg hydrocortisone at a 97% discount to a competitor? That is a matter not addressed in the after-the-event evidence of Pinsent Masons<sup>64</sup> nor in the advice that was given at the time.

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<sup>63</sup> Particularly given the history. Waymade had originally been supplied at market price: see [35].

<sup>64</sup> We refer to the statement of an associate lawyer in Pinsent Masons’ competition team, produced in around February 2017, and exhibited to Sully 1. The statement simply reasons from the conclusion: “...both AMCo’s legal team and we were concerned that they may be open to misinterpretation as a resale price fixing agreement”.

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- (4) The furthest Mr Sully goes as to the agreement is to say that:<sup>65</sup>

“I was informed that in order to start being recognised as a supplier of HT, Waymade had arranged to purchase 10mg HT from Auden under an own label supply (“OLS”) agreement whilst [certain] development issues were being resolved.”

*(f) Reducing the oral agreement to writing*

(i) The need arises

44. As we have described, the advice of Pinsent Masons was that the oral agreement be reduced to writing. Mr Sully says that “AMCo had two written agreements with Auden for the supply of its full indication (adult and child’s version) 10mg HT product: the First Written Agreement and the Second Written Agreement, both prepared with the assistance of Pinsent Masons.”<sup>66</sup> As we have described, the Hydrocortisone Decision found that:

- (1) These agreements were, in and of themselves, not infringing of the Chapter I prohibition.
- (2) But there was a side agreement – existing alongside these agreements – whereby AMCo agreed to stay out of the 10mg “immediate release” hydrocortisone tablet market.<sup>67</sup>

45. It is important to record that Mr Sully, who took the lead within AMCo for the conclusion of the First Written Agreement and the Second Written Agreement denied the second finding in unequivocal terms:<sup>68</sup>

“...these were prepared with the assistance of Pinsent Masons who also cleared them from a competition perspective. I did not arrange for those agreements with the knowledge or intention that they were “sham” supply agreements intended to disguise the CMA’s inferred 10mg Agreement. If that was the purpose of the two written supply agreements, that was never communicated to me.”

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The question that AMCo was providing something in return other than resale price maintenance, and that there was something questionable about the price, appears to have occurred to no-one – yet the price oddity was obvious to all.

<sup>65</sup> Sully 1/28.

<sup>66</sup> Sully 1/24.

<sup>67</sup> Hydrocortisone Decision/6.884, 6.922.

<sup>68</sup> Sully 1/24.

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(ii) Purpose of the agreements

46. We will come to what AMCo said the purpose of the First and Second Written Agreements was in due course, but we should summarise here Mr Sully’s evidence in this regard:

(1) The Marketing Authorisation that AMCo had derived from Waymade, which it obtained it on 27 September 2012, was for the sale of a “skinny label” product only. This was because this Marketing Authorisation was obtained after the Marketing Authorisation and Orphan Drug designation of Plenadren on 3 November 2011. AMCo would, therefore, only be able to sell “skinny label” product.<sup>69</sup>

(2) AMCo had a history of problems with its manufacturer – Aesica – which affected the development of AMCo’s own 10mg “immediate release” hydrocortisone tablets. It was for that reason Waymade, and then AMCo, entered into the supply arrangement with Auden.<sup>70</sup>

47. As we have already noted, Mr Sully expressed the view that the 10mg Agreement’s purpose was to achieve a supply of hydrocortisone to AMCo pending resolution of its own development issues.

(iii) The First Written Agreement and its negotiation

48. Turning, then to the First Written Agreement, this is an “Own Label” product supply agreement between Auden and AMCo, which has an effective date of 24 January 2013.<sup>71</sup> The agreement has a term of 15 months.<sup>72</sup> Given that the CMA does not find that the First Written Agreement is, of itself, infringing the Chapter I prohibition, and that the agreement – if it existed – not to enter the market lay outside the First Written Agreement, there is little point in parsing its provisions in any great detail. However, we note the following points:<sup>73</sup>

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<sup>69</sup> Sully 1/30 to 43.

<sup>70</sup> The difficulties in supply are described in Sully 1/27 to 28.

<sup>71</sup> Clause 1.1 of the First Written Agreement says January 2014. This is inconsistent with the date on the first page of the agreement, which states the effective date as being “1 January 2013”. That this is the correct effective date is confirmed by clause 1.28, which defines the term of the agreement as being “a period of fifteen (15) months from the Effective Date (i.e., until the end of March 2014)...”.

<sup>72</sup> Clause 1.28.

<sup>73</sup> Mr Sully describes the negotiations that resulted in the First Written Agreement at Sully 1/45ff.



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- (1) The arrangement was intended to be an exclusive one, in that AMCo would procure all its requirements for 10mg “immediate release” hydrocortisone from Auden during the term of the agreement.<sup>74</sup> The supply, by Auden, would be on a non-exclusive basis.<sup>75</sup>
- (2) The agreement made provision for AMCo to amend its Marketing Authorisations so as to become an “own label” distributor of the product. Provision was made for the creation of AMCo “trade dress”, whereby its product would be differentiated from the (identical) product that would be supplied by Auden to AMCo and elsewhere.
- (3) The agreement is framed so as to oblige AMCo to sell and achieve certain monthly volumes. Thus, clause 5.1 provides:

“[AMCo] shall use reasonable commercial endeavours to market and sell the Product in the Territory during the Term of this Agreement and to order and acquire the estimated monthly volumes set out in Schedule A.”

Schedule A provides that 6,000 packs will be ordered per month, at the price (paid by AMCo to Auden) of £1/pack. It goes without saying that the language of obligation in clause 5.1 sits uneasily with the purpose of the agreement (to supply AMCo for AMCo’s purposes) and with the price stated. An obligation to sell a product at a rate of above £1/pack is scarcely onerous at all, and only serves to underline who was the winner, and who was the loser, under this arrangement. Given a market price of £30/pack – which is conservative – AMCo’s margin per month would be £174,000.<sup>76</sup>

- (4) Similarly dissonant with the purpose of the agreement as articulated by Mr Sully is clause 6.1:

“Throughout the term of this Agreement, [AMCo] shall supply Auden with a 12 month’s rolling forecast (to be provided and then updated monthly by the last working day of each month of the Term) for its requirements for the Product (“Forecast”). The first three (3) months of each Forecast shall be deemed to be firm orders. The remaining nine (9) months of the Forecast shall be non-binding estimates. [AMCo’s] estimated monthly order quantities are shown in Schedule A and Auden agrees to use all reasonable commercial efforts from the Effective Date to accept those levels.”

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<sup>74</sup> Clause 3.2.

<sup>75</sup> Clause 3.3.

<sup>76</sup> I.e. £30 less £1 to Auden multiplied by 6,000.

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Again, this is in tension with the stated purpose of the agreement which was to supply AMCo, not to enable Auden better to supply the market for its own purposes. It is also not how the agreement was performed. We are not aware that any Forecasts were submitted, and the evidence was clear that AMCo were keen to obtain more quantities than the 6,000/month specified in Schedule A; but that Auden were (unsurprisingly) less keen to provide these.<sup>77</sup>

49. According to Mr Sully, negotiations with Mr Amit Patel were difficult. The following gives a flavour:

“57. On 14 January 2014, in an internal email, Guy Clark (who John Beighton had put in charge of the potential acquisition [of Auden]), updated a number of us on a call in which Amit Patel had implied that, if AMCo did not make an offer to purchase Auden’s hydrocortisone business soon, “he therefore wouldn’t sign the supply agreement and had threatened that he would “take action to protect his product by advising all parties (mentioning DoH and MHRA amongst others, including major multiples) that [AMCo’s] product should not be dispensed against generic prescriptions”. When we received the letter from the MHRA in April 2015 (referred to above), I recall thinking that this was exactly what Auden had been threatening in January 2014.

58. I remember discussing Auden’s approach with John Beighton and Guy Clark, and there was a real dislike for what we felt were attempts by Auden to blackmail us into purchasing his business. In January 2014, I wrote internally: “We had hoped to be able to secure continued supply of hydrocortisone [from Auden] until our [Aesica] product hits the market, but I don’t like the way that things are progressing and I don’t much like what I hear about Amit [Patel of Auden].”

59. A decision was made to bring our dealings with Auden in respect of the supply agreement to a close. I drafted an email to be sent to Brian McEwan to Amit Patel to retract our offer to contract on the existing draft of the supply agreement that had been provided, and to express our frustrations, as follows:

“I understand you have called Guy [Clark, of AMCo] today to say that you are not willing to sign the supply agreements, or accept any orders, unless and until AMCo agrees to acquire your hydrocortisone product. I also gather you made various noises about approaching the DOH and the MHRA with respect to our MA, alleging that it is inferior.”

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<sup>77</sup> See, for instance: Sully 1/51: “We had hoped to use the negotiations to increase the volumes supplied under the interim 10mg HT supply agreement but this was rejected outright...”. Given the limited demand, every pack supplied by Auden to AMCo would have meant one less pack Auden could sell directly to the market. This was not a case where the First Written Agreement could be used by Auden to expand the market using AMCo’s efforts, and this was never stated to be the purpose of the First Written Agreement. The purpose of the First Written Agreement was to supply AMCo.

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60. Around the middle of January 2014, there appeared to be more positive reports that Aesica would be able to resolve the manufacturing issues and supply fully compliant and saleable product. Indeed, by 19 February 2014, it appeared that Aesica had completely overcome the assay issues in the manufacture. Although this turned out to be inaccurate, since Aesica continued to have problems as explained below, it re-affirmed our decision to bring the supply agreement with Auden to a close.
61. Accordingly, on 24 January 2014, I created drafts in which the term of the interim supply agreement was set to expire on 31 March 2014. I recorded this in a contemporaneous internal email on 24 January 2014, where I said that, “we will document the agreement to date, and will bring it to a close...This mean [sic] that we achieve the clarity that Pinsents advised, plus we end the arrangement as we get ready to launch our own hydrocortisone from Aesica.”
50. A number of matters can be drawn from this:
- (1) First, Mr Amit Patel was not acting altruistically. He was seeking, at this point, to leverage AMCo’s need for 10mg “immediate release” hydrocortisone into a means of persuading AMCo (or the group of which AMCo was a part) to buy Auden.
  - (2) Secondly, Mr Sully was not seeking to regularise a forward-looking agreement, but rather bring to a close what he saw as an irregularly documented arrangement. That explains the issue with dates in the First Written Agreement. The First Written Agreement was negotiated well after its effective date of 24 January 2013, in early 2014 and was essentially backward-looking. Its forward-looking duration was measured in weeks.
  - (3) Thirdly, the reason for this limited forward-looking approach was AMCo’s confidence that it would have a viable product to bring to market (i.e. its own 10mg “immediate release” hydrocortisone, sold under its own Marketing Authorisation). What Mr Sully did not tell us was the extent to which this fact was used or disclosed in negotiations with Mr Amit Patel. AMCo’s thinking is expressed by Mr Sully in these terms:<sup>78</sup>

“AMCo had been exchanging drafts of the agreement with Auden (reflecting the different purposes of the agreement at different times) between November 2013 and February 2014. On 25 February 2014, Auden and AMCo finally signed a written agreement for the supply of Auden’s full indication 10mg HT (the “First Written Agreement”). The First Written Agreement was expressed to be retroactive to 1 January 2013 (the date when Cinven took full control of the Amdipharm business from

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<sup>78</sup> Sully 1/64.

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Waymade) and it was expressed to expire on 31 March 2014, in line with management’s expectation at the time that Aesica would soon be in a position to successfully manufacture and supply AMCo.”

We consider that it is likely that Mr Amit Patel was induced to sign the First Written Agreement on the basis that it was commercially meaningless or insignificant, regulating (as it did) only one month’s prospective supply. We also consider that it is likely that this would have been appreciated by AMCo, given the hard-nosed approach that Mr Amit Patel had previously adopted.

(iv) The need for the Second Written Agreement

51. The Second Written Agreement arose out of what Mr Sully described as “multiple set-backs”:<sup>79</sup>

“In April and May 2014, after the First Written Agreement expired at the end of March 2014, we suffered multiple set-backs and the situation became increasingly difficult as I explain in the sub-sections below:

- 67.1 Aesica’s inability to resolve the manufacturing issues continued and the estimated date for supply kept on being delayed, despite AMCo’s pressure on Aesica;
- 67.2 We were going out of stock of Auden’s full indication 10mg HT and had to obtain bridging stock from Auden in order to maintain a foothold in the market;
- 67.3 We tried many other routes to market in order to get around the [Orphan Drug issue]<sup>80</sup> but were not successful;
- 67.4 Our UK Commercial Director approached our customers hoping to generate orders in anticipation of launch, but our customers said that they were not interested in a reduced indication (child’s version) 10mg HT, making clear to us the effect of the [Orphan Drug issue] on market receptivity; and
- 67.5 Given the circumstances, we sought further external legal advice about how to proceed, which led to the Second Written Agreement.”

52. We will return to some of these pressures on AMCo – for that is what they were – in due course. For the moment, it simply needs to be noted that (i) Auden had negotiated hard during the course of agreeing the First Written Agreement and (ii) AMCo were in an even weaker negotiating position, in that they could not even count on a supply of

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<sup>79</sup> Sully 1/67.

<sup>80</sup> A point that we will come to.

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“skinny label” 10mg hydrocortisone.<sup>81</sup> Mr Sully describes alternative routes to market: it is unnecessary to set these out, but it is necessary to note that they failed.<sup>82</sup>

53. It would appear that two, equally telling, concerns weighed on AMCo at this time: (i) the absence of supply of any hydrocortisone tablets at all; and (ii) the fact that, even if Aesica produced hydrocortisone tablets for AMCo to sell, these would be “skinny label”. These dual concerns emerge clearly from the evidence of Mr Sully.<sup>83</sup> Judging by the terms on the minutes of an AMCo Board meeting on 30 April 2014, the latter appears to have been the more serious:<sup>84</sup>

“As the minutes of the AMCo Board meeting on 30 April 2014 record:

“The legacy [Auden] oral arrangements had been put into written form, with the advice of Pinsent Masons, and had then been brought to an end on 31 March 2014. However, Mr Beighton advised that there was still an on-going issue with hydrocortisone, since the Aesica product that was being developed by Amdipharm Limited did not have the adrenal insufficiency indication that was protected by Orphan Drug status” and “that there was nothing that could [be] done to challenge this [Orphan Drug] status which protected the Auden product.”

54. There is a singularity in this statement of AMCo’s position that is difficult to accept. As we have described, the First Written Agreement was given an early termination date of the end of March 2014 precisely because AMCo were, at that time, confident that supplies from Aesica would come through. However, those supplies would always have been skinny label, because this was not a manufacturing issue, but an issue to do with AMCo’s Marketing Authorisation, which was not going to change. In other words, if AMCo’s concern was in relation to “skinny label” supply, it is difficult to understand why that concern faded such that the First Written Agreement terminated as it did, only for the same concern to resurrect itself a month or so later.
55. This is a point to which we will return. It is, at this stage, necessary to articulate the evidence regarding AMCo’s “skinny label” concern.

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<sup>81</sup> As Mr Sully himself noted (Sully 1/69), “running out of stock is a serious matter”.

<sup>82</sup> Sully 1/71 to 76, in particular 76.

<sup>83</sup> For instance, Sully 1/80.

<sup>84</sup> Sully 1/81.

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(v) Plenadren, Orphan Drugs and AMCo’s “skinny label” MA

56. AMCo knew more-or-less from the point of acquisition of Waymade’s Marketing Authorisation that Waymade’s 10mg hydrocortisone tablets MA had one indication only, namely “replacement therapy in congenital adrenal hyperplasia in children” and not in adults.<sup>85</sup> AMCo had been told – as early as November 2013 – that their intended patient information leaflet for their hydrocortisone product was unacceptable to the MHRA because it suggested that it might be used for adults, which was not authorized.<sup>86</sup> Unsurprisingly, AMCo found the implications of a “skinny label” MA concerning, and AMCo sought to test the limits of the regime.<sup>87</sup> By December 2013 – well before the conclusion of the First Written Agreement – Pinsent Masons had advised AMCo that “the [Orphan Drug Issue] could not be challenged in any way.”<sup>88</sup>
57. Mr Beighton “did not believe that the HT Market could be closed in this way and instructed us to keep looking for ways around this OD Issue and, in the meantime, to continue the interim supply of full indication 10mg HT product from Auden on the basis of the arrangements that I was in the process of documenting...”<sup>89</sup>
58. In these circumstances, it is puzzling that AMCo should have so readily acceded in an end March 2014 conclusion for the First Written Agreement. Mr Sully’s explanation is that “it was not until April/May 2014, when our customers told us that they were not interested in reduced indication (children’s) 10mg HT, that the reality of the situation really hit home”.<sup>90</sup>
59. This realisation is explained more fully by Mr Sully as follows:<sup>91</sup>
- “77. During this period [i.e. April/May 2014], AMCo’s Commercial team approached our key customers, including our main customer Alliance, hoping to generate orders in anticipation of having launch-ready product from Aesica in the coming months. I recall that in May 2014, John Beighton approached me about this feedback and was very alarmed. I got the impression that he had finally realised the gravity of the OD Issue. I was also informed by Jane Hill, our UK Commercial Director, that she had approached several customers who had said they were not interested in buying our reduced

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<sup>85</sup> Sully 1/30.

<sup>86</sup> Sully 1/33.1.

<sup>87</sup> Sully 1/34 to 37.

<sup>88</sup> Sully 1/38.

<sup>89</sup> Sully 1/42.

<sup>90</sup> Sully 1/43.

<sup>91</sup> Sully 1.

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indication Aesica product. She subsequently showed me the email she received on 29 May 2014 from Day Lewis.

78. This position in April and May 2014 continued until we received our first customer interest in April 2016, as I explain below.
79. I also learned more in early 2014 about the ABPI Code and the prohibition on promoting a medicine for “off label” use. Accordingly, I knew that we were not allowed to market or sell our reduced indication product as a substitute for the Auden product.”
60. As Mr Sully recognises, the Orphan Drug problem persisted.<sup>92</sup> However, given the effect of the Orphan Drug regulation and the advice Mr Sully had received from Pinsent Masons, he can have had no reasonable expectation of any other outcome. We consider that AMCo will have proceeded on the basis that their Marketing Authorisation would – until the expiry of the period of protection accorded to Plenadren – have continued to be skinny label.

(vi) Conclusion of the Second Written Agreement

61. There was obviously a sensitivity in regard to this proposed agreement. Mr Sully says this about the process leading to the conclusion of the Second Written Agreement:<sup>93</sup>

“Pinsent Masons reviewed the situation and advised that it would be compliant and permissible for Auden and AMCo to enter into a new supply agreement for Auden’s full indication 10mg HT product for adults and children. Pinsent Masons advised on 30 May and, again, on 6 June 2014 that: “from a competition law perspective”, Auden and AMCo “would not be considered competitors whilst the orphan designation was in place”. In the same email chain, Pinsent Masons also noted that “As a result of the orphan designation, AMCo has decided that the best commercial option is to source 10mg supply from Auden whose product is capable of being marketed for adrenal insufficiency.”

62. We make two points about this. First, it is our conclusion that skinny label and full label hydrocortisone are substitutes and that – to this extent – Pinsent Masons’ advice was wrong.<sup>94</sup> However, secondly, this error is not material provided AMCo did not promise to keep a rival product off the market: AMCo, of course, are adamant that no such promise – however vague – was ever made.

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<sup>92</sup> See the heading above Sully 1/103, although the point is not discussed in paragraphs under this heading.

<sup>93</sup> Sully 1/83.

<sup>94</sup> Not only is this the conclusion expressed in the Judgment (Abuse of Dominance Infringements), but it also clear from the evidence in the case. See, for instance, [128] and [129].

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63. In terms of negotiating the Second Written Agreement:

- (1) Mr Sully took the lead – albeit with the benefit of legal advice – in negotiating the terms,<sup>95</sup> apart from in relation to “value and volume of supply” (the critical issues), where Mr Beighton took the lead.<sup>96</sup>
- (2) The Second Written Agreement is dated (as the “Effective Date”) 25 June 2014. The agreement is broadly similar to the First Written Agreement, and had a term of two years from 25 June 2014.<sup>97</sup> Although AMCo’s obligation to purchase from Auden was exclusive, in that “Amdipharm shall procure all its requirements in the Territory for hydrocortisone product(s) in tablet and capsule formulation from Auden on an exclusive basis”,<sup>98</sup> “nothing in this Agreement prevents Amdipharm and/or its Affiliates from applying at any time for a marketing authorisation from the MHRA in relation to a hydrocortisone product (whether in tablet, capsule or other formulation) and/or manufacturing (either itself or through a contract manufacturer) and supplying in the Territory hydrocortisone product(s) under a licence granted to it or any of its Affiliates provided that Amdipharm shall not and shall procure that none of its Affiliates shall do so directly or indirectly without giving give [sic] Auden at least three (3) months’ written notice of its intention to do so.”<sup>99</sup>
- (3) In his witness statement, Mr Sully stressed that “AMCo would be expressly free to continue its endeavours to bring its own hydrocortisone product to market by whatever means (whether via Aesica/MIBE/Dermapharm or via an acquisition, including of Plenadren which was under consideration at the time)”.<sup>100</sup> We accept this: but the price paid for this freedom (assuming it existed) was an obligation to notify Auden of AMCo’s plans, with a minimum of three months’ notice. There was thus, in-built into the Second Written Agreement, an

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<sup>95</sup> Sully 1/84.

<sup>96</sup> Sully 1/84.

<sup>97</sup> Clause 1 of the Second Written Agreement and the definition of “Term”.

<sup>98</sup> Clause 2.2 of the Second Written Agreement.

<sup>99</sup> Clause 2.2 of the Second Written Agreement.

<sup>100</sup> Sully 1/86. See also Sully 1/88. Of course, these are merely the terms of the Second Written Agreement. The Hydrocortisone Decision found that additional terms had been agreed, and that to this extent the Second Written Agreement was a “sham”. Although we make no findings at this stage, it is obviously necessary to treat the terms of the Second Written Agreement with some care.



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obligation on AMCo to provide market intelligence to Auden with regard to AMCo’s competitive entry onto the market.<sup>101</sup>

- (4) Schedule A to the Second Written Agreement sets out the price (£1.78) that AMCo was to pay for product from Auden and the monthly quantities to be received (12,000/month). We will come to the manner in which price/quantity was negotiated in due course. For the present, we would only observe that – as with the First Written Agreement – there is a mismatch between what was in fact going on (AMCo was receiving a considerable amount of product at a massive discount, so that it could sell into the market at high margins that it would retain), and what the Second Written Agreement records. Thus, clause 4 of the Second Written Agreement provides:

“4.1 Amdipharm shall use reasonable commercial endeavours to market and sell the Product in the Territory during the Term of this Agreement and shall order and acquire the Minimum Volume set out in Schedule A.

4.2 Amdipharm shall distribute the Product in the Territory in accordance with all legislative requirements and applicable industry codes of practice in the Territory and shall comply with the terms of the Marketing Authorisations.”

Mr Sully explains the extraordinarily beneficial terms (to AMCo) in this way:<sup>102</sup>

“As with the First Written Agreement, the per pack supply price was based on Auden’s role being akin to that of a CMO. As preamble C to the Second Written Agreement described: “...Amdipharm wishes to engage Auden to manufacture and supply the Product on the terms of this Agreement and Auden wished to manufacture and supply the Product to Amdipharm on the terms of this Agreement”. At that time our cost of goods for Aesica were £1.17/per pack, so Auden’s cost of goods was higher than our expected Aesica costs, not lower.”

We regard this as an entirely insufficient explanation of the terms of the Second Written Agreement:

- (i) This was a two-year forward-looking agreement, and the question that must be asked is why Auden would choose to behave in the manner of a CMO to a rival, when it was perfectly capable of selling on its own

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<sup>101</sup> Notification gave Auden the option to bring the Second Written Agreement to an end on three months’ notice to AMCo: clause 17.2 of the Second Written Agreement.

<sup>102</sup> Sully 1/85.

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account and keeping for itself the margin that AMCo would earn under this arrangement.

- (ii) There was no equivalence between AMCo receiving a supply of product from Auden and AMCo receiving a supply of product from Aesica. That is because the Auden product came with the benefit of a Marketing Authorisation, whereas the Aesica product did not. Although we accept that these products would be pharmacologically the same, the former (the supply from Auden) would be sold by AMCo under Auden’s MA, whereas the latter (the supply from Aesica) would have the benefit of no MA save AMCo’s own – which was “skinny label”. There was, therefore, an enormous difference between the two sources of supply, and to treat Auden and Aesica as rival CMOs is at odds with the reality of the case. Given the appreciation, on the part of AMCo, of the problems of its “skinny label” Marketing Authorisation,<sup>103</sup> we do not accept the explanation provided by Mr Sully for the terms of the Second Written Agreement.

64. The Second Written Agreement was reported by Mr Sully to the board of AMCo as dealing not with the supply problem from Aesica (which the Second Written Agreement could resolve) but with the problem of the limits on AMCo’s own Marketing Authorisation (which the Second Written Agreement could only resolve if it was a permanent solution).<sup>104</sup>

65. Mr Sully was also, clearly, conscious of the fact that Auden and AMCo were competitors (contrary to the (incorrect) advice received from Pinsent Masons that “skinny label” and “full label” hydrocortisone were not competing):<sup>105</sup>

“In view of AMCo’s ongoing projects towards independent entry, following the conclusion of the Second Written Agreement, I was careful to establish “firewalls” in order to ensure that those responsible for the Aesica or other development projects and those managing the supply relationship with Auden conducted themselves entirely independently of each other...The firewalls meant that all communication with Auden had to be through the legal and supply chain teams only, so that there was no commercial or business development team interaction with Auden.”

66. It was common ground that AMCo had production problems in regard to its own hydrocortisone product. According to Mr Sully, its manufacturer, Aesica, let AMCo

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<sup>103</sup> See Sully 1/56 to 60.

<sup>104</sup> Sully 1/93 and 94.

<sup>105</sup> Sully 1/94.

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down. Mr Sully was very clear in his evidence that these problems were of Aesica's making, not AMCo's, and that AMCo wanted to have the capability of bringing a product to market quickly.<sup>106</sup>

67. The CMA sought to contend that AMCo deliberately slowed down Aesica's processes, and cross-examined Ms Lifton on this basis. The point we think the CMA was seeking to make was that a deliberate slowing down of Aesica's processes by AMCo was evidence of the agreement to stay out of the market that the CMA had found in the Hydrocortisone Decision.<sup>107</sup> We do not think that this actually follows: AMCo's position in promising to stay off the market (which is what the CMA found) would have had far more traction if AMCo had actually been able to enter the market. A promise – or threat – to do something that cannot be done is empty. It is our view that AMCo seeking to be able to enter the market independently is either neutral as to whether there was a promise to stay out of the market or else points in favour of the findings in the Hydrocortisone Decision.
68. This is a point that we will return to. For the present, we should note that Ms Lifton's evidence – the evidence of a third party – was unequivocal: the fault was that of Aesica, not AMCo.<sup>108</sup>

**Q: Ms. Demetriou, KC**

I understand, but does that now make you -- does that now make you think -- so your statement is -- you say in your statement, well, Aesica were pushing this -- sorry, AMCo were pushing this forward very, very quickly, but do you now see that was not always the case?

**A: Ms Lifton**

No, it is still not how I understood that project to be. I was intimately involved in that project and I never ever felt that they were stalling or.... They were pushing. They were pushing. So I...no, it is not my recollection of it. I do not know about their internal...I cannot comment on their internal things, but that...I was the project manager and, as far as I was concerned, they wanted the product, they wanted

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<sup>106</sup> Mr Sully is very clear in his evidence that these were problems of Aesica's making, and that AMCo was not responsible for the delays: Sully 1/67.1, 68 and 103 to 105.

<sup>107</sup> The CMA certainly did not make this point in closing, but that was because Ms Lifton denied in clear terms the point being put to her by the CMA in cross-examination, leaving the CMA nowhere to go in closing. However, the point that the delay was caused by AMCo was the clear (indeed only) objective of the cross-examination of Ms Lifton. The fact that there was delay was not in dispute by anyone. What was in dispute – and which was explored in cross-examination – what why there was delay. Here, the CMA put their case, and Ms Lifton repudiated it in no uncertain terms.

<sup>108</sup> Day 4/pp. 93 to 94.

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it as soon as possible and we were having great difficulty delivering it to them.

**Q: Ms. Demetriou, KC**

So where they say – where Mr Middleton has said here: “Aesica are chasing for an answer”. You do not remember that?

**A: Ms Lifton**

No, I mean that is likely to be Aesica commercial team, sales team, and they would always push, because all they were interested in was getting the money into the company. So... yes, that is not – that is nothing to do with me. That is commercial.

**Q: Ms. Demetriou, KC**

But do you accept now, stepping back, that you asking for a decision on packaging at the end of September 2013 and then not getting a response until January 2014 that that really cannot fairly be described as pushing the project forward? That is a delay, is it not, Ms Lifton?

**A: Ms Lifton**

I – no, I disagree, because there is not – when you make decisions about how to progress there are – there would be a number of considerations as well, because if they were – they would not be making – they would be investigating what they would need to submit a variation, what data they would need. There would be – I could see why it would take time to make that decision.

69. We accept the evidence of Ms Lifton and find that any delays in bringing the product Aesica were manufacturing to market cannot be laid at the door of AMCo. To the extent that anyone was at fault, it was Aesica.

**(g) *The process of agreeing quantity and price under the First and Second Written Agreements***

**(i) Introduction**

70. Although a number of people were involved in the supply of hydrocortisone from Auden to Waymade and then AMCo, we only heard evidence from two: Mr Sully and Mr Beighton. Mr Sully, as we have described, could assist on a large number of matters, but not on the negotiation of prices and quantities under the First and Second Written Agreements.<sup>109</sup> Although we have no doubt there are others who could give evidence

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<sup>109</sup> The First Written Agreement followed the terms of the anterior oral agreement, which was not negotiated by Mr Sully. The relevant parts of the Second Written Agreement were not negotiated by Mr Sully but (in whole or in part) by Mr Beighton.

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on the point, the only person we heard from was Mr Beighton. It is on Mr Beighton’s evidence that we therefore focus.

(ii) Mr Beighton’s knowledge and understanding of the market

71. Mr Beighton had a clear and sophisticated knowledge of the markets in which he was operating. This is evidenced by an exchange where Mr Beighton explained the approach he would have taken if AMCo had been in a position to enter the market for “immediate release” hydrocortisone tablets in competition with Auden. The evidence that we quote did no more than repeat – in terms helpfully responsive to the questions put to him – the content of Beighton 1/85:<sup>110</sup>

**A: Mr Beighton** ...Typically what happens in these circumstances when only one competitor comes to market and this is – remember I am a generics guy so I am used to bringing these products to market. Usually there are – when a patent expires, there are or competitors come out, coming in at the same time and the market immediately shoots down to barely above cost of goods. In a situation like this where only one competitor comes in, clearly depending on the – how rational that competitor is, he or she, me, would have come in with Hydrocortisone, for example, at a discount of whatever I felt was needed to take half of the business. I would not go for more than that for rational reasons, because I did not want to see the competitor backlashing in some way and then ending up in that downward spiral just between the two of us. So I would take 50% at, let us say a 10% or 15% discount. So there is obviously always a danger that Auden McKenzie in this circumstance start fighting with me and we end up just at cost of goods, but I do not think that would have happened. That sort of thing usually happens when the competitor is – does not really care too much or they've got – they have so many other products. They've got junior product manager looking after them. In this case, Mr Patel would have been very eager to have maintained the value in his business, I am sure.

**Q: The President** So...

**A: Mr Beighton** So do you see? What I am trying to say is that the price in this case would not have dropped substantially.

**Q: The President** You would not have had the spiral down to just above cost in your view?

**A: Mr Beighton** Yes, exactly, and I think it is a proven view with lots of evidence supporting that that does not happen with two competitors.

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<sup>110</sup> Day 3/pp.49 – 52.

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- Q: The President** Putting ourselves for a moment, and I appreciate that we are speculating here, in Auden's shoes, they might – if your product entered the market at, say, a 10% to 15% discount on their price, they might have stuck at their existing price.
- A: Mr Beighton** Yes.
- Q: The President** Provided they maintain their 50% market share on that basis.
- A: Mr Beighton** Exactly.
- Q: The President** But if the nature of the demand was such that a 10% to 15% discount for what is in effect the same product results in a move away from Auden's product to yours, such that you get -- and I am sure you will be very pleased about this – 80/90% rather than 50%, then you would have to reconsider your position as Auden?
- A: Mr Beighton** He would, though I think that what my position would be, as the competitor, as I have been on a number of occasions, is not to go for - - not to take 80% or 90% of the market, but to take half of it.
- Q: The President** Indeed. What I am putting to you is you might have the intention at a 10%/15% discount on the competitor rate to only get 50%, but you cannot be 100% absolutely confident?
- A: Mr Beighton** You cannot. With pharmaceutical supply chains you put your forecast in, you say how much stock you have got and you cannot just turn on the tap. So you have to forecast well in advance of how many – how much product you are going to sell, so, effectively, you would only be able to sell 50% of the market.
- Q: The President** It is Keynes' point about in the long run we are all dead. You are saying that in the short run the ability to take over the market on your part is going to be constrained by how much you produce.
- A: Mr Beighton** Choose to produce.
- Q: The President** Choose to produce, indeed.
- A: Mr Beighton** Yes.
- Q: The President** But, of course, if they're flying off the shelves, then you will choose to produce more after the short term.
- A: Mr Beighton** There is a balance, isn't there, because what I do not want to do is to provoke the other party to have this downward spiral.

Thus, Mr Beighton disagreed with the suggestion (put to him by the President) that in the longer term a rival to an incumbent would increase supply in this market.<sup>111</sup> Supply would be unilaterally limited by the competitor, according to Mr Beighton, in order to

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<sup>111</sup> Other markets – with a more elastic demand – would be different. Here, however, demand was constrained by medical need as articulated by prescriptions from doctors.

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avoid a price war and to maintain margin for both the incumbent and the competitor. We accept this evidence as an accurate description of how this market worked where there was an incumbent and a single competitor entering this type of market.

(iii) Mr Beighton’s appreciation of the dangers of conversations with competitors

72. The AMCo Competition Law Compliance Manual, which Mr Beighton circulated to all employees in March 2013, set out “essential safeguards” for contacts with competitors, including agendas, minutes recording each meeting, and taking legal advice on proposed initiatives. Mr Beighton did not comply with these safeguards in his meetings with Mr Patel – which he accepted.<sup>112</sup>

(iv) Mr Beighton’s awareness of the pre-First Written Agreement arrangements

73. Mr Beighton was aware of the arrangements between Auden and AMCo from about the time at which AMCo acquired Waymade’s hydrocortisone capability:<sup>113</sup>

“...I recall being informed that an MA had been granted for Waymade’s 10mg HT as a line extension to its 20mg HT MA, and that whilst a number of manufacturing issues with its product were being resolved with its CMO, Aesica, Waymade had arranged an own label supply (“OLS”) of HT from Auden. I think I was informed by Vijay Patel of Waymade, around the time the acquisition completed although I cannot be sure after all this time.”

74. Mr Beighton was informed that the price under the pre-First Written Agreement arrangement with Auden was “in the region of £1/pack”.<sup>114</sup> In his witness statement, Mr Beighton explained that this “reflected a price that was very close to the price of £1.16, that Aesica would charge to manufacture Waymade’s 10mg HT product. In light of the ongoing work I understood still needed to be done by Aesica on the development and manufacture of Waymade’s 10mg HT product, it seemed to me an ordinary interim OLS arrangement.”
75. In short, Mr Beighton’s witness statement was that the Second Written Agreement was commercially completely explicable. The problem with the explanation is that OLS arrangements involve the manufacture of a medicinal product that the manufacturer cannot themselves sell into the market. They require a marketing authorisation to do so, which is where the value in the medicinal product lies. No doubt many people are

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<sup>112</sup> Day 3/pp. 10 to 11.

<sup>113</sup> Beighton 1/23.

<sup>114</sup> Beighton 1/25.

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capable of producing medicinal products, but they cannot legally be sold without a Marketing Authorisation. Auden, of course, had exactly such a Marketing Authorisation: Aesica did not. Auden could sell to the market; Aesica could not. Of course, Auden might, as a manufacturer, choose to sell its product via wholesalers, but it would expect to pay a price for this commensurate with the value added by the wholesaler – which would be distribution. One would not expect substantially all of Auden's margin to be transferred to AMCo, if this were the arrangement.

76. Mr Beighton acknowledged, in cross-examination, that Auden's behaviour was inexplicable.

**Q: Ms Demetriou, KC<sup>115</sup>** Is that normal in your experience for one company to effectively transfer a lot of its profits to another company for nothing in return?

**A: Mr Beighton** I thought it was very odd, very odd.

**Q: Ms Demetriou, KC** You thought it was very odd?

**A: Mr Beighton** Yes, and throughout the whole term of this period on this deal, I found it quite odd that Auden McKenzie were prepared to continue supplying us.

...

**Q: Ms Demetriou, KC<sup>116</sup>** This is the transcript. What happened under the deal with Auden was that instead of the product going from Tiofarma to Auden to the wholesaler it went from Tiofarma to Auden to AMCo and then to the wholesaler, yes

**A: Mr Beighton** It did, yes

**Q: Ms Demetriou, KC** So the move from Auden to AMCo was essentially an unnecessary move, was it not, from Auden's perspective?

**A: Mr Beighton** In my opinion it was, though obviously to use your words, sir, it was a gift horse that I was presented with and we were able to then use that as a bridging arrangement until we were able to launch our own product which...

**Q: Ms Demetriou, KC** We will come on to that. If we go back to paragraph 24 of your witness statement you say that the rationale for an MA holder entering into this kind of arrangement would be to keep its own CMO costs of goods down by ensuring higher manufacturing volumes, yes?

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<sup>115</sup> Day 2/p.135.

<sup>116</sup> Day 2/pp.135 – 154.



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- ...
- Q: Ms Demetriou, KC** But it is not your evidence, is it, that Auden wanted the deal with Waymade and then with AMCo to increase its volumes of 10mg tablets and therefore secure a better price from Tiofarma. That is not your evidence, is it?
- A: Mr Beighton** I am not saying that, no
- Q: Ms Demetriou, KC** In fact it would not make sense, would it, because Auden was the only supplier of 10mg tablets so it was supplying the whole market anyway?
- A: Mr Beighton** Yes.
- Q: Ms Demetriou, KC** So what you are saying is a hypothetical. It does not fit the facts of this case, yes?
- A: Mr Beighton** Hypothetical? If a manufacturer's volumes drop for whatever reason then probably their costs per unit will go up.
- Q: Ms Demetriou, KC** But I think you have agreed that that does not fit the fact pattern of this case so that would not have been Auden's interest in supplying this product because it was already supplying the whole market so it did not need to --
- A: Mr Beighton** I see. If Tiofarma's volume stays the same, then the costs will stay the same
- Q: Ms Demetriou, KC** Yes, so -- sorry -
- Q: The President** I think what counsel is putting to you is that what you are here saying whilst it might in other cases hold true is not a sufficient explanation for Auden's conduct in this matter
- A: Mr Beighton** Sorry, for Auden's conduct, no, I agree, sorry.
- ...
- Q: Ms Demetriou, KC**<sup>117</sup> So this increase, threefold increase in the supply, was obviously contrary to Auden's commercial interest, was it not?
- A: Mr Beighton** Look, I think I have suggested this before. If I had been Mr Patel, I would not have done this, but he did. It was an arrangement, as you can see from previous documents, that somehow Vijay had persuaded Amit to do this deal. We inherited it. As I think I have said, I asked Mr Sully to investigate, to check that everything was okay with it and we just continued with it.
- ...

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<sup>117</sup> Transcript Day 2/p.163.

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**Q: Ms Demetriou, KC**<sup>118</sup> Mr Beighton, I want to ask you what -- Mr Sully yesterday speculated as to what might have been in Mr Patel's head so he had various things that he shared with us. Are you saying that you just did not give it any thought at all

**A: Mr Beighton** I gave it thought, but I did not speculate. I really -- this was -- I asked Rob to sort out the agreements to make sure that they were legal, because, as you say, it just looks a bit odd, but apparently it was.

...

**A: Mr Beighton**<sup>119</sup> I have been invited on a number of occasions to put myself into Mr Amit Patel from Auden's mind, and I have tried to and I just do not get why he would do this, unless there was some, I do not know, somehow Mr Vijay Patel or somebody else in Amdipharm was able to persuade him for some other reasons.

...

**Q: Professor Mason**<sup>120</sup> Mr Beighton, I would be grateful if you could just elaborate a little bit on your understanding of the purpose of the rebate arrangement and anything that you can recall about any reasons that Mr Patel gave for wanting a rebate arrangement.

**A: Mr Beighton** No. I do not remember why he said he wanted it. I certainly cannot even now think of a reason why he might have. There was a practice many, many years ago when NHS list prices were -- NHS pharmacy reimbursement prices were based on list prices of certain products. So the generics industry used to have list prices at a relatively high level, much higher than the actual selling price, so that their customers could have the profit in between. The Department of Health, quite rightly, wiped that out over time, but why Mr Patel wanted his, I really do not know. I cannot think why.

77. Mr Beighton was fully aware of Aesica’s manufacturing problems, and the problems this was causing AMCo.<sup>121</sup> Mr Beighton’s thinking was as follows:<sup>122</sup>

“...I considered it commercially beneficial to have an interim supply arrangement with Auden for its 10mg HT whilst AMCo progressed its projects for the development and manufacture of

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<sup>118</sup> Transcript Day 3/p.167.

<sup>119</sup> Day 3/p.45.

<sup>120</sup> Day 3/p.59/– 60.

<sup>121</sup> See, e.g., Beighton 1/27.

<sup>122</sup> Beighton 1/28.

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its own 10mg HT and securing the necessary MAs. That would enable us to begin to be seen by our customers as a reliable supplier of 10mg HT, which would position us excellently for the successful launch of our own hydrocortisone product. As to the price, as I have described above, I was aware of the supply price Waymade had negotiated with Auden and I was aware of the price Aesica would be charging AMCo to manufacture what was now our 10mg HT product (£1.16), I was not going to volunteer to pay Auden more to supply AMCo.”

78. Of course, one can entirely appreciate that every sensible businessman would not wish to offer in payment more than would be acceptable to the counterparty to achieve a deal. But – as we have emphasised a number of times now – Auden’s conduct is simply impossible to understand, and Mr Beighton’s rationalisation does not come close to explaining Auden’s willingness to accept so low a price and concede massive margins to AMCo. This, we consider, would have been obvious at the time to Mr Beighton – as indeed he conceded in cross-examination.<sup>123</sup> It follows that Mr Beighton was either himself offering more (on AMCo’s behalf) – something he denied – or he should have appreciated that something was going on within AMCo requiring of close and careful explanation.

(v) Mr Beighton’s awareness of AMCo’s problems in bringing a rival product to market

79. Mr Beighton was aware of the problems that AMCo had in bringing a competitive product (i.e. a product competitive to Auden) to market. We have dealt with these issues already (i.e. the manufacturing problems with Aesica; and the Plenadren Orphan Drug problem, meaning that AMCo’s Marketing Authorisation would be “skinny label”), but it is necessary to appreciate Mr Beighton’s understanding. Mr Beighton’s evidence was that he came to be aware of both, but that the Orphan Drug issue was a matter that he only came to appreciate later.<sup>124</sup> Mr Beighton put the timing of his understanding at around August 2013.<sup>125</sup> That, of course, is a date well-before the conclusion of both the First and the Second Written Agreements (which were concluded in 2014). Certainly, by the end of 2013, Mr Beighton appreciated this:<sup>126</sup>

“...Pinsent advised that Auden’s 10mg HT MA had the adult indication because its MA preceded the OD designation for Plenadren and the OD designation gave Auden’s 10mg HT

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<sup>123</sup> See [76].

<sup>124</sup> Beighton 1/33.

<sup>125</sup> Beighton 1/36. Mr Beighton makes clear that he tested the Orphan Drug problem in the period after this date, and that AMCo obtained specialist legal advice in December 2013. We do not consider the details of this process to be particularly material. The fact is that by the time the First Written Agreement was concluded, AMCo was subjectively aware of the Orphan Drug problem.

<sup>126</sup> Beighton 1/[42].

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MA an insurmountable monopoly protection. As a result, Pinsent advised that acquiring Auden’s 10mg HT MA was an appropriate commercial option.”

As at December 2013, AMCo clearly appreciated that they were dealing with a counterparty – Auden – that (admittedly through regulatory happenstance) was in a monopoly position. We do not consider that Mr Beighton regarded Auden’s “monopoly” as unassailable. In other words, he did not regard AMCo’s skinny label product as an entirely uncompetitive product:<sup>127</sup>

“45. And so by around the end of December 2013, approximately nine months following the creation of AMCo, we were in a position whereby (a) we have come to realise that the 10mg HT MA that Waymade had sold to Cinven was not what it had been made out to be; (b) we had been advised by our external regulatory lawyers that Plenadren’s OD protection resulted in Auden’s 10mg HT MA having exclusivity for the key indication adrenal insufficiency in adults until November 2021, and that the OD protection could not be challenged in any way; and (c) our CMO, Aesica, were continuing to fail and were therefore still far from producing compliant product that could be relied upon for launch. In terms of next steps, they were pretty well summed up I think in an email from our General Counsel, Robert Sully, on 10 December 2013:

“I think it’s pretty simple, which is that we source from Auden for the time being while we work out if we have fully compliant supply from Aesica, and also while we investigate the orphan status of the Auden product and what it would take to get adrenal [sic] onto our licence. But I have emails suggesting otherwise and we need to agree on a plan.”

46. I responded to that email to express agreement but also to emphasise that:

“we should [act] as fast as we can to have a saleable product of our own.”

47. The Pinsent Masons’ advice came as a blow. **Nevertheless, on the basis of my experience of opening up markets to competition, I remained determined to find a way to market with a competitive product of our own. For example, on 2 January 2014, I sent an email to Guy Clark (AMCo’s Chief Strategy Officer) that “I really wish that we could find a way to put our own product on the market even without the indication.”**

48. In this context I reiterated my previous instructions that the teams should continue to press on with the development projects with Aesica and MIBE/Dermapharm. In addition, there were ongoing efforts to document in writing the interim supply arrangements with Auden...”

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<sup>127</sup> Beighton 1. Emphasis added.

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80. We accordingly turn to the negotiations that Mr Beighton had with Auden as regards the price and quantity of product that Auden would supply to AMCo pursuant to what came to be the Second Written Agreement. In this regard, we attach a great deal of importance to the quantities and rates agreed in the Second Written Agreement. That is because, whereas the First Written Agreement was essentially backward looking (effectively, regularising that which had been going on even before AMCo’s acquisition of Waymade’s product), the Second Written Agreement was entirely forward-looking.
81. The quantities and rates were negotiated in circumstances where we consider Mr Beighton was subjectively aware of the following facts and matters:
- (1) That by virtue of the Orphan Drug regime, Auden had a significant market advantage in what was otherwise an identical product – namely 10mg “immediate release” hydrocortisone tablets. Auden had a “full label” product; AMCo only a “skinny label” product.
  - (2) That AMCo would not, at least until 2021, be able to challenge this advantage, but could only compete by putting a “skinny” label product on the market.
  - (3) That AMCo were not – because of the problems with Aesica – in a position to go to market at once, but that once these problems were resolved could do so (albeit with only a “skinny” label product).
- (vi) Negotiations as to price and quantity
82. Mr Beighton mentions – as Mr Sully did – Mr Amit Patel’s desire to sell Auden.<sup>128</sup> Doubtless that prospect of acquisition – had it occurred – might have shaped the terms of the First and/or Second Agreements. But, in the event, AMCo did not seriously consider this approach, although AMCo was willing to “play Mr Amit Patel along”.<sup>129</sup>

“At the same time, Amit Patel of Auden had started to respond to our endeavours to get the interim supply agreements into writing by suggesting we had a good look at buying Auden from him. He appeared to have been impressed by Vijay Patel’s sale of Amdipharm to Cinven and wanted to duplicate it. We decided to show interest in acquiring Auden whilst at the same time getting the unwritten interim supply agreements committed to writing. We were also keen to keep Amit Patel of Auden happy as Aesica were behind schedule and a long way off being able to supply us with saleable product, so we did not want to find ourselves out of stock and risk customers perceiving us as unreliable suppliers...”

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<sup>128</sup> See, for example, Beighton 1/49.

<sup>129</sup> Beighton 1/49.

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Whilst there were no doubt prudent business reasons to attempt to “play” Mr Amit Patel, we reject as fanciful the suggestion that Mr Amit Patel was indeed “played”:

- (1) Mr Amit Patel was (as we have described) supplying 10mg hydrocortisone at a gross undervalue well before AMCo ever came upon the scene. He clearly did so for reasons nothing to do with a potential sale of Auden.
- (2) So far as the First Written Agreement is concerned, we are prepared to accept that Mr Amit Patel would also have seen this as an effort to document that which had previously been undocumented, at no particular cost to himself. Given the termination date for the First Written Agreement (signed 25 February 2014, termination 31 March 2014), there would have been little reason for Mr Amit Patel not to conclude the agreement.
- (3) The Second Written Agreement is an altogether different matter. Mr Amit Patel ceded substantial revenue to AMCo in circumstances where (i) AMCo’s need was vastly greater than Auden’s, and (ii) it is difficult to see any commercial benefit accruing to Auden.<sup>130</sup>

Unless there was a concrete proposal from AMCo to buy Auden woven into the Second Written Agreement, Mr Amit Patel would not (on the basis of a mere *spes*) have ceded so much.<sup>131</sup> We consider that Mr Amit Patel would have had other reasons for agreeing the Second Written Agreement (and in permitting the informal arrangements that pertained prior to the First Written Agreement). We will, in due course, explore what those reasons were.

83. Mr Beighton’s evidence – later on in his witness statement – is that it was Mr Amit Patel who approached AMCo in relation to the Second Written Agreement. This, of course, is interesting because the need appears to have been all on the side of AMCo.<sup>132</sup>

**“In or around mid-April 2014, Amit Patel of Auden approached me, proposing a new supply agreement for its 10mg HT product and, at the same time, disparaging reduced indication 10mg HT, threatening litigation and that he was asking the MHRA to ensure that suppliers of reduced indication 10mg HT product were required to ensure that their products**

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<sup>130</sup> The Second Written Agreement ran for a maximum of 2 years, with an agreed price of £1.78/pack and an agreed of supply of 12,000 packs/month. Assuming a sale price of £35.00/pack (which is conservative for 2014), AMCo was receiving – for no readily apparent reason – revenue in excess of £9,000,000 in circumstances where Auden was assisting AMCo to stay in a market when AMCo had no equivalent product to sell and no present means of producing even an inferior product.

<sup>131</sup> Indeed, Mr Beighton does not appear to have disagreed with this. See Beighton 1/51.

<sup>132</sup> Beighton 1. Emphasis added.

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carried a prominent warning label on the external packaging for their product. I believe this approach may have flowed from us purchasing bridging stock...On 19 April 2014, I emailed Guy Clark (AMCo) to say:

**“Amit [Patel (Auden)] offered to continue to supply us [10mg HT for adults and children] I think that he is not keen to get into a battle over the orphan drug status and its validity and so probably would do a better deal on better terms. I have asked Karl [Belk (AMCo)] what our Aesica cost and volume expectations are and I would say if Amit could get close to them it would be worth having a long term supply agreement with him. I am also not keen on having a fight over the status or indeed having customers that see our product as somehow risky.”**

It may be that Mr Amit Patel approached AMCo because of a concern that AMCo might enter the market with an unpredictably competitive product (namely a “skinny label” rival):

- (1) If AMCo was simply entering the market with a rival “full label” product, then the outcome was predictable. AMCo would seek to maintain price, and do so by sacrificing volume, supplying only 50% of the market whilst only marginally undercutting Auden on price.<sup>133</sup>
- (2) On the other hand, if AMCo was entering the market with a rival “skinny label” product then, given the prudential concerns of the pharmacies,<sup>134</sup> a 10% to 15% reduction in price of AMCo’s product might not be enough to encourage demand from pharmacies. A bigger price differential might well be required. If that was right, a competitor to Auden like AMCo might very well seek to obtain more than 50% of the market.

Thus, the “skinny label” dynamic introduced significant uncertainty on all sides because that supply, although competitive, was unpredictably so.

84. In the event, AMCo offered £1/pack, and Auden countered with £1.78/pack, which AMCo accepted.<sup>135</sup> Mr Beighton appears to consider that he is to be criticised for not unilaterally offering a higher price:<sup>136</sup>

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<sup>133</sup> See [71].

<sup>134</sup> Which we have described in the Judgment (Abuse of Dominance Infringements).

<sup>135</sup> Beighton 1/78.

<sup>136</sup> Beighton 1/78. See also Beighton 1/84, where Mr Beighton states:

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“When Auden countered with a 2 year term at £1.78, which was broadly similar to the £1.16 price that AMCo had agreed with its CMO Aesica, I was not going to counter by offering to pay a higher price, as the CMA seems to suggest I should have done...”

The CMA was making no such point. The point is not that AMCo should have offered more. The point is that the asymmetry in commercial outcome between what AMCo paid and what AMCo received is so stark as to warrant explanation. The point is not why AMCo did not offer more, but why Auden was prepared to offer so little. We do not consider that it is sufficient for AMCo to say that they simply did not understand what was going on in Auden’s mind. The point is that, when considering covert cartel agreements, competition authorities are inevitably driven by inference. Here, there is a great deal of material for inferring that something more was being offered to Auden by AMCo. That is how the CMA saw matters in the Hydrocortisone Decision – and we consider that they had every right to do so. There is something about the Second Written Agreement that is in need of explanation and – absent explanation – it may be that the inference that something more was offered becomes irresistible.

85. Inconsistently with the tenor of the Second Written Agreement, AMCo regularly sought – and Auden refused – to increase the volumes supplied by Auden to AMCo under the Second Written Agreement:

(1) In Mr Beighton’s witness statement he stated:<sup>137</sup>

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“In my formal section 26A interview, the CMA asked why Auden would supply product at this price. I cannot speak on behalf of Auden, and I do not know what Auden’s intention may have been, but from my perspective, as I said in my section 26A interview, that was irrelevant to me. We wanted product at a cost comparable to our CMO’s Aesica (£1.16), Auden countered with a price that was higher than Aesica’s. I was not going to negotiate against myself by offering him an even higher price. Whilst the cost to us was higher than our Aesica costs, the supply allowed us to retain (and expand) our foothold in the sale of hydrocortisone, to generate revenue that was otherwise unattainable, while at the same time to continue with our various initiatives to bring our own product to market. At that time, we had no Aesica product because of the on-going issues with Aesica and our customers had no interest in a reduced indication child’s 10mg HT product.”

We return to this paragraph, which we consider revealing, below. We have the following points of concern: (i) Although Mr Beighton asserts that Auden’s thinking was irrelevant to him, that is not the way commercial businessmen negotiate. They seek the best deal from a close understanding of the other side’s thinking; (ii) Mr Beighton in fact impliedly asserts that both parties were negotiating on the basis of a CMO agreement. For the reasons we have given, this will not have been Auden’s stance; (iii) To equate the value provided by Aesica with the value provided by Auden is incomprehensible. Aesica were manufacturing a product for AMCo to sell under its (skinny label) MA. Auden were supplying a ready-for-sale product under its (Auden’s) MA. In short, there is no proper comparison.

We expand upon these points below but, given their importance, it is appropriate that we flag now our concerns with this paragraph in Beighton 1.

<sup>137</sup> Beighton 1/[80].



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“I recall our Supply Chain team trying to get more volumes from Auden in the months that followed [conclusion of the Second Written Agreement], but I do not think this was successful.”

(2) The Hydrocortisone Decision records that:<sup>138</sup>

“...although the Second Written Agreement stated that AMCo’s Minimum Volume would be 12,000 packs, this was the maximum volume of 10mg hydrocortisone tablets available to AMCo at the £1.78 price during the term of the Second Written Agreement”.

86. Understanding the Second Written Agreement in its true commercial context makes it clear why Auden refused – and why AMCo sought – increases to the volumes supplied under the Second Written Agreement:

- (1) The level of demand in the market was inelastic, in the sense that demand would neither fall nor increase very much with price changes up or down.
- (2) Accordingly, every additional quantity of product supplied by Auden to AMCo will have cost Auden revenue. Assume a conservative price per pack of £35.00 and a sale price to AMCo of £1.78. Each increase in quantity of product supplied to AMCo costs Auden £33.22.

**(4) The 10mg Agreement as a Cartel Infringement: an approach to an analysis of the facts**

***(a) Our approach***

87. We have sought to set out the factual history in relation to the 20mg Agreement and the 10mg Agreement. We now proceed to analyse those facts and to reach some conclusions.

88. As we have noted, this is a case where the infringement is in the nature of a Covert Chapter I infringement. The nature of the agreement at issue is controverted and controversial. The outcome of the controversy regarding the agreement will be material to the very existence of an infringement of the Chapter I prohibition.

89. Accordingly, we consider we must carefully evaluate the facts, and seek to be as clear as we can when we are finding facts and drawing inferences from found facts. Equally,

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<sup>138</sup> Hydrocortisone Decision/3.584.

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we will endeavour to state the conclusions we reach distinctly from the findings we made and the inferences we draw.<sup>139</sup>

90. We begin by reiterating the factually elusive question that is before us. This is not an exercise in the construction of an agreement nor an effort to find an implied term in a contract. There were times – particularly in the submissions of the Cinven Appellants – where there was more than a suggestion that a contractual approach needed to be taken, and that the CMA had fallen short in the Hydrocortisone Decision in failing to spell out, in more-or-less contractual terms, the nature of the 10mg Agreement that constituted the infringement. In their written opening submissions, the Cinven Appellants asserted that “the CMA has failed to adequately particularise its case”,<sup>140</sup> going on to say:<sup>141</sup>

“...However, the CMA contends that the Written Agreements do not contain the whole of the parties’ bargain. Thus, it is said that the CMA did not find clause 2.2 “in the context of the Second Written Agreement, by itself, to be unlawful. But that does not prevent the finding that a different and broader common understanding – i.e. that AMCo would forego market entry – was unlawful.” But the problem is that the CMA fails to explain how the supposedly broader (and unlawful) common understanding differs from the promise contained in clause 2.2 of the Second Written Agreement, which required AMCo not to enter independently for a limited, rolling, three-month period and which it does not condemn. In particular, the CMA fails to identify for what term AMCo is said to have unlawfully promised not to enter.”

This discloses an overtly contractual approach to an understanding that the Hydrocortisone Decision found to exist but which the Hydrocortisone Decision never asserted to be contractual in nature. Thus, the suggestion (seriously advanced by the Cinven Appellants<sup>142</sup>) that the no oral variation and entire agreement clauses in the First and Second Written Agreements in some way might preclude an unlawful collateral understanding only needs to be stated to be rejected.

91. We reject such “contractual” approaches as unduly fettering and disregarding of the process we are engaged upon, which is (as we say) far more elusive than merely contractual interpretation. An informal arrangement, provided it “crosses the line” between the parties to that arrangement and represents an informal *consensus ad idem* is enough to constitute an infringement of the Chapter I prohibition. We consider that the Hydrocortisone Decision articulates with sufficient clarity the nature of the 10mg Agreement which it finds objectionable.

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<sup>139</sup> Cf *BGL* at [226].

<sup>140</sup> At [16].

<sup>141</sup> At [18].

<sup>142</sup> At [20(2)].

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***(b) The need to assess understanding on both sides***

92. Whilst we appreciate that a common, unshared, intention is insufficient to satisfy the requirements necessary to establish the Cartel Infringements, we do consider that it is necessary to consider the position of both Auden and AMCo over time and their individual states of mind as a means of informing what common intention might have existed. Accordingly, we propose to consider:
- (1) The market in which Auden and AMCo operated over time, so as to understand the position that both actors found themselves in.
  - (2) Auden’s state of mind both at the inception of the arrangement with (then) Waymade and at the time of the conclusion of the Second Written Agreement. We consider that these two points in time represent the best way of ascertaining what the parties had in mind (because independent choice was exercised on each occasion).
  - (3) Waymade’s state of mind at the inception of the arrangement.
  - (4) AMCo’s state of mind at the time of the Second Written Agreement.
93. We stress that there can be no infringement of the Chapter I prohibition without something “crossing the line”. But in order to understand what crossed the line, the state of an actor’s uncommunicated state of mind will be of considerable inferential assistance. If a given state of mind or intention did not exist, that may be suggestive of the fact that it was not communicated. On the other hand, if a given state of mind existed on both sides, and a common course pursued, the inference of a communication “crossing the line” will be strong.
94. Before we turn to the facts, however, it is necessary to return to the question of attribution of knowledge and states of mind to undertakings.

***(c) An approach to attribution***

***(i) Generally***

95. The theory of liability underlying the Chapter I and Chapter II prohibitions was considered in Judgment (Abuse of Dominance Infringements)/[161]ff. As we have described, the “unit of account” for purposes of competition law infringement and penalty is the “undertaking”, an economic and not a legal characterisation of an organisation. Thus, provided that legally recognised entities (be they natural persons, legal persons or organisations of natural and legal persons like partnerships or

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unincorporated associations) form part of the same economic unit, their conduct, knowledge and state of mind can be pooled and collectively attributed to the undertaking. (Nothing we say here affects the process by which state of mind is to be inferred from conduct. Of course, it is trite that it is permissible to infer that persons intend the natural and probable consequences of their actions, and state of mind usually has to be inferred from extrinsic conduct. Precisely what can be inferred is, quite fundamentally, a question of fact, which we will be turning to in due course.<sup>143</sup>)

96. This was explained very clearly in *Media Saturn Holding GmbH v. Panasonic Marketing Europe GmbH*, where Barling J considered the case law regarding “undertakings”,<sup>144</sup> and then stated that “where both parent and subsidiary were members of a single economic unit or “undertaking” and by their conduct contributed to the implementation of an infringement of [the Chapter I prohibition], liability for the infringement was attributable to both, even if the subsidiary had no knowledge of the parent’s actions and its own contribution was made “in a subordinate, accessory or passive manner”.<sup>145</sup> This, of course, is entirely consistent with the “unit of account” approach that we have already described in Judgment (Abuse of Dominance Infringements). As we have said, and as Barling J noted (albeit without deciding) in *Media Saturn*, the traditional English law approach of attribution and agency is not appropriate.<sup>146</sup>

“For reasons given earlier, I do not consider that use of the word “participated” should be understood in the rigidly restrictive way advocated by the Defendants. In *Biogaran*, the General Court refers also to “implementation” and “contribution”. Further, I consider that Mr Singla has to some extent misinterpreted the Claimant’s argument. The *Provimi* ground claim, as I understand it, is not that liability passes up one corporate chain from MTPD to TC and then down a different corporate chain from TC to TIS. It is rather that TC, MTPD, TIS and the other Toshiba Defendants formed a single economic unit or “undertaking” which (along with PC and others) infringed Article 101, and whose knowledge is “one and the same”...”

97. We consider that this helpfully states the law as we understand it in this regard.

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<sup>143</sup> Thus, in *Napp*, it was uncontroversially stated that “[i]f, therefore, a dominant undertaking pursues a certain policy which in fact has, or would foreseeably have, an anti-competitive effect, it may be legitimate to infer that it is acting “intentionally” for the purposes of section 36(3)”; *Media Saturn Holding GmbH v. Panasonic Marketing Europe GmbH*, [2019] EWHC 1095 (Ch) at [130]ff.

<sup>144</sup> [2019] EWHC 1095 (Ch) at [139]ff. Barling J was influenced by the earlier decision of Aikens J in *Provimi Ltd v. Aventis Animal Nutrition SA*, [2003] EWHC 961 (Comm) at [30]ff. This is another interlocutory (strike-out) decision, but the approach is consistent with the one here adopted and, if we may respectfully say so, entitled to considerable weight.

<sup>145</sup> At [152].

<sup>146</sup> At [155]. We should stress that Barling J did not decide this point on a summary judgment application, but his views are entitled to considerable weight.

**This judgment must be read in light of the Tribunal’s later judgment at [2024] CAT 17. That is because the provisional findings made against witnesses called are unsafe and are repudiated by the Tribunal. They were made because of a failure, on the part of the CMA, to observe fundamental principles of due process, and for that reason they cannot stand.**

(ii) “Unit of account” and communications between undertakings

98. So far, we have been considering the attribution of conduct, knowledge and state of mind within a single undertaking. The Cartel Infringements, of course, involve such questions of attribution and (when considering a single undertaking) this is the approach we will follow.
99. However, Cartel Infringements involve “understandings” between undertakings, and in order for there to be such “understandings”, they must “cross the line” from one undertaking to another and give rise to a common understanding. To this extent – and to this extent only – drawing on the analogy with the law of contract has some benefit. It is not possible for a single undertaking to infringe the Chapter I prohibition. If, therefore, entities all part of the same undertaking communicate understandings that would otherwise be infringements of the Chapter I prohibition, there is in fact no infringement because nothing “crosses the line”. The Chapter I prohibition is not engaged.
100. Accordingly, where a court is considering the existence of a communication “crossing the line” between one undertaking and another so as to give rise to the necessary “common understanding”, it is necessary to tread with extreme care:
- (1) Suppose it could be said that Undertaking *A* has a given state of mind (*X*) as a result of the attribution of the conduct, knowledge and states of mind of entities that are part of Undertaking *A*. Suppose that exactly the same can be said of Undertaking *B*.
  - (2) It is not enough to found a “common understanding” for there simply to be communications between Undertaking *A* and Undertaking *B*. Indeed, we doubt whether it is enough for those communications to relate to the subject-matter of the common understanding (i.e. to discuss *X*) without the engagement of the two actors (natural persons) participating in those communications. Otherwise, it would be far too easy, on a “cherry-picking” basis, to select communications crossing the line, combine them with a general intention attributable to the undertaking as a whole, and to conclude that that general intention has “crossed the line”. This, we consider, would not without more be enough to meet the requirements of the Chapter I prohibition.
  - (3) On the other hand, it may very well be possible to infer an arrangement (quite possibly between unknown actors within each undertaking) sufficient to engage the Chapter I prohibition from such general communications. Suppose there is evidence that Undertaking *A* wants to pay Undertaking *B* to stay out of a market, and Undertaking *B* can be shown to be keen to be paid to stay out of the market.

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Such evidence – which relates to each Undertaking’s uncommunicated state of mind – can be used to justify an inference that individuals within Undertakings *A* and *B* must have reached such an arrangement, and so infringed the Chapter I prohibition. Whether the evidence is sufficiently strong to make such an inference is of course a difficult and very sensitive question of fact.

101. We can further illustrate the point by reverting to the “elaborate conspiracy” argument that the CMA rightly dismissed, and which we have summarised at [7(9)]. Chapter I infringements require no such elaborate conspiracy, certainly not within an undertaking: although, of course, the existence of such a conspiracy may very well assist in making good the allegation of an infringement. But such a conspiracy is neither a necessary nor a sufficient condition to meet the requirements of the Chapter I prohibition. What is generally required is some form of communication crossing the line between the undertakings, where it can be concluded (on the balance of probabilities) that the communicators on each side shared a common understanding. Since legal persons can only act through natural persons, it must follow (unless a case is very unusual) that the communications constituting the common understanding were between natural persons within each undertaking who shared that understanding.<sup>147</sup> That, it seems to us, is what is required: how it is proved, and on what evidence, is altogether a different matter.

(iii) Cases of successive ownership

102. As Annex 3 describes, these appeals concern multiple instances where the ownership of companies changes over time. The shape or size of the undertaking changes, accordingly, as we have described in the case of the Abuse of Dominance Infringements.<sup>148</sup>
103. In the present instance, the question arises as to how knowledge or states of mind of an undertaking as constituted at a particular point in time transmits itself to a (differently constituted) undertaking at a later point in time. It seems to us that this case is clearly answered by the law that we have already articulated. Provided that the undertaking remains the same undertaking over time (and all that has happened is that the shape of the undertaking has expanded or contracted over time) a common understanding that has (according to the test we have described) been found to exist continues and is attributed to the undertakings on each side of the line until it can be shown that one or other of the undertakings has taken steps to and in fact has ended that common

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<sup>147</sup> This is why Overt Chapter I Infringements are – in this regard at least – easier to make good than Covert Chapter I Infringements. In the case of the Overt Chapter I Infringement, the communications constituting the common understanding that crosses the line will be manifest and uncontroversial. For example, they will be contained in a contract between Undertaking *A* and Undertaking *B* and neither Undertaking will be permitted to say “this was not my act, and not a communication crossing the line”. By definition, the contract does exactly that.

<sup>148</sup> See Annex 3 and Section I of the Judgment (Abuse of Dominance Infringements).

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understanding. We revert to and expand upon the hypothetical example given in [100] above:

- (1) Suppose that state of mind *X* has been communicated across the line between Undertaking *A* and Undertaking *B* by two actors (*A(I)* and *B(I)*) respectively, who at the time of communication both held state of mind *X* and were communicating it one to the other such that state of mind *X* became a common understanding.
- (2) That state of affairs – the common understanding – is from that point on attributed to each of Undertaking *A* and *B* by virtue of the “unit of account” rules described above. It is nothing to the point that either or both undertakings have contracted or expanded over time, nor even that the individual actors (*A(I)* and *B(I)*) have departed the undertakings of which they were once part. The common understanding put in place by them subsists until it is broken by subsequent acts of the undertakings in question.

104. Although it is a decision concerned with penalty, Case C-248/98 P, *NV Koninklijke KNP BT v. Commission of the European Communities* says this about the duration of a cartel infringement, which is supportive of the law we have stated:

- “71. As regards the duration of the period of the infringement to be attributed to the appellant and, in particular, the attribution to it of Badische’s infringement over the period prior to its acquisition by the appellant, it should be noted that it falls, in principle, to the legal or natural person managing the undertaking in question when the infringement was committed to answer for that infringement, even if, at the time of the decision finding the infringement, another person had assumed responsibility for operating the undertaking.
72. In the present case it is undisputed that Badische participated in the cartel from mid-1986 until 1 January 1987 when it was the production unit of the German packaging producer Herzberger Papierfabrik Ludwig Osthusenrich GmbH und Co. KG. The latter entity was acquired, without loss of legal personality, by the appellant only on 31 December 1986, which, according to the second paragraph of point 149 of the Decision, became its “95% owner” throughout the period of the infringement in question.
73. For the reasons given in paragraphs 46 to 50 of the contested judgment, the appellant must be held responsible for the infringement committed by Badische over the period from January 1987 to April 1991. As the Court of First Instance observed:

- “46. First, the applicant does not contend that it was unable to exert a decisive influence on the commercial policy of KNP Vouwkarton and Badische.

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47. Moreover, it is not disputed that a member of the applicant's management board participated in, and even presided over, the meetings of the PWG until 1988. According to the Decision, the main discussions with an anti-competitive object took place in the PWG and that finding is not disputed by the applicant.
48. In those circumstances, the Commission has proved that through the involvement of the member of its management board the applicant was actively implicated in the anti-competitive conduct of KNP Vouwkarton. In involving itself in that way in the participation of one of its subsidiaries in the cartel, the applicant was aware, and must also have approved of, Badische's participation in the infringement in which KNP Vouwkarton took part.
49. The applicant's responsibility is not affected by the fact that the attendance of the member of its management board at meetings of the bodies of the PG Paperboard ceased in 1988. It was for the applicant, as parent company, to adopt in regard to its subsidiaries any measure necessary to prevent the continuation of an infringement of which it was aware. Furthermore, the applicant has not disputed that it did not even attempt to prevent the continuation of the infringement."

**(5) The market in which Auden and AMCo operated over time**

***(a) The period to the conclusion of the 20mg Agreement (Period 4 to Period 42)***

105. From Period 4 onwards, Auden was in a monopoly position with regard to both 10mg and 20mg immediate release hydrocortisone tablets and – since these were substitutes – in a monopoly position in the market generally. The basis for that monopoly was the Merck, Sharpe & Dohme MAs. There is no reason why these tablets cannot be manufactured by others – they easily can be, and at minimal cost. The point is that they cannot be sold (at least not lawfully).
106. That position pertained until Period 42. Prices rose from £4.54 (10mg in Period 4) and £5.14 (20mg in Period 4) to £27.71 (10mg in Period 42) and £30.27 (20mg in Period 42).
107. In July 2011, the 20mg Agreement with Waymade was entered into. From Period 43, therefore, there was another supply on the market, save that it was not really a new supply, merely a permission given by Auden to Waymade to sell under its Merck, Sharpe & Dohme MA on beneficial terms. Waymade was, therefore, effectively, acting as a distributor on peculiarly beneficial terms. The market remained 100% controlled by Auden.



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108. The critical question is why, at Period 43, Auden decided to let Waymade share in the profits it was making in relation to 20mg tablets. As we have described, the terms of the 20mg Agreement involved the supply – at nominal cost – of 1,000 packs of 20mg hydrocortisone tablets, 800 of which would be bought back, and 200 of which Waymade would sell.
109. Waymade had commercial stock ready for sale as at May 2011, and Period 43 (July 2011) comes shortly after this. We do not know from primary evidence why Waymade chose to forsake its own route to market, and sell Auden's product instead, but there is (as it seems to us) only one possible explanation:
- (1) Waymade's 20mg product would have been a new entrant onto the market. It would have had to compete with an established product – Auden's – and that would have involved cost (in terms of marketing to wholesalers, etc). Waymade would almost certainly have had to compete on price – in other words, would have had to undercut Auden.
  - (2) Auden would have wished to avoid this. Competition on price would erode margins, and it was possible that Waymade might seek to contest the whole 20mg market and even attempt to make in-roads into the 10mg market. Inevitably, there would be:
    - (i) A downward pressure on price, which Auden would be keen to avoid.
    - (ii) A loss of volume to Waymade, which Auden would not be able to make up through lower prices.

In short, Auden would have had every incentive to pay Waymade to keep out of the market. Of course, we bear in mind what Mr Beighton said (see [71]) about the first new competitor limiting competition on price by unilaterally limiting its supply to the market. Waymade may very well have behaved in this way. But from Auden's point of view one new competitor was one too many, and would or might lead to further competitors entering the market, at which point prices would fall because of competition, and margins would not be capable of being maintained. Therefore, even accepting Mr Beighton's evidence, there was sense in the 20mg Agreement.

- (3) Waymade would have had every incentive to accept that offer – and to induce its being made by threat of independent entry. In this way, Waymade would avoid the costs of competing; and would maintain the price at its high levels.

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110. We have considered very carefully whether there is an alternative explanation for the 20mg Agreement; and we do not consider there to be one. Auden were paying Waymade to stay out of the market and maintain the existing (high) prices.

***(b) The period from the conclusion of the 20mg Agreement (Period 43) to the conclusion of the 10mg Agreement (Period 57) and thereafter***

111. Before we come to the 10mg Agreement, we note the following about Waymade’s pricing of 20mg hydrocortisone tablets. It is, we consider, significant that Waymade’s supply to the market was at a generally higher price than that of Auden itself. This is an indicator of the market power that Auden and Waymade – through their agreement – had conferred on each other. Auden granted Waymade a limited ability to “compete” (200 packs/month) and bought Waymade off through the sale and repurchase of the remaining 800 packs/month. The monopoly rents that accrued to Waymade alone have been set out and were on any view substantial.
112. In September 2012, Waymade obtained a Marketing Authorisation in respect of 10mg “immediate release” hydrocortisone.<sup>149</sup> The 10mg Agreement was concluded shortly thereafter, in October 2012. In the period that followed, Waymade’s prices, for the products it sold trended at above Auden’s prices – exactly the opposite from what one would expect if there were competition.
113. For exactly the same reasons as we have articulated in relation to the 20mg Agreement, the 10mg Agreement can only have been an agreement between Auden and Waymade for Waymade to be paid to stay out of the market. The essence of the agreement is the elimination of competition; and the only way to procure that elimination is to pay a competitor to stay away. That, in our judgment, was the only effect of the 10mg and 20mg Agreements.
114. In the time following the conclusion of the 10mg Agreement, Waymade’s prices generally continued (for both 10mg and 20mg products) at above the Auden price.
115. There was, however, in the case of the 10mg Agreement, a further reason for Waymade to sign up to the 10mg Agreement:
- (1) Plenadren came to market (as we will describe) significantly after its Marketing Authorisation was approved. The Plenadren MA was conferred in Period 46 (3 November 2011), although Plenadren did not come to market until Period 73. However, from the point of grant onwards, subsequent Marketing

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<sup>149</sup> I.e. immediately after Period 57, on 27 September 2012.

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Authorisations were (until 2021) going to be unavoidably “skinny label”. This, as we will see, served to protect the market position not just of Plenadren, but also of Auden’s hydrocortisone products.

- (2) The Waymade MA – granted in September 2012 – was a skinny label MA. This meant that Waymade was less able to compete with Auden than was the case with 20mg “immediate release” hydrocortisone. That fact would have made Waymade even more eager to agree the 10mg Agreement.
- (3) However, it must be asked why Auden would have agreed to the 10mg Agreement. That turns on the extent to which a 10mg “skinny label” product acts as a competitor to a 10mg “full label” product. As to this:
  - (i) We have found – using our test of market definition – that these are indeed substitute products. That test was based upon a common price (£10 as between all products) and a hypothetical consumer having the characteristics we have described.<sup>150</sup>
  - (ii) As we have described, market definition is an objective process used to identify and describe market power. It does not assist in informing the decisions of participants in the “real world”, where the prices are not as we have assumed them to be, and where the consumer we have hypothesised neither exists nor has the agency which (for market definition purposes) we are attributing to them.
  - (iii) In this case, the full label product was selling at prices far above the £10 we have hypothesised for market definition purposes and we have found those prices to be excessive and abusive within the meaning of the Chapter II prohibition. However, the purchasers of this product – pharmacies – would not bear the economic cost of purchasing Auden’s product; and nor would the doctors prescribing it. For the reasons articulated by Dr Newton, we consider that pharmacies would think carefully before dispensing on an open prescription skinny label product to adults, even if no harm could arise.
  - (iv) In the real world, therefore, “skinny label” was not a non-competitor, but an unpredictably constraining competitor. This unpredictability would manifest itself in two (related) regards: first, any new entrant into the market would almost certainly have to price the “skinny label” product

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<sup>150</sup> Judgment (Abuse of Dominance Infringements)/[243(6)] and [243(7)].

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well below the prevailing price for the “full label” product, in order to overcome the pharmacies’ issues with “skinny label”.<sup>151</sup> Secondly, and relatedly, if this approach made an impression on the market – in that pharmacies decided to stock “skinny label” product – the impact on the price of “full label” product would likely be considerable. This would not be a case of a new entrant competitor selling exactly the same product at a slightly lesser price, but a case of a new entrant selling a product encumbered with a disadvantage (the “skinny label” limit on therapeutic indications) and for that reason selling at a substantial discount.

- (v) That can be seen from the effect of actual market entry on prices of “skinny label” hydrocortisone from Period 94 onwards.<sup>152</sup> Over time, because “skinny label” was priced at below “full label”, and because multiple entrants competed against each other, an inevitable downward pressure on both “skinny label” and “full label” prices manifested itself.
- (vi) We consider that Auden would have been well-aware of the dangers of multiple new entrants into the market and – in this case – the dangers of a single new entrant selling an “inferior” skinny label product. Averting this danger by buying off Waymade would have been worthwhile.

**(c) *The entry of Plenadren***

116. Plenadren entered the market in Period 73, at a price well-above that of the “immediate release” hydrocortisone. Thus, as at Period 73, the prices were:

- (1) AM Pharma 10mg: £37.20;
- (2) AM Pharma 20mg: £39.13;
- (3) Waymade sales of product supplied under the 20mg Agreement: £46.00;
- (4) AMCo sales of product supplied under the 10mg Agreement: £38.00;
- (5) Plenadren 5mg: £212.00;

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<sup>151</sup> That would significantly improve the margins of pharmacies, because the gap between the price of the product and the Drug Tariff reimbursement rate would be that much greater.

<sup>152</sup> We refer to Annex 3.

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(6) Plenadren 20mg: £350.00.

117. We should make clear that we do not consider these prices to be in any way sufficient to deter pharmacies from dispensing Plenadren. The Drug Tariff rate would have allowed plenty of margin (in this Period, the reimbursement rate was £242.50 and £400.00 respectively). However, the attitude of CCG’s to the cost affected doctors’ prescribing practices, such that Plenadren was not a constraint on the immediate release hydrocortisone on the market. That is clear from the volumes of Plenadren sold.
118. The market positions of Auden and Waymade thus remained unchanged and the dynamics informing the 20mg and 10mg Agreements also unchanged. Plenadren was not, therefore, a product liable to act as a competitive constraint on “immediate release” hydrocortisone – as the volumes sold make clear.<sup>153</sup>

***(d) The market position at the conclusion of the First and Second Written Agreements***

119. The period after the conclusion of the First Written Agreement (Period 75) shows that Plenadren’s sales were nil, Auden’s sales of 10mg hydrocortisone were 88,919 at £41.66/pack, and AMCo’s sales of 10mg hydrocortisone were 6,000 at £43.50/pack. At the time of the First Written Agreement, therefore, market shares by revenue were:
- (1) Auden: £3,704,365.54 (93.4%).
- (2) AMCo: £261,000 (6.5%).
- (3) Total: £3,965,365.54 (100%).
120. AMCo must have appreciated that they had a small, but significant, market share, which was entirely dependent on third party supply, and entirely uncompetitive. The packs sold were not differentiated, and there would have been no point in AMCo seeking to compete on price: all that would have happened is that AMCo’s revenue would have fallen, but its market share could not have increased, because Auden controlled AMCo’s supply. AMCo therefore did the logical thing, and generally priced at just above AM Pharma.

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<sup>153</sup> For the reasons given at [115], the fact that a product is a substitute for the purposes of market definition, but not a substitute in the “real” world, is not an inconsistency that derails our analysis. The fact is, as we have explained, market definition is an analytical tool, not a descriptor of the “real world”.

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121. Pricing decisions are – we consider – deliberate ones made by undertakings, and a great deal can be inferred from them. We infer that at the time of the First Written Agreement, AMCo priced in this way for this reason.
122. Although the First Written Agreement ended on 31 March 2014, it is evident that AMCo had sufficient supply to maintain its market share for a limited time only. Looking simply at quantities sold by AMCo, the position is as follows:

| Date                         | Event                                                   | Quantity sold<br>(where applicable) |
|------------------------------|---------------------------------------------------------|-------------------------------------|
| 24 Feb 2014                  | Conclusion of the First Written Agreement               |                                     |
| <b>Period 75</b><br>Mar 2014 | Volume of 10mg sold by AMCo                             | 6,000                               |
| 31 Mar 2014                  | Termination of supply under the First Written Agreement |                                     |
| <b>Period 76</b><br>Apr 2014 | Volume of 10mg sold by AMCo                             | 6,500                               |
| <b>Period 77</b><br>May 2014 | Volume of 10mg sold by AMCo                             | 5,500                               |
| <b>Period 78</b><br>Jun 2014 | Volume of 10mg sold by AMCo                             | 2,530                               |
| 25 Jun 2014                  | Conclusion of the Second Written Agreement              |                                     |
| <b>Period 79</b><br>Jul 2014 | Volume of 10mg sold by AMCo                             | 12,000                              |

123. It is thus clear that AMCo’s stated concern about losing supply and so market share was borne out, and that in Period 78, AMCo were running out of supply. There would have been pressure to agree the Second Written Agreement on AMCo, but not on Auden. As a direct result of the Second Written Agreement, AMCo’s supplies were not only maintained (or restored) but increased by a factor of two (from 6,000 packs/month to 12,000 packs/month).

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124. The evidence of AMCo was that the price at which Auden agreed to supply AMCo was an oddity, but not one that needed to concern AMCo. In the most literal sense, that is true. If Auden is credibly to be regarded as commercially idiotic (we do not think this an overstatement, and was clearly not the case) or hugely altruistic (we do not consider this to have been the case either), then perhaps such an answer might be accepted. But Auden was commercially hard-nosed, and (at this point) held all the aces. This is not an agreement, in our judgement, that Auden would have entered into without getting something in return from AMCo to justify the commerciality of the transaction. In short, we consider the inference that there was something more to the 10mg Agreement to be quite overwhelming at this point in time.

***(e) Period from the conclusion of the Second Written Agreement to the entry of skinny label products***

125. The first skinny label product (Alissa Healthcare 10mg) came onto the market in Period 94. In the period between Period 79 (the month after the conclusion of the Second Written Agreement) and Period 94, AMCo's sale to the market was 12,000/packs a month at prices generally just above the price charged by Auden for the equivalent product.
126. In other words, the pattern we have described continued during this period.

***(f) Acquisition of Auden by Actavis***

127. The 10mg and 20mg Merck, Sharpe and Dohme MAs transferred to Actavis at Period 89 (i.e. in the middle of the period we have just described). The precise date of the completion of the acquisition was 29 May 2015. Nothing changed in terms of the position of the hydrocortisone products in the market over this period, as we have also described.
128. It is at this point worth considering some documents which evidence exactly what Actavis must have known (because these are Actavis' documents concerning "Project Apple", the acquisition of AM Pharma). We begin with a document dated 11 December 2014 by PwC entitled *Project Apple: Financial and Tax Due Diligence – Key Issues Report*. This was a draft report:
- (1) The report was explicitly "for the purpose of your proposed acquisition of the Target", the Target being AM Pharma.<sup>154</sup>

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<sup>154</sup> See the introductory or covering letter.

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- (2) The Target was described as “highly cash generative, selling niche, high margin drugs primarily to UK based distributors and pharmacies”.<sup>155</sup> In particular, “[t]he hydrocortisone product has been the foundation of the business and supported the development and acquisition of other niche products”.<sup>156</sup>
- (3) In the main body of the report, PwC note that “Hydrocortisone is the key product line, upon which the Company is heavily reliant in order to sustain current sales and profitability. We also understand that this has Orphan drug status in the UK and minimal competition – we defer to your consideration of these matters which are outside of our scope...”.<sup>157</sup> On the same page, the report noted the prices and quantities sold:<sup>158</sup>

“The largest SKU<sup>159</sup> (by sales) is Hydrocortisone 10mg Tablets x 30. ASP increased from £34.38 per unit in FY13 to £39.32 in LTM15. These factors have resulted in a revenue increase for this SKU of 39%.”

Later:<sup>160</sup>

“Price increases across the Hydrocortisone and the other SKUs displayed opposite are within the maximum price dictated by the Government’s drug tariff and have to be negotiated with their customers. **The increases reflect successful negotiations with customers. We understand that significant price increases have been achieved in Hydrocortisone largely due to the orphan status that it holds in the UK and the current lack of competition.**

Price increases were predominantly applied with effect from August 2014 therefore we have yet to see full year impact in FY14 or LTM15 P&L. We have quantified the impact of these increases for a full year (along with the corresponding increase in supply costs) as part of our LTM15 run rate analysis.

We understand there were further price rises applied post 31 October 2013, however, we have not been provided with any details of these increases as yet, despite requesting information from management. If these prices are sustained into 2015, this will positively impact the run rate.”

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<sup>155</sup> “At a glance – our views (1 of 2)”.

<sup>156</sup> “At a glance – our views (1 of 2)”.

<sup>157</sup> At p4 (sales analysis).

<sup>158</sup> At p4 (sales analysis).

<sup>159</sup> I.e. “Stock Keeping Unit”, the unique identifying code for the product.

<sup>160</sup> At p.4 (second so numbered page) (sales analysis). Emphasis added.



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- (4) The high margins on sales were noted<sup>161</sup> and the manufacturing cost was stated as being “£1.1 per pack” – which makes the size of the margins self-evident.<sup>162</sup>

129. Secondly, we refer to a December 2014 presentation regarding the transaction. In this presentation:

- (1) Auden is described as a “private family-owned generic pharma based in UK”,<sup>163</sup> where “R&D and Manufacturing are outsourced”.<sup>164</sup> The “Auden portfolio and pipeline is well aligned with our existing Gx strategy – specialised, niche, low competition products”,<sup>165</sup> and “Auden Mckenzie has a solid business that is highly profitable – 70%+ EBITDA margin driven by exclusive, semi-exclusive products and low cost structure”.<sup>166</sup>
- (2) Specifically, as regards hydrocortisone, the presentation records:<sup>167</sup>

“Hydrocortisone Background

- Hydrocortisone Tablets is the lead Auden product with an expected decline in contribution due to new generic entrants
- Auden’s Hydrocortisone 10mg Tablets are the only Generic for Adrenal Insufficiency in adults
- Plenadren (Brand) is protected by Orphan designation until 2022, protecting the indication on Hydrocortisone MAs, this designation prevents new MAs being granted for the indication
- Until November – MHRA had approved 1 other 10mg Gx Hydrocortisone (AmCo) without the Adrenal indication – AmCo has not launched yet

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<sup>161</sup> E.g. at p.5 (cost of sales and gross margin).

<sup>162</sup> At p.7 (quality of earnings and run rate).

<sup>163</sup> At p.2.

<sup>164</sup> At p.2.

<sup>165</sup> At p.3.

<sup>166</sup> At p.3.

<sup>167</sup> At p.4.

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- 2 weeks ago – MHRA approved another MA from Orion, again without the Adrenal indication, not launched yet
- Actavis has modelled competitors entering in 2015 without indication for adrenal insufficiency and being launched and dispensed off label
- Modeled share erosion of 60% and price erosion of 90%
- Non binding bid of GBP 522 accounted for generic competition”

Elsewhere in the presentation, the threat from skinny label is emphasised.<sup>168</sup> It is to be observed that the disruptive effect of skinny label, that we referenced above, is fully borne out by this assessment.

- (3) The presentation contains<sup>169</sup> a base case profit and loss projection assuming 2015 competitor entry (which would be skinny label) in 2015, resulting in a revenue reduction of 90% in 3 years. The table reads as follows:

| Assumptions         | 2012  | 2013  | 2014  | 2015  | 2016  | 2017 | 2018 | 2019 |
|---------------------|-------|-------|-------|-------|-------|------|------|------|
| Market growth (%)   | 5%    | 4%    | 4%    | 4%    | 4%    | 4%   | 4%   | 4%   |
| Market share (%)    | 100%  | 100%  | 100%  | 70%   | 40%   | 40%  | 40%  | 40%  |
| Price (£)           | 32.75 | 33.57 | 42.98 | 43.90 | 32.00 | 8.55 | 6.41 | 4.81 |
| Price change ('000) |       | 3%    | 28%   | 2%    | -27%  | -73% | -25% | -25% |
| Volume ('000)       | 914   | 930   | 1,027 | 693   | 412   | 428  | 446  | 463  |
| Volume change (%)   |       | 2%    | 10%   | -33%  | -41%  | 4%   | 4%   | 4%   |

- (4) Given that this is a December 2014 document, the figures for the years 2012 to 2014 are probably “actuals”, with the later figures “projected”. The picture that is painted is stark. Auden is in a monopoly position (at least between 2012 and 2014), able to increase prices irrespective of competition (between 2012 and

<sup>168</sup> E.g. at pp.7 and 9.

<sup>169</sup> At p.14.

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2015), in circumstances where competition from skinny label products (from 2015) would erode quantities sold by Auden and prices charged. It is quite obvious that the beneficial effects of competition are not being felt in the market in the 2012 to 2014 period, as the text makes explicit:

“Assumed competition on Hydrocortisone from Q2 2015 impacting growth in near term adversely (assumed 40% share at 90% discount of current prices)”

**(g) *Skinny label entry***

130. As we have noted, skinny label entry began in Period 94 (Alissa Healthcare) and accelerated in Period 99, when Alissa Healthcare was joined by two other providers. Looking only at the sale prices and volumes of Auden 10mg hydrocortisone, we see the following:

| Period                 | Sale price/pack | Volume |
|------------------------|-----------------|--------|
| Period 94<br>Oct 2015  | £67.74          | 89,710 |
| Period 95<br>Nov 2015  | £69.16          | 58,844 |
| Period 96<br>Dec 2015  | £71.70          | 70,764 |
| Period 97<br>Jan 2016  | £68.93          | 58,162 |
| Period 98<br>Feb 2016  | £70.84          | 53,155 |
| Period 99<br>Mar 2016  | £72.14          | 56,006 |
| Period 100<br>Apr 2016 | £68.65          | 64,660 |
| Period 101<br>May 2016 | £68.13          | 61,643 |
| Period 102<br>Jun 2016 | £62.63          | 64,894 |
| Period 103             | £58.60          | 58,123 |

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|                        |        |        |
|------------------------|--------|--------|
| Jul 2016               |        |        |
| Period 104<br>Aug 2016 | £62.73 | 51,977 |
| Period 105<br>Sep 2016 | £63.01 | 44,227 |
| Period 106<br>Oct 2016 | £59.08 | 35,708 |
| Period 107<br>Nov 2016 | £59.74 | 48,385 |

131. The effects of skinny label entry can also be seen from the graphs at Annex 4. We have explained the general effects of skinny label entry above. The point of returning to the matter is to understand what – if anything – can be derived by way of inference to understand the state of mind of the parties to the 10mg Agreement. We consider that there was a general understanding that skinny label entry would erode the Auden monopoly. This is clear from the documents we have referenced, as confirmed by the subsequent effects on the market. That erosion would take place in a “fixed cake” market, where lower prices would not result in a larger market. The incumbent, Auden, would have appreciated the importance of keeping other holders of Marketing Authorisations for hydrocortisone – even if only skinny label – out of the market.

## **(6) Auden’s state of mind**

### ***(a) Different emanations***

132. It is necessary to consider separately the various emanations of the holder of the 10mg Merck Sharpe and Dohme MA:
- (1) The 10mg Agreement was concluded in October 2012 (Period 58), when the holder was AM Pharma, directly controlled by Mr Amit Patel and Mrs Meeta Patel. Very shortly after this point (Period 59), Auden Mckenzie Holdings Ltd was interposed between the Patels and AM Pharma. We draw no inferences – one way or the other – from this development, and it does not seem to us to be material in any way. Auden Mckenzie Holdings was part of the same undertaking, but was purely a holding company. This state persisted until Period 89, when Actavis acquired AM Pharma and Auden Mckenzie. During this period, therefore, the 20mg Agreement was made, the 10mg Agreement was made, orally and by way of the First and Second Written Agreements.

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- (2) Thereafter, the holder of the Merck Sharpe and Dohme MA moved into various different holding regimes, which correspond to the phases described in the Judgment (Abuse of Dominance Infringements)/[180]. We will consider these subsequent phases together.

**(b) Findings in the Hydrocortisone Decision**

133. Before we turn to these various states of mind, it is appropriate now to set out what the Hydrocortisone Decision found in relation to states of mind. The parties’ subjective intentions are considered generally at Hydrocortisone Decision/6.929ff, and we propose to quote the relevant passages in their entirety, and even though they go beyond Auden, to include Waymade and AMCo:

“6.929 As explained in Section 6.D.I above, the parties’ subjective intentions are not a necessary element in the assessment of whether the Agreements were restrictive of competition. They may however, be taken into account as corroboration of the objective assessment.

- 6.930 The subjective intentions of Auden/Actavis, Waymade and AMCo support the assessment of the Agreements’ content and objective. The evidence shows that each acted in full knowledge of the objective of the Agreements, which was to make substantial payments to Waymade and AMCo in exchange for each of Waymade and AMCo agreeing not to enter the market independently with its own hydrocortisone tablets.

**Auden Actavis**

- 6.931 Auden/Actavis’ subjective intention was to preserve its position as sole supplier of hydrocortisone tablets in the UK, and the ability to charge high and increasing prices that it derived from that position. In order to achieve this, it was willing to make payments to Waymade and to AMCo. As explained above:

- a. Amit (Auden) Patel stated that Auden needed Waymade’s business to maintain sales volumes of Auden’s product (manufactured by Tiofarma), and therefore Auden’s order volumes from Tiofarma: “it was always in our interest to try to keep the volumes reasonably level at the CMO. This was why we entered into the arrangement with Waymade for a low supply price.” As explained above, maintaining Auden’s CMO volumes necessarily entails avoiding independent entry.
- b. From the outset, Auden had therefore sought to calibrate a deal that ceded around a third of the market by value to Waymade, on the understanding that Waymade would make “cost savings...in not bringing the product to market”. Auden acknowledged that both parties had an interest in maintaining a high

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resale price – which the preservation of its position as sole supplier would allow. As Alan Barnard stated in his 28 June 2011 proposal to Amit (Auden) Patel: “Would be happier allowing a lower price on the 20mg because it would be in their [Waymade’s] interest to maintain high resale price”.

- c. Amit (Auden) Patel stated: “I recall having an internal discussion which acknowledged Waymade was our competitor and that we could supply it with hydrocortisone tablets...”. Waymade’s status as a potential competitor (signified most clearly by its MAs) was what prompted Auden to offer it the 20mg Agreement, and later the 10mg Agreement.
- d. “Amit [(Auden) Patel’s] terms to us [Waymade]” were that “if and when we see another 20mg licence granted on RAMA, then we’ll have to come to discuss, but until that happens, the deal is sound.” In other words, the payments in the 20mg Agreement were contingent on the absence of independent entry.
- e. The 10mg Agreement was reached on the same basis as the 20mg Agreement: Auden saw this as another way of protecting its volumes and therefore its position as sole supplier in the market.
- f. Actavis, which took over sales of hydrocortisone tablets from 1 September 2015, acknowledged at the time that “currently in UK we have all the market” – though “we expect competition which will impact volume and price” following genuine independent entry.
- g. When other potential entrants emerged, Actavis continued the approach of Auden. Not only did Actavis continue making payments to AMCo under the 10mg Agreement and implement its own “communications plan”...., drawing on the Project Guardian materials AM Pharma had prepared, it also attempted to agree a similar deal with another competitor, Alissa...Though Alissa ultimately did not accept this offer, this demonstrates that having taken on Auden’s business, Actavis continued Auden’s strategy of attempting to buy off competition on hydrocortisone tablets.

6.932 This evidence demonstrates that Auden/Actavis had a consistent intention when dealing with its potential competitors: it would make payments available to a counterparty in possession of an MA which it perceived as a threat to its position as sole supplier, with the expectation that in return the potential competitor would refrain from entry and allow Auden/Actavis to prolong its position as sole supplier and associated ability to charge high prices.

## **Waymade**

6.933 Waymade’s subjective intention was to use its MAs – and the threat of competitive entry that they represented – as leverage to secure favourable supply terms (i.e.

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payments) from Auden. This would allow it to share in the high and increasing profits Auden derived from its position as sole supplier, rather than face the uncertainty of competition after entry. As explained above:

- a. From the outset, Waymade had intended to negotiate a supply deal with Auden alongside developing its own product, noting that: "the earliest launch of our Hydrocortisone product in glass bottles is May or June 2011" and that "With regards to a negotiation with Auden McKenzie, I suggest that opening a discussion in January would be about right".
- b. Brian McEwan confirmed that the fact that Waymade had an MA for 20mg hydrocortisone tablets helped it to secure a significantly lower supply price from Auden: "The marketing authorisation changed Waymade's position towards Auden McKenzie". This change in position was reflected in the fact that during those negotiations, Auden reduced its proposed supply price from £34.50 to £4.50 in the space of two weeks.
- c. Mr McEwan explained: "They [Auden] know that we can get product made at our own CMO, or they can supply us at a price which we feel is competitive...then we have a choice as to whether we take product from them or whether we manufacture it ourselves." He stated: "at some point in our discussions, I may have made it clear that Waymade had a marketing authorisation [for 20mg hydrocortisone tablets]". When asked why, he said, "so that we could negotiate a better supply price". He went on to say that "if we made the product elsewhere, then they [Auden] would lose those volumes", because Waymade would enter and take business from Auden. He gave the same rationale for the 10mg Agreement, noting that Auden "will lose margin on the product but they will at least retain their manufacturing volumes."
- d. Vijay Patel provided a similar explanation: "we had agreed that we had a licence and we could produce the product at £4.50, and by buying it from him [Amit (Auden) Patel], then we wouldn't produce it, even though we were paying him more than it would cost us. He went on to explain: "If we...when we came to the market, they could actually have lost a lot of the market share to us, therefore they would have said, "Look, we'll supply you or we will come to an agreement". He noted that "the fact that there's not a second player is always in their [Auden's] interest", and went on to say "if I have my product, I would be able to penetrate the market...I suppose he [Amit (Auden) Patel] was selling us a product which he [Amit (Auden) Patel] would normally not have sold if we were in the market, that is all it is. Simple. You see? They can make a certain amount for a finite market and when there is a second player in it, his sales would be diminished."
- e. When asked how Waymade was able to secure such a low supply price from Auden, Andrew Tittershill explained that "the fact that the product is there in the warehouse in Basildon, is the leverage in that Waymade could have placed

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that product on the market...the leverage is it’s in the warehouse in, in Basildon, it could be released for sale.”<sup>170</sup> When asked separately what Waymade’s leverage was, Mr Tittershill said: “the product could be launched”.

- f. Waymade approached the 10mg Agreement in the same way:
- i. In relation to the 10mg Agreement, Vijay Patel stated: “His [Amit (Auden) Patel’s] volumes would start dropping, once we fight him in the market, which we would”. He stated: “They gave the product to us at a price because we have told them [Auden] that we can manufacture it at a certain price, and for them not to lose their volumes, it would be attractive for them to supply the product.”
  - ii. In relation to the 10mg Agreement, Brian McEwan stated: “maybe the inference from me is that, you know, he [Amit (Auden) Patel] can supply me or I’ll get someone else to supply me, and if he wants to retain the manufacturing volumes, then he might agree to supply me.”

## **AMCo**

6.934 AMCo – which acquired Waymade’s 10mg MA, its project to develop its own 10mg hydrocortisone tablets, and key individuals who had negotiated and implemented the 10mg Agreement (especially Brian McEwan) – had the same subjective intention as Waymade. It used its 10mg MA – and the threat of competitive entry that it represented – as leverage to preserve and improve the terms of the 10mg Agreement, allowing it to substitute for the uncertainty of competition the certainty of sharing in Auden/Actavis’ high profits. For example, as explained above:

- a. In the interim period between the currency of the two Written Agreements, John Beighton noted that Amit (Auden) Patel “would probably do a better deal on better terms” as he was “not keen to get into a battle”. “I am also not keen”, he stated, “on having a fight”.
- b. During the negotiation of the Second Written Agreement, Robert Sully asked in an internal email to John Beighton when supply would begin. Mr Beighton replied to Mr Sully, “As for the start date, yes it is for delivery this month...I told him [Amit (Auden) Patel] that if not we will launch our own”. Mr Beighton intended Mr Patel to understand that if Auden did not supply AMCo on the agreed terms that month, AMCo would launch its 10mg hydrocortisone tablets.

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<sup>170</sup> This, of course, is why the supply from Aesica was so important to AMCo, and why a “go slow” on development to production on AMCo’s part is not supportive of the findings in the Hydrocortisone Decision.



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- c. Mr Beighton later explained to AMCo staff that he had used the threat of AMCo’s launch to secure the Second Written Agreement, on the understanding that this meant AMCo would not enter the market: “we have subsequently signed a deal with Auden Mckenzie [sic] to source product from them and therefore our own product will not be launched in UK”; “the work that you did to provide certainty of launch of our product gave those of us who were negotiating with Auden Mackenzie [sic] confidence to achieve the best deal possible for AMCo and I am sure that, as a result, Auden Mackenzie [sic] felt that they should agree to our terms”.”

**(c) *Auden (AM Pharma) as held (directly or indirectly) by the Patels***

134. The Hydrocortisone Decision found that there was actual knowledge of an agreement infringing the Chapter I prohibition (in the manner found by the decision) on the part of Auden during this period. We consider the CMA’s finding in this regard to be unimpeachable:

- (1) Auden had, from the outset, a monopoly over the hydrocortisone market, and (as we have found) abused that dominant position to increase prices at will over a period of many months and years. Auden were in no sense an altruistic organisation, they spotted an opportunity that escaped Merck, Sharpe & Dohme, and leveraged it for all it was worth. Obviously, that was a position that Auden wanted to continue for as long as possible.
- (2) The facts regarding excessive pricing and abuse of dominance, as we have found them, speak for themselves and form the essential backdrop to the conclusion of the 10mg Agreement.
- (3) Auden would, therefore, have been alert to the dangers of competition. We consider that Auden would have been well aware of the Plenadren MA, and would have seen that Plenadren (although a potential competitor) had priced itself so as not to be. But we also consider that Auden would have appreciated the significance of Plenadren’s orphan status as an inhibitor of competition, albeit not a perfect inhibitor. We consider – just as the acquirer of Auden did<sup>171</sup> – that skinny label MAs would be competitors, but competitors at a disadvantage. They would have to price remarkably low in order to gain a market foothold, and although skinny label MAs would not want to do this, Auden would be even more concerned about a major erosion in prices. At the same time, skinny label MAs might find the notion of a deliberate market sharing

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<sup>171</sup> See the documents set out [128] and [129] above.

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arrangement quite attractive – provided the way in which the market was shared was advantageous to them.

- (4) We have described the 20mg Agreement. We consider that it is perfectly valid to use the 20mg Agreement to draw inferences as to Auden’s state of mind in relation to the 10mg Agreement, since Auden was party to all of the material agreements, namely: (i) the 20mg Agreement; (ii) the oral 10mg Agreement; (iii) the First Written Agreement; and (iv) the Second Written Agreement. These agreements all have the same essential purpose, and it is wrong to so narrowly parse a course of conduct as to leave relevant material out. We do not consider that there is any other inference possible than that Auden was paying Waymade considerable amounts of money in order to receive something in return. Given the proximity between Waymade’s readiness to enter the 20mg market to the conclusion of the 20mg Agreement, we consider that it must be concluded that the “deal” was that Waymade stay out of the market.
- (5) We consider that this was exactly what happened when Waymade obtained its 10mg MA (31 October 2012, Period 58). The oral 10mg Agreement was concluded at about the same time, and the timing cannot be a coincidence. The purpose was exactly as with the 20mg Agreement. The First and Second Written Agreements – from Auden’s point of view – did no more than continue an arrangement that Auden found (for the reasons we have described) beneficial to it. The reason for the increase in supply under the 10mg Agreement reflects, we anticipate, AMCo’s increased ability to enter the market: in other words, AMCo could demand a higher price to be “bought off”.

135. We make two further points in relation to this:

- (1) First, the paragraphs we have quoted (Hydrocortisone Decision/6.929ff) refer to a great deal of “secondary” evidence, such as quotations from emails and interviews. We were shown very little of this material in context during the course of a long appeal, and should make clear that our conclusion regarding Auden’s state of mind – and our affirmation of the Hydrocortisone Decision’s conclusion in this regard – is based on the analysis set out in this judgment. The “secondary” evidence cited by the Hydrocortisone Decision is, of course, in further support, but it does not form the basis for our conclusions.
- (2) Secondly, although Hydrocortisone Decision/6.929 quite rightly records that intention is not a pre-requisite for finding an infringement of the Chapter I prohibition, where, as here, the case is one of a disputed Covert Chapter I Infringement (as these infringements are), it will be difficult to conclude that such an infringement existed without considering the states of mind of the

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protagonists, in order to see whether inferences as to conduct properly fall to be drawn.

**(d) *Later phases: holders of the Merck, Sharpe & Dohme MA after Auden***

136. For the reasons we have given,<sup>172</sup> we consider that where one undertaking knows of an unlawful agreement like the 10mg Agreement, and that undertaking is acquired by another company in circumstances where the acquiring company becomes a part of the same undertaking (or, *vice versa*, the acquired undertaking becomes part of a larger undertaking) then the “guilty knowledge” of that undertaking “infects” the rest provided the test defining an undertaking (here, generally, the Decisive Influence Test as far as subsequent acquirers are concerned) is met.<sup>173</sup> This is a consequence of the law regarding undertakings that we described above.
137. However, because it is relevant to penalty, it is important that we state that we do not consider that any of the later entities acquiring the holder of the Merck, Sharpe & Dohme MA did know (intention) or should have known (negligence) of the illegal aspects of the 10mg Agreement:
- (1) We note that the Hydrocortisone Decision does suggest that there was a guilty state of mind on the part, at least, of Actavis.<sup>174</sup> Although it is true that Actavis carried on the commercial approach of Auden, we do not consider that this is sufficient to form a guilty state of mind; and although we note the reference to an attempt to “buy off” Alissa, we were not taken to any of the relevant material, and it would be inappropriate to affirm a conclusion of negligent or intentional infringement on the part of successors to Auden on the basis of their individual subjective state of mind.
  - (2) We accept, of course, that the First Written Agreement and the Second Written Agreement would have been susceptible of discovery, and may even have been known about. But we have seen no evidence of this, and although – if inquiry had been made – the remarkable features of these agreements would have been easily discernible, in the scheme of things the supply to AMCo of hydrocortisone was small (given the overall market share held by Auden). We do not consider

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<sup>172</sup> See [95]ff.

<sup>173</sup> As we have described, the nature of an undertaking is variable according to the economic purpose under consideration. Assuming that a subsidiary is implicated in an infringement, a parent will be part of the undertaking (even if not directly involved) provided the Decisive Influence Test is met. Whether “sister companies” of the subsidiary are – for this purpose – also part of the undertaking will depend on their involvement. They will certainly not automatically be part.

<sup>174</sup> See Hydrocortisone Decision/6.931(g).

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that any later acquirer of Auden can be criticised for failing to appreciate that there was an improper agreement between Auden and AMCo.

However, we do not consider that these conclusions are in any way relevant to the question of the intentional infringement of the Chapter I prohibition by these later holders of the Merck, Sharpe & Dohme MA. That is because the acts and state of mind of Auden – because Auden was part of the same undertaking – are the acts and state of mind of these entities also. If Auden was infringing, then so were they.

138. In reaching this conclusion, we reject the contentions that were made that some kind of affirmation or at least knowledge on the part of the later parent undertaking is required. For the reasons we have given, it is not. This approach accords with the practical reality. The fact is that when Actavis acquired Auden, the arrangements with AMCo continued uninterrupted between these two entities. The whole point of the undertaking as a “unit of account” in competition law is that liability – although ultimately personal – operates at the level of the undertaking, which is (as we have said) an economic and not a legal term of art.

**(7) Waymade’s and AMCo’s state of mind**

**(a) Approach**

139. We are very conscious that the 10mg Agreement was made – orally – between Auden and Waymade, and did not involve AMCo. The timing – just to recap – was as follows:
- (1) On 27 September 2012 (Period 57), Waymade obtained a Marketing Authorisation in respect of 10mg “immediate release” hydrocortisone tablets.
  - (2) In October 2012 (also Period 57), Waymade concluded the 10mg Agreement (orally).
  - (3) On 31 October 2012 (Period 58), this part of Waymade’s business transited to what became AMCo.

In terms of receipt of supplies (packs of 10mg hydrocortisone), Waymade received one month’s worth – if that. The true beneficiary of the 10mg Agreement was AMCo.

140. Waymade did not appeal the Hydrocortisone Decision and did not appear on this appeal. It was AMCo that resisted – in very firm terms – the conclusion reached by the CMA that AMCo had been party to the Cartel Infringements.

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141. Ordinarily, we would approach the question of knowledge and state of mind in a chronological order, beginning with Waymade, considering along the way questions of attribution and AMCo’s knowledge. In this case, we consider such an approach to be inappropriate. We consider that it is important to seek to determine whether AMCo was culpable and whether AMCo committed the Cartel Infringements without reference to Waymade. That is because this is an allegation made against AMCo, not Waymade (which has accepted the findings of the Hydrocortisone Decision) and it would, in our consideration, be unsatisfactory to establish an infringement by AMCo through or using an (uncontested) infringement of Waymade.
142. We therefore propose to look – when considering this question – not at the First Written Agreement (which was, in essence, an attempt by Mr Sully to “regularise” what he perceived as an irregular state of affairs) but at the Second Written Agreement, which was concluded after the supply arrangements pursuant to the oral/First Written Agreement had ended, and constituted a “re-boot” of the arrangement. We will then consider what our conclusions in relation to the Second Written Agreement tell us about what went on before.

***(b) State of mind in regard to the Second Written Agreement***

143. We conclude that the CMA was right in finding that the Second Written Agreement was a sham, not because its terms were not reflective of the relationship between Auden and AMCo,<sup>175</sup> but because those terms only reflected a part of the deal between Auden and AMCo. The terms set out in the Second Written Agreement focussed on what Auden would provide to AMCo (supply of product at a massive discount), and omitted what AMCo agreed with Auden, which was to stay out of the market for as long as Auden’s monopoly position could be maintained. The Second Written Agreement was, therefore, in the true sense, a sham because, whilst it purported to be a complete and self-standing commercial arrangement, it was no such thing.
144. We have reached this conclusion for the following reasons:
- (1) Auden, as we have found, was gouging the market because of their monopoly position, and would have gone (and did) go to considerable lengths to protect that position. For the reasons we have given, such a deal (assuming a willingness to behave unlawfully) would be a “no-brainer”.
  - (2) AMCo, for different reasons, would have found such a deal extremely attractive (assuming, again, a willingness to behave unlawfully). AMCo were not a

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<sup>175</sup> See [15] above, and the consideration of *Snook* at [15(6)] and [15(7)].

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powerful entity in the hydrocortisone market but were seeking to establish themselves. To that end, they had a (skinny label) Marketing Authorisation, and were getting into a position where they might be able to manufacture product in accordance with that Marketing Authorisation (through Aesica).

- (3) The position immediately pre-dating the conclusion of the Second Written Agreement (and assuming no prior knowledge of the oral 10mg Agreement or the thinking that may or may not have underlain the First Written Agreement) was as follows:
- (i) AMCo had – since it had acquired Waymade’s business – received a supply of 10mg “immediate release” hydrocortisone from Auden, enabling it to sell (under Auden’s MA and Auden’s branding) around 6,000 packs of 10mg hydrocortisone a month.
  - (ii) That arrangement ceased as at 31 March 2014 (end Period 75). Although AMCo had been able to continue to sell into the market (presumably using supplies it had stockpiled) during Periods 76, 77 and 78, by Period 78 AMCo could only supply 2,530 packs into the market (instead of around 6,000, as previously).<sup>176</sup>
  - (iii) AMCo was in no position to obtain alternative supplies. We accept that AMCo was doing its very best to obtain such alternative supplies, and that it was Aesica that was at fault here.<sup>177</sup> However, for present purposes, what matters is not why there was no supply, but the fact that there was none.
  - (iv) Even assuming AMCo could have obtained supply to sell under their own Marketing Authorisation, that supply would have been “skinny label”. AMCo in general, and Mr Beighton in particular, were aware of the problems that the Plenadren Orphan Drug designation gave rise to, which would have presented AMCo with serious problems in gaining market share for what would have been perceived by some as a new and inferior product. It is also worth noting that – given AMCo had previously been selling Auden’s “full label” product, AMCo would inevitably have taken a “hit” in relation to those parts of the market it supplied. It is a fair inference that had AMCo been able to source and supply skinny label product: (i) it might have sold less (even though their

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<sup>176</sup> See [122]. Some “bridging stock” was supplied in April 2014: see [Hydrocortisone Decision](#)/3.531.

<sup>177</sup> See [69].

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ability to supply the market was constrained by the limited supply from Auden); and (ii) it would certainly have had to sell at a significantly lower price.

- (4) The position, therefore, in Period 78, is that AMCo were faced with a choice of either leaving the market or obtaining a continuation of the supply from Auden. In negotiating with Auden, it is necessary to ask what negotiating leverage AMCo had. Apart from one factor – to which we will come, and which seems to us the explanation for the deal that was reached – AMCo had no leverage at all. Auden was a monopoly supplier, able to increase price at will, gouging the market. There was absolutely no reason for Auden to agree supply terms of any sort to AMCo. Yet Mr Beighton achieved:
- (i) An increased quantity of supply from Auden, up from 6,000 packs a month to 12,000 packs a month.
  - (ii) At the same, massively reduced price. AMCo paid £1.78/pack. In Period 79, Auden was selling that product at £45.77/pack.
- (5) Mr Beighton accepted that Auden's position was odd. It was not odd, it was commercially imbecilic and we decline to accept that Auden would have concluded the Second Written Agreement without something more coming from AMCo. We also decline to accept Mr Beighton's attempt at explaining the deal, namely that the price to Auden was informed by what AMCo would have paid Aesica to produce supply under AMCo's MA. The two cases are poles apart, for reasons that we have given.
- (6) We conclude that something, not recorded in the Second Written Agreement, was promised by AMCo to Auden. This is where the one card of any value in AMCo's hand could have been, and in our judgement was, played. This was the threat of alternative entry into the market of skinny label product under AMCo's MA. That would have been – for reasons we have described – damaging to Auden's market position and we consider that Auden was prepared to pay a steep price to keep AMCo out. To recap the damage that would be done:
- (i) Generally speaking, the first rival entry onto a market for medicinal products will seek only marginally to undercut the incumbent, limiting supply to achieve that end.
  - (ii) In this case, however, the rival supply would be an imperfect substitute, where the imperfection was unpredictable and odd. The product itself was identical. The problem was that supply to adults (not to children)

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was not an indication for this particular product. The extent to which pharmacies would be prepared to dispense “off-label” was unknown and highly unpredictable. What could be predicted was that the perception of prudential risk might be overcome by reductions in price.

- (iii) We therefore consider that both Auden and AMCo could have anticipated a skinny market entry on the part of AMCo where AMCo would contest the entire market (i.e. no limitation on supply) at a price very significantly below Auden’s. That, of course, would be extremely damaging to Auden’s (unlawful) business model.
- (7) The advantages to AMCo of such a deal (we have already discussed the advantages to Auden) would have been considerable. At the price of a limited supply (12,000 packs/month), AMCo would be able to sell at or above monopoly prices, whilst paying minimal sums in procuring that supply. We have described the monies that flowed AMCo’s way, and we consider that a businessman prepared to disregard competition law would have found this option more attractive than the far riskier alternative of own supply (had this even been possible).
- (8) We therefore infer that there was a conversation between Mr Amit Patel and Mr Beighton at which an agreement was reached, not only that AMCo would stay out of the market, but also that AMCo would take Auden’s product and sell it at around the prevailing market price (as set by Auden). In other words, this was a deal to enable Auden to maintain its monopoly position, and we consider that the deal would have persisted (as indeed it appears to have done) until genuine (skinny label) competition emerged. We make two further points:
  - (i) First, there was ample opportunity for Mr Beighton to strike this deal with Mr Patel. There were, as we have described, a number of conversations between these persons which were not documented, and which should not have taken place.<sup>178</sup>
  - (ii) Secondly, AMCo’s determination to get Aesica to supply product to them to sell under their own “skinny label” marketing authorisation is entirely consistent with this agreement. In order to maximise pressure on Auden, AMCo needed a credible alternative supply. Of course, Mr Beighton would have bluffed – as he said he did<sup>179</sup> – but (as a

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<sup>178</sup> See [72].

<sup>179</sup> Transcript Day 2/p.197



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sophisticated player) he would have known that a credible threat of alternative supply is far better than an incredible one.

- (9) The correctness of this conclusion – which we reach conscious that we must be satisfied to a very high standard – can be tested in this way. The one, big, difference between the First and the Second Written Agreement was the increase in supply. What could Mr Beighton have said to induce Auden to agree to such an increase? We consider that there is only one plausible answer, which is the one given above.

145. We therefore affirm the conclusion reached in the Hydrocortisone Decision, including in particular as to AMCo's state of mind. The qualifications which we set out earlier at [135] also apply.

*(c) Consequential matters from this conclusion*

146. Reasoning from this conclusion as regards the Second Written Agreement, there are two further areas that we need to consider in order to make our findings complete and clear. The first such topic concerns the characteristics of the oral 10mg Agreement and the First Written Agreement. The second concerns the implications of the findings that we have made. We consider that it is both necessary and appropriate to delimit these.

(i) The nature of the oral 10mg Agreement and the First Written Agreement

147. Our conclusion is that the Second Written Agreement was a more aggressive manifestation of what had gone before. We are not in a position to say, with any precision, how the oral agreement between Auden and Waymade was concluded, but we are in no doubt that the substance of that agreement was as it was in the case of the Second Written Agreement:

- (1) Auden were supplying Waymade and then AMCo with full label 10mg product at a massively reduced price, which product Waymade/AMCo could not otherwise obtain, but where Waymade/AMCo had a Marketing Authorisation enabling them to threaten to enter the market with an alternative competitive supply to that of Auden, in circumstances where such competitive supply would have been damaging to Auden's market position.
- (2) Waymade/AMCo were agreeing (i) to stay out of the market with their own supply and instead use a discounted supply from Auden; and (ii) not to use Auden's supply to undercut Auden. We consider these two aspects to be fundamentally linked and the second to be implicit in the first. It would not be in Waymade or AMCo's interests to price low and Auden would expect any

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discounted supply made by them to Waymade or AMCo not to be used to undercut Auden’s own price and so bring about the competitive outcome that Auden, Waymade and AMCo were striving to avoid. In short, it would have been important to Auden to maintain a high price across the market. We consider that such a common understanding would have been an inevitable part of the arrangement, so obvious that it would not require express statement.

148. The First Written Agreement merely formalised the legitimate parts of the deal and left unstated the illegitimate parts of the deal. The increase over time in volumes of product that Auden supplied is explicable by the fact that Auden perceived the risk of rival market entry to have increased. There is a reason the 10mg Agreement was concluded shortly after Waymade received its Marketing Authorisation: the Marketing Authorisation enabled rival supply, which was not otherwise lawful.

149. Again, our conclusions align with those in the Hydrocortisone Decision.

(ii) Findings of dishonesty

150. We have stressed the considerable care with which facts need to be parsed in the case of disputed Covert Chapter I Infringements.<sup>180</sup> We have noted, in this case, that the finding of an infringement in this case might come very close to or in fact amount to an allegation of dishonesty against someone, even though such a finding is not a necessary requirement to establish even an intentional infringement of the Chapter I prohibition.<sup>181</sup>

151. The problem is that it is extremely difficult – and, in this case, we consider, impossible – to find an intentional infringement of the Chapter I prohibition (as we have done) without also making at least an implicit finding of dishonesty. Whilst (i) it may be possible to sweep such allegations under the carpet – to refer to “intention” and to leave the question of dishonesty unspoken – and (ii) this may, in some cases, be appropriate, generally speaking making implied findings of dishonesty is neither fair to the persons against whom such findings are made, nor is it good practice in terms of gathering the best evidence.<sup>182</sup>

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<sup>180</sup> See [10], [11] and [15].

<sup>181</sup> See [16].

<sup>182</sup> See [21] and in particular the cases cited at fn 27. *Bhaur* may be just such a case where dishonesty could not be put. In that case, as here, dishonesty did not have to be established, merely a mistaken state of mind; and the nature of the process before the trial judge meant that there was no-one available to cross-examine the witnesses and put (if that was appropriate) a case of dishonesty. The questioning of the witnesses was, in fact, conducted as neutrally as possible by the trial judge. Clearly it would have been inappropriate for the judge to “descend to the arena” and themselves put a case of dishonesty to the very witnesses whose credibility the judge would in due course be assessing.

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152. In this case, it is obvious from the findings made in the Hydrocortisone Decision itself that issues of dishonesty arose. Although we have already quoted Hydrocortisone Decision/6.930, it is appropriate to set it out again. When describing the subjective intentions of Auden, Waymade and AMCo, the decision records:

“The subjective intentions of Auden/Actavis, Waymade and AMCo support the assessment of the Agreements’ content and objective. The evidence shows that each acted in full knowledge of the objective of the Agreements, which was to make substantial payments to Waymade and AMCo in exchange for each of Waymade and AMCo agreeing not to enter the market independently with its own hydrocortisone tablets.”

153. It is not surprising that this judgment raises questions of dishonesty, and we consider that that needs to be recognized. As a result, two, very difficult, issues arise:

- (1) First, there is the question of the extent to which we can properly make these findings when dishonesty appears not to have been put to the witnesses who were called and who were cross-examined by the CMA. As we have described, such a case was disavowed in closing, and (for obvious reasons) we find this troubling. We deal with this question, which we foreshadowed in Section A(5), in Section D below.
- (2) The second issue we deal with now. Because the findings we have made are redolent with dishonesty, we consider that it is important to delimit the extent of the findings we are making, because we recognise both their unavoidability and their seriousness:
  - (i) We consider that as undertakings, without making any findings in regard to individuals, Auden, Waymade and AMCo behaved dishonestly in concluding the 10mg Agreement. That is consistent with what the Hydrocortisone Decision itself found.
  - (ii) We make no findings whatsoever regarding the individuals who did not give evidence in relation to the 10mg Agreement. They were, of course, part of an undertaking found to have been dishonest (see the preceding sub-paragraph) but we have no clarity as to how events developed within these undertakings and no ability to make more specific findings. We do not need to do so, and we do not do so.
  - (iii) That leaves the position of those who were called before the Tribunal in regard to the 10mg Agreement, Mr Bighton and Mr Sully. We could, of course, evade the question and say that we are making no specific finding at the individual level at all. In other words, all we are doing is making

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findings at the undertaking level. In theory, that is an approach that commends itself, but as a practical matter it is unfair to Mr Sully:

- (a) The consequence of our analysis and our conclusions is that Mr Beighton was dishonest at the time of the conclusion of the Second Written Agreement; and that he lied about it in the witness box.
- (b) It is necessary to be as bald as this partly because it is the inevitable consequence of necessary findings of fact that we have made, but mainly because we do not consider that the same applies to Mr Sully, who also gave evidence before us.
- (c) Mr Sully, as we have described, was at the coal face when negotiating both the First Written Agreement and the Second Written Agreement, both of which were dishonest shams. But we do not consider that he, personally, was dishonest. He had no involvement that we have found in the negotiating of price and/or quantity of product supplied, and it is these aspects which drive the dishonest bargain that was reached. If Auden had chosen to leverage its position in the market by using a distribution agreement with AMCo, whereby AMCo would receive a small share of the revenue (a very limited percentage), then this transaction would be viewed differently. It is the enormous margin that Auden appears to have gifted AMCo that is key, and this was not negotiated by Mr Sully.
- (d) We consider that, as a counsel of perfection, Mr Sully ought to have asked himself – and perhaps asked Pinsent Masons – about the enormous margins that AMCo were making. But we say that having spent many days considering the evidence in this case, and we cannot and do not say that this is anything other than a counsel of perfection.

## **C. CONCLUSIONS REGARDING THE GROUNDS OF APPEAL**

- 154. For the reasons we have given, we uphold the findings of Cartel Infringement in the Hydrocortisone Decision. We set out the various grounds of appeal in [8]. In light of the findings that we have made, it is possible to deal with them relatively quickly.
- 155. We have found that the holder of a dominant position in the market for hydrocortisone products (Auden, and the successive other holders of the Merck, Sharpe & Dohme MA:

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we shall refer to “Auden”) not only abused that dominant position by charging excessive prices (see the Judgment (Abuse of Dominance Infringements)) but also:

- (1) Entered into a series of agreements (with both Waymade and AMCo) to preserve that dominant position and to enable the ability to charge excessively to persist.
- (2) Those agreements involved Waymade and AMCo agreeing not to enter the market with a rival product, but to be supplied (at a significant discount) with Auden’s own hydrocortisone tablets, which would then be sold (generating considerable profit) at the same (excessive and abusive) price as that charged by Auden.

156. All of the grounds of appeal fail. The 10mg Agreement – as we have described it at [155] is a by object infringement of the Chapter I prohibition. The object was flagrantly anti-competitive and the anti-competitive effects significant, in that an abused monopoly position was maintained and supported. The 20mg Agreement is part of a pattern of fact that supports the findings we have made. But we should be clear that the significant product in the market was 10mg immediate release hydrocortisone tablets, and that even without the 20mg Agreement and the findings in the Hydrocortisone Decision regarding the 20mg Agreement, our findings in relation to the 10mg Agreement would have been the same. Furthermore, although there is a link between the dominance of Auden in the market and the subject matter of this judgment, we regard the conclusions of this judgment as standing independently of the findings and conclusions in the Judgment (Abuse of Dominance Infringements).

#### **D. QUESTIONS OF DUE PROCESS**

157. We have not heard from the parties on this question, and it is therefore not appropriate to anticipate. We confine ourselves to saying this:

- (1) In these appeals, it is the role of the CMA to defend the Hydrocortisone Decision. The Hydrocortisone Decision makes the findings we have summarised in Section A(3) and – in particular – the findings of sham and intention that we have set out extensively at [133]. We have affirmed those findings, for the reasons given in this judgment.
- (2) Had no witnesses been called to rebut the findings of Cartel Infringement, then the concerns that we have would not arise. However, Mr Beighton and Mr Sully were called, and it would have been appropriate for the relevant findings in the Hydrocortisone Decision to be put to them specifically. Without stating a final position, because we have not heard submissions, we are concerned that the

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CMA's case in defending the Hydrocortisone Decision was not fully put. We want to hear from all interested parties on this point.

- (3) Assuming, without deciding, that the CMA's case was not fully put, we want to hear from all interested parties as to the implications of this. If this were a civil matter, where the Tribunal was acting at first instance and not in an appellate capacity, our course would be clear: the party failing to put its case when it could have done ought, absent very good reason, to fail. Here, however, matters are very different. The CMA has made a decision which we consider on the merits to have been correct. Had Mr Sully and Mr Beighton not been called, then we are entirely satisfied that the appeals ought to be dismissed for the reasons we have given.

158. It would be inappropriate to proceed further without hearing from all interested parties. We therefore propose and direct that:

- (1) This Judgment be circulated within an extremely tight confidentiality ring, so that if the appeals are allowed, but for reasons not appearing in the grounds of appeal, the damaging findings we have made do not receive wide circulation. On this basis, although of course we would welcome submissions, the Judgment would always remain a "closed" one.
- (2) The appeals be restored to us for further argument on these matters, so that we can (in light of those submissions) properly determine the appeals.

159. Given that we are, for these reasons, in no position finally to determine the appeals in relation to the Cartel Infringements, and that there will have to be a further substantive hearing in order to do so, it would be inappropriate to consider the appeals in relation to the penalties imposed by the CMA in respect of the Cartel Infringements (including, to be clear, in relation to the 20mg Agreement). For this reason, we consider the question of penalty no further.

160. Although we are not finally disposing of the appeals in relation to the Cartel Infringements, we confirm that this judgment is unanimous.

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Sir Marcus Smith  
President

Professor Simon Holmes

Professor Robin Mason

Charles Dhanowa OBE, KC (Hon)  
Registrar

Date: 29 September 2023