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IN THE COMPETITION

Case No.: 1407/1/12/21, 1411/1/12/21-1414/1/12/21:

APPEAL
TRIBUNAL

Salisbury Square House
8 Salisbury Square
London EC4Y 8AP

Tuesday 22nd November-Friday 23rd December 2022

Before:

The Honourable Mr Justice Marcus Smith
Professor Simon Holmes
Professor Robin Mason
(Sitting as a Tribunal in England and Wales)

BETWEEN:

Appellants

(1) ALLERGAN PLC (“Allergan”)

(2) ADVANZ PHARMA CORP. LIMITED & O’RS (“Advanz”)

**(3) CINVEN CAPITAL MANAGEMENT (V) GENERAL PARTNER LIMITED &
O’Rs (“Cinven”) (4)**

(4) AUDEN MCKENZIE (PHARMA DIVISION) LIMITED (“Auden/Actavis”)

(5) INTAS PHARMACEUTICALS LIMITED & O’RS (“Intas”)

AND

Respondents

COMPETITION AND MARKETS AUTHORITY (“The CMA”)

APPEARANCES

Mark Brealey KC (On behalf of Advanz)

Daniel Jowell KC & Tim Johnston (On behalf of Allergan PLC)

Sarah Ford KC & Charlotte Thomas (On behalf of Auden/Actavis)

Robert O'Donoghue KC & Emma Mockford (On behalf of Cinven)

Robert Palmer KC, Laura Elizabeth John & Jack Williams (On behalf of Intas)

Marie Demetriou KC, Josh Holmes KC, Tristan Jones, Nikolaus Grubeck, Michael Armitage,
Professor David Bailey & Daisy Mackersie (On behalf of the ("CMA"))

1 Wednesday, 23 November 2022

2 (10.30 am)

3 MR ROBERT SULLY (continued)

4 Cross-examination by MS DEMETRIOU (continued)

5 THE PRESIDENT: Ms Demetriou. Good morning. Bear with us
6 one moment and we'll log ourselves into Opus.

7 MS DEMETRIOU: Of course.

8 (Pause).

9 THE PRESIDENT: Ms Demetriou, thank you very much.

10 MS DEMETRIOU: Good morning, Mr Sully.

11 I think before we go on to look at orphan
12 designation, which is the main topic I am going to come
13 on to in a moment, I just want to go back on a couple of
14 questions relating to the agreements, and so we saw
15 yesterday that AMCo tried in autumn 2013 to negotiate an
16 increase in the volume of packs from 6,000 to 18,000,
17 yes?

18 A. Yes.

19 Q. And you accepted yesterday that an obvious reason why
20 Auden might not have agreed to increase was because that
21 would entail them losing a lot of money, yes?

22 A. Yes, we suspected that.

23 Q. Yes. And that's because, as we canvassed yesterday, the
24 supply from Auden to AMCo was at 1 pound per pack when
25 Auden could instead have been supplying the product at

1 the market price to wholesalers, yes?

2 A. Yes.

3 Q. So every additional pack, I think it follows, that was

4 transferred from Auden to AMCo meant a further loss of

5 profits for Auden?

6 A. Instead of selling it to the wholesaler market, yes.

7 Q. And then if we go to paragraph 84 of your witness

8 statement, so that's at {B2/2/22}. So you say here that

9 AMCo committed -- so this is the bottom of paragraph 84

10 I am looking at, do you have that, Mr Sully?

11 A. Yes.

12 Q. So it says --

13 A. The second agreement, paragraph 84, yes.

14 Q. Yes, exactly, thank you. And it says that:

15 "AMCo committed to purchase a minimum of 12,000

16 packs per month at £1.78 ..."

17 Yes?

18 A. Yes.

19 Q. And then we know that AMCo tried to get more volume.

20 You say that there in the last sentence:

21 "We tried to get more volume, but that was as much

22 as we could negotiate."

23 Yes?

24 A. Yes, so it was a minimum purchase order. We wanted to

25 make sure we got at least 12,000. We wanted to get

- 1 more, but that was as much as we could get.
- 2 Q. When you talk about a commitment to purchase, that
3 wasn't a difficult commitment to fulfil, was it, because
4 you wanted as much as you can get? That is fair, is it
5 not?
- 6 A. Yes, we wanted as much as we could get and by signing
7 the contract, it had a minimum quantity, so that was the
8 commitment I am referring to there.
- 9 Q. And the barrier to getting more, to getting more
10 volumes, was Auden being unwilling to supply more, yes?
- 11 A. Yes, Auden refused to supply -- to agree to more in the
12 contract. I believe we tried to get more afterwards,
13 but that's a belief on what I was told and I believe
14 they said no.
- 15 Q. And I think you would agree again that the obvious
16 reason why Auden was not willing to supply more than the
17 12,000 was the same as before, that a higher volume of
18 sales to AMCo meant loss of profits to Auden?
- 19 A. We suspected that, yes.
- 20 Q. Now, pausing there. I asked you some questions
21 yesterday about this idea in your witness statement that
22 Auden was akin to a CMO, do you remember that?
- 23 A. Yes.
- 24 Q. And so if -- the question I want to put to you now is if
25 a business like AMCo were to approach an actual CMO like

1 Tiofarma or Aesica for higher volumes of a product, then
2 that CMO would presumably be keen to supply higher
3 volumes, would they not, because it would mean more
4 sales for them?

5 A. Yes.

6 Q. So for an actual CMO supplying more volumes is a good
7 thing, it is profitable for them?

8 A. Yes, (inaudible).

9 Q. Yes, exactly, so it means higher revenues?

10 A. Yes.

11 Q. Now you refer in your witness statement to 12,000 packs
12 being a minimum. We have just looked at that in
13 paragraph 84 and that is because that is what is written
14 in the second written agreement, yes?

15 So let us look at that to remind ourselves. That is
16 at {H/528/22}. So you see there it says "minimum
17 volumes" in the third column, yes?

18 A. Yes.

19 Q. And then 12,000 packs?

20 A. Yes.

21 Q. If we go to page 8, {H/528/8}, of this same document, we
22 saw clause 5.1. That, again, says that "the parties
23 agree", I am looking about halfway down:

24 "Notwithstanding anything stated in the Forecast the
25 Parties agree that Amdipharm must place and Auden must

1 supply and deliver to Amdipharm each calendar month
2 commencing June 2014 at least the Minimum Volume
3 Quantities ..."

4 A. Yes.

5 Q. And the initial forecast is 12,000 packs.

6 Do you accept that although this agreement refers to
7 12,000 packs as a minimum and it also contains
8 a reasonable endeavours clause, I think, so let us just
9 look at that. It is in 5.2. So there is a reasonable
10 endeavours clause:

11 "Auden shall use reasonable endeavours to accept all
12 orders but is only obliged to accept orders representing
13 the Minimum Volume for each calendar month."

14 So moving on, Mr Sully. Looking at clauses 5.1 and
15 5.2, we have seen the minimum order and we have seen
16 a reasonable endeavours clause in 5.2. And I think you
17 would accept, would you not, that although this refers
18 to minimum volumes as 12,000 packs, and although we have
19 got this reasonable endeavours clause, everyone at AMCo
20 understood that in fact Auden would not supply higher
21 volumes than 12,000?

22 A. I think it would be fair to say we suspected they would
23 not. We were in the part of the negotiation we wanted
24 to make sure we absolutely got 12,000. We wanted more.
25 Our suspicion was they were not going to give us more.

1 There certainly was not an understanding that that was
2 a volume cap, but that was the -- the suspicion was they
3 will not give us more. That would be fair to say.

4 Q. And in fact, if you're thinking about -- I am not
5 suggesting anything in terms of an understanding. I am
6 just thinking now about your internal position. It
7 would have been a bit more than a suspicion, right? You
8 knew they had no commercial incentive to supply you with
9 more than 12,000 packs. That is fair, is it not? You
10 would have been surprised if they had?

11 A. Yes, probably, I mean, there is potentially -- there
12 were potentially ways if we were more at effective at
13 getting it to market but then given the price I think,
14 yes, I think that would be fair to say.

15 Q. In practice, I think you would also agree that this
16 operated as a capped volume?

17 A. Subsequently, when we saw that they had definitely not
18 ever given us more than 12,000 packs, effectively we
19 understood that to be the case. We had put it in place.
20 We just wanted to make sure we absolutely got 12,000
21 packs. We wanted to get more if we could, but, as I
22 say, we suspected they would not give us more. It was
23 never referred to as: this is a volume cap. You will
24 never get this much.

25 Q. I understand, so I think -- is this a fair summary of

1 your evidence, that it is not referred to as a volume
2 cap so in fact we see it is referred to as a minimum
3 volume, but that your understanding was that in practice
4 it would operate as the fixed amount, that the volumes
5 would not be exceeded because Auden would be losing
6 money if they supplied you with more volumes than
7 12,000. Is that a fair assessment of what you thought
8 about it at the time?

9 A. No, I think we thought -- not quite. I think we thought
10 about it at the time. This is the minimum we want. We
11 knew, retrospectively if we looked backwards, they had
12 supplied all over the place, so it was 8,000 packs,
13 1,000 pack, 6,000, 2,000 and we had hoped we would be
14 able to get a bit more than that. We just wanted to
15 make absolutely sure we did not get less than that.
16 Effectively, we wanted to make sure we were not signing
17 up to something that there was a three-month clause to
18 hold us off the market, because of the reasons we
19 discussed yesterday with the orphan designation. We
20 wanted to make sure this wasn't something that they sort
21 of signed us up to and then in fact it dribbled through
22 and actually ended up being less on average. It was not
23 we know this is 12,000 packs, we will not get one more,
24 one less. This was us going: we need to make sure
25 contractually we have at least 12,000 packs. We hoped

1 to get more.

2 THE PRESIDENT: To put it another way you were not
3 particularly troubled by the minimum? In other words,
4 you were confident that you could sell more than 12,000.
5 That is why you wanted more.

6 A. Exactly, yes, yes.

7 MS DEMETRIOU: So looking at what you have just said, you
8 were keen to ensure you did not get less than 12,000
9 packs, yes?

10 A. Yes.

11 Q. But because you have accepted already that Auden was
12 losing a lot of money in making these sales to you, you
13 would have appreciated, just as a matter of basic
14 business and economics, that they would be unlikely to
15 sell you more than 12,000 packs. That must be right,
16 must it not, Mr Sully?

17 A. Yes, I think that flows from saying we suspected they
18 would not sell us more. But this wasn't, you know, as
19 I said, the order pattern is never exactly this amount
20 each month. If we could have got more, that would have
21 been great. We really would have liked that.

22 Q. Of course. Let us go to {H/652/1}. Now, this is an
23 email exchange that you are not copied in to and in fact
24 you said yesterday that you were not involved in supply
25 chain matters, but Ms Hill, who we see this is from, was

1 involved in supply chain matters, was she not?

2 A. Yes, well, she was head of UK commercial, so she would
3 have told supply chain what she wanted to order.

4 Q. Yes, so she was, you are saying, head of UK commercial?

5 A. Yes.

6 Q. And she was on the executive team?

7 A. She was on the executive team, yes.

8 Q. And that the problem being flagged here is, if you go to
9 the middle, do you see it says:

10 "Please see the attached orders received from
11 Mawdsleys.

12 "In total we have received 7,000 packs from them and
13 already have back orders of AAH and Waymade 5000 & 1500
14 packs respectively.

15 "As far as I am aware monthly we are getting 12000
16 packs of Hydrocortisone tabs and the total of all these
17 orders are coming up to 13500 packs."

18 So what she is saying there is we are getting orders
19 from our customers for more than the 12,000. In fact,
20 we have got orders for 13,500, yes?

21 A. That appears to be what this says, yes.

22 Q. And then if we scroll up, you see that what she is
23 saying there is -- she doesn't say, well let us go back
24 to Auden and ask them to use their best endeavours to
25 supply us with 13,500 packs, does she? She says that

1 you'll need to take 750 packs off each of the biggest
2 orders. In other words, you'll have to tell your
3 customers they cannot have as much as they have asked
4 for, yes?

5 A. That looks like what it says, yes.

6 Q. So it looks from this that Ms Hill, at least,
7 understands that there is no real scope to get more from
8 Auden, yes?

9 A. That's what it looks like, yes.

10 Q. Let us go to {H/758/1}. This exchange -- there is a lot
11 of redaction here, but it doesn't terribly matter. It
12 is dated August 2015 and if we scroll down -- we can see
13 the -- do you see the subject matter is:

14 "Hydrocortisone 10mg tabs ... export to Sudan", yes,
15 and that seems to be what this exchange is about.

16 If we go down to page 2, {H/758/2} and we look in
17 the middle of the page there is an email from
18 Mr Beighton to you, do you see that?

19 A. The 12,000 packs we get from Auden.

20 Q. Yes, "the 12K packs" that we get from Auden are sold to
21 specific customers every month and we do not have any
22 spare -- I am sure we would struggle to get more?"

23 A. Yes.

24 Q. So, again, you both understood at the time, did you not,
25 that you were not really going to get more from Auden?

1 A. As I said, we suspected when the agreement was signed we
2 were not going to get more. Certainly by 2015 when they
3 had not given us more, they were clearly only giving us
4 12,000 packs. That was the understanding of what we
5 were going to get and we were not going to sell to
6 customers, tell customers we could deliver what we did
7 not have. That is what I assume Jane meant and here
8 I think John is saying we only get 12,000 packs, but
9 certainly we understood by 2015, certainly
10 by August 2015, it was clear Auden did not intend to
11 give us more than 12,000 packs.

12 Q. And that is presumably why there is no response from you
13 along the lines of: do not worry, there is a reasonable
14 endeavours obligation. This is only a minimum. We can
15 go and ask for more. It is because you understood that
16 would not really lead to anything positive, as far as
17 AMCo was concerned, in terms of more volumes, yes?

18 A. That is a fair assessment. By now we knew they were not
19 going -- if they had gone under 12,000 packs, we had
20 effectively resigned ourselves to the fact that was what
21 they were going to give us.

22 Q. I just want to look at {H/479/2}, please. Now, again,
23 this is -- I think that is a wrong reference. Do not
24 worry about that. So let us go to {H/778/1}, please.
25 We can see from the top email -- the top of the email

1 that it is a chain between you and people at Concordia
2 but there is redaction as to who at Concordia, and it is
3 dated 1 October 2015. So that is the period shortly
4 before Concordia's acquisition of AMCo, yes?

5 A. Yes, they had signed to acquire us in early September,
6 but I think the acquisition closed on 21 October, so
7 just before.

8 Q. And if you go -- if we go to the top of page 3,
9 {H/778/3}, this is part of the chain and it is an email
10 from you of 23 September?

11 A. Mm-hm.

12 Q. It is quite a long email. But let us go -- I am just
13 showing you that so you can see what it is, but if we go
14 to page 4 {H/778/4}. I think we need to scroll down?

15 A. The top of page 4.

16 Q. Maybe it is the top of page 4. Yes, that is it. So
17 what we see there at the top of page:

18 "AMCo currently sells Hydrocortisone in the UK which
19 it sources from Auden McKenzie ... under an OLS
20 agreement as the Auden product has an 'orphan drug'
21 status which gives it a form of protection. There is
22 a volume cap in this OLS agreement."

23 So you were thinking, were you not, of the 12,000 in
24 practice being a cap on the volumes that are sold?

25 A. By this time. As I say, this is 18 months in. It was

1 clear they were not giving us any more. I think this
2 arose out of our -- so effectively I wanted to be honest
3 and say we are only getting 12,000 packs. I think at
4 the time Concordia were looking -- there was a sort of
5 project underway to say what can we get more, what is
6 the upsides and this was his cap control for the report.
7 So I wanted to make sure there wasn't any misleading
8 them. Actually, you can look at this contract and say
9 you can have 20,000 or 50,000 packs. We knew by then.
10 As I said, we were resigned to the fact that this was
11 going to be 12,000 packs and that is what I was
12 referring to.

13 Q. When you say by then, Mr Sully, I think in fact when you
14 think back to how the supply had been operating, even
15 before the written agreements, the principle on which
16 the parties were working was that the volumes that were
17 agreed were in effect maximum volumes, no?

18 A. I do not know if that is actually right, because the
19 volumes, as I understand it, fluctuated quite a lot. We
20 were not entirely sure really until we put the draft in
21 place for the first agreement which is the autumn of
22 2013. When you looked at it was 6,000 packs a month,
23 but it had fluctuated a lot during that period and
24 certainly I do not know what it was before Cinven had
25 acquired Amdipharm. But I accept that certainly

1 by August -- sorry -- this was October 2015, we
2 certainly looked at this and thought they were only
3 going to supply us 12,000 packs.

4 Q. So let us go back a time in bit. So let us go to
5 {IR-H/554/20}. We looked at this yesterday. We saw
6 this yesterday, yes? You recognise this, it is the
7 Pinsent report?

8 A. Yes.

9 Q. And Pinsent say, this is 8.1.3:

10 "We are instructed that Amdipharm has an
11 undocumented arrangement with Auden, under which Auden
12 supplies a limited volume of its 10mg
13 Hydrocortisone ..."

14 Those were your instructions, were they not?

15 A. Yes, well that was -- I think we looked at the
16 documents. That was me passing on the instructions, the
17 explanation I had been given by Brian McEwan to them,
18 but effectively that is the instruction and then the
19 further digging information I had also given that to
20 them, yes.

21 Q. But you were aware, were not you, Mr Sully, that efforts
22 had been made periodically to increase the volumes that
23 Auden was going to supply?

24 A. Yes, yes, absolutely.

25 Q. And that once agreement had been reached at each stage,

1 the business appreciated that those were the volumes
2 that were going to be supplied. So when there was an
3 agreement for 6,000 packs, you did not treat that as
4 being a minimum. You appreciated, did you not, that
5 Auden would have no incentive to supply more than 6,000
6 packs, because if it did it would be losing a lot of
7 money?

8 A. Well, so I think the 6,000 packs was proposed
9 in December 2013 and I know that we tried to get 7,000
10 packs in January 2014. When we signed in February 2014
11 the first agreement and it had 6,000 packs, we only had
12 six or five weeks to go, so I think it would be to say
13 that at that time it was -- we knew that was 6,000 packs
14 as a minimum and we were unlikely to get more. As
15 I say, when we signed the second agreement and 12,000
16 had been agreed as a minimum order of quantity, we
17 suspected they would not give us more, but we certainly
18 were trying to get more and would have liked to have
19 more.

20 Q. Can we go briefly to {H/763/1}. This is
21 dated August 2015 "AMCo's pricing expertise" I just want
22 to show you the front page so you can see the date. But
23 let us go to page 5 {H/763/5}. What you see here is at
24 the top you see "very stable and -- " so this is about
25 Hydrocortisone 10mg, yes? And then you see:

1 "Very stable and slowly growing market", yes?

2 A. Yes. Sorry, I see where you're looking, yes.

3 Q. And "very stable market share ..."

4 A. Yes.

5 Q. And then do you see the two sort of speech bubble-type

6 things?

7 A. Yes.

8 Q. So that says -- these are the monthly volumes, yes, over

9 time and do you see that the second one says:

10 "Small monthly discrepancies due to month end

11 ordering but yearly volumes fixed."

12 Yes?

13 A. Yes.

14 Q. And so that was the position, was it not, so it is not

15 right, is it, that there were fluctuating volumes.

16 There may have been some discrepancies due to just the

17 ins and outs of the ordering, but in fact the volumes

18 were fixed under these agreements, were they not?

19 A. No, I think that's commenting that -- that fluctuation

20 is exactly what I was talking about and if we could have

21 ordered more and they had given us more and had not

22 noticed or had agreed to give us more, that would have

23 been great, but, as I say, we suspected they would not

24 and I think this is saying, when you look at it, it is

25 clear they are sticking to that 12,000 and we are not

1 going to be able to get more, which I think is why it is
2 forecast going forwards.

3 THE PRESIDENT: What you are saying is when you get volume
4 actual you may for any given month, take February 2015,
5 receive more than 12,000, but the price you pay for that
6 is in other months you get less.

7 A. Yes, that, exactly. That looks like the case. I think
8 we would have liked that if they had not noticed they
9 had given us a bit more than expected, fantastic. We
10 did not want them to be able to say we've given you too
11 much, give it back. But, as I say, the fluctuating
12 picture is what I understood to be the case, but we
13 recognised and clearly when this was produced they
14 looked at it and said, look, it is clear that they are
15 only sticking to 12,000 packs. I assume that is the
16 average of that. That's why it says that.

17 Q. All right, thank you very much, Mr Sully. I want to
18 move on now to the issue of the orphan designation?

19 THE PRESIDENT: In that case, Ms Demetriou, just two
20 questions which arise out of this topic. I wonder if we
21 could bring up {H/214/1}. If we could just move to the
22 next page so we can identify what this document is
23 {H/214/3}. You see this is an email from you and if we
24 spool through you will see - let me take you to the bit
25 that I am interested in reading and you can then get the

1 context.

2 If we go to page 5 {H/214/5}, the passage that
3 I want to ask you about is the second bullet point on
4 this page. Perhaps if you read that to yourself?

5 A. The second bullet point, sir?

6 THE PRESIDENT: Yes, the second bullet point. The one
7 beginning:

8 "We also discussed ..."

9 (Pause).

10 A. Yes, sir.

11 THE PRESIDENT: And then, Mr Sully, just so you can see what
12 this is, if we move to the top of page 4, {H/214/4}, you
13 will see that it is an email to you. I do not know if
14 you need see any more to understand the context.

15 A. Yes, I can see that, yes.

16 THE PRESIDENT: Great. Let us go back then to that bullet
17 point. What it says is, as you can see:

18 "We also discussed that you would also check whether
19 any other commercial arrangements were in place with
20 AM."

21 So that sounds like a communication to you about
22 what was discussed?

23 A. Yes.

24 THE PRESIDENT: And then you have got what looks like an
25 answer to that, "Yes, we supply AM with Carbimazole".

1 Is that a response from you or can you not say?

2 A. I suspect so, yes. It looks like it to me.

3 THE PRESIDENT: It looks like a confirmation.

4 A. I know the Pinsent report covered in the same section

5 the concern about the Hydrocortisone agreement and the

6 Carbimazole agreement. I am pretty sure that would have

7 been me saying, yes, this is the point you need to look

8 at.

9 MR O'DONOGHUE: If you look at page 3 it says "Please see

10 below comments from Brian."

11 THE PRESIDENT: Yes, I am very grateful.

12 MR SULLY: So I guess it would be me passing on Brian's

13 comments.

14 THE PRESIDENT: You may not be able to expand on this, but

15 if you can it would be very helpful. Can you explain

16 what your understanding was as to the nature of the

17 arrangements regarding the supply of Carbimazole under

18 an arrangement which is almost exactly the opposite of

19 Hydrocortisone?

20 A. Yes, sir. So this came about through the digging and so

21 it covers a period, but so when they were raised with

22 me, these informal agreements with Auden McKenzie, they

23 were raised as: are you aware there are two agreements,

24 Carbimazole and Hydrocortisone? And when I looked into

25 it what Brian --- Managing Director of Amdipharm

1 explained was a company called NRIM had obtained an MA
2 in June 2012 for Carbimazole, but had not been able to
3 supply, did not have a validated supply source, so it
4 had said to Amdipharm -- get the names right -- will you
5 supply us with Carbimazole? This is before the
6 acquisition of the Cinven of Amdipharm.

7 He explained that Amdipharm had agreed to and for
8 that period had supplied NRIM with Carbimazole; there
9 were two strengths and it was supplied at £2 and £3 a
10 pack. NRIM had then been acquired -- I think this is
11 referred to in Pinsent's report -- had been acquired by
12 Auden McKenzie in early November 2012, so around the
13 same time as Cinven acquired Amdipharm, and Brian
14 explained that Amdipharm had agreed with Auden to carry
15 on supplying Carbimazole until it resolved its
16 manufacturing issues. And then that -- so there was
17 then an agreement put in place to document that, to make
18 sure it was clear. That agreement came to an end at the
19 end of March 2014 and, effectively, it was always
20 supplied to Auden as: here's the draft Hydrocortisone
21 agreement, here's the draft Carbimazole agreement. It
22 came to an end at the end of 2014 and Auden McKenzie
23 then sorted out their supply issues and they launched
24 in June 2014.

25 I think the only other detail which I think

1 I mentioned yesterday is that when Cinven took control
2 of Amdipharm in January 2013 the price had changed to
3 a drug -- to a drug tariff less wholesaler margin cost.

4 THE PRESIDENT: Yesterday we used the terms "quid pro quo"
5 to describe, as it were, arrangements going both ways.
6 I do not want to put words in your mouth, so do tell me
7 if I am barking up the wrong tree, but was the
8 Carbimazole arrangement the exact opposite of the
9 Hydrocortisone, what you would call the quid pro quo in
10 this situation?

11 A. So I do not know, because we did not negotiate it. That
12 effectively was one of the concerns we said to Pinsents
13 There are these two agreements that go each way. What
14 do you think the risk is? They say that they have got
15 manufacturing issues and they're resolving them and they
16 did and they launched. But we wondered internally did,
17 was part of -- did Vijay Patel of Waymade agree with
18 Auden well I will carry on supplying you Carbimazole if
19 you give me Hydrocortisone, because I have got
20 manufacturing issues on that, but that was us
21 speculating. I do not know if that is true or not.

22 THE PRESIDENT: That is very fair. Then just a final
23 clarification in respect of your witness statement. If
24 we could bring up your witness statement at paragraph 54
25 {IR-B2/2/15} and if you just read that, but the bit I am

1 interested in, simply by way of clarification, is the
2 quote three lines from the bottom:

3 "But I have seen emails suggesting otherwise and we
4 need to all agree on the plan."

5 A. Yes, sir.

6 THE PRESIDENT: If there is anything you can do to unpack,
7 to explain to us what emails you are referring to and
8 what they were doing in suggesting otherwise, that would
9 be very helpful. It may be you cannot remember, but if
10 you can.

11 A. This is the point I touched on. Perhaps I did not say
12 it very clearly yesterday, on -- so this
13 is December 2013 and effectively when -- we had been
14 looking at this acquisition in Sweden and I was picking
15 up a lot of stuff by email and I came back and there was
16 a lot of confusion in the business. And I think there
17 were sort of four or five things underway.

18 So the first was the Amdipharm supply chain --
19 everyone had moved to the London office, so the Croydon
20 Mercury company and Basildon Amdipharm moved to the
21 London office and new AMCo teams were taking over
22 everything. So the Amdipharm supply chain team that had
23 been working with Aesica, trying to get the product to
24 market, had handed over to the new product team of AMCo.
25 So that was Wayne Middleton, Paul Frankland across to

1 Rahul Dhorajiwala and Genevieve Parent and they were
2 unclear on a number of things. There was a handover,
3 what is going on here, what is this project, what is
4 this orphan drug thing? I come back to that issue.

5 At the same time, Aesica had manufactured under that
6 arrangement the batch that we all hoped would be
7 saleable and we could launch in February at the time and
8 in fact on 10 December it had failed stability
9 completely. So then all the new AMCo technical staff,
10 the technical senior guys had come in and said hold on
11 a minute, this is a problem. It looked like the
12 Amdipharm guys had resolved all these stability assay
13 problems and actually it has just failed all over again.

14 In addition -- so that issue generated a whole bunch
15 of work and then the senior head of -- like the global
16 head of quality, the global head of regulatory, a lot of
17 senior people were involved in. This is a product we
18 are supposed to be launching next year. It is our
19 biggest launch for 2014 and it has just failed stability
20 in December. There is no way we can launch this.

21 Then at the end of November we had applied for
22 a marketing authorisation for the project that Mercury
23 had been undergoing with MIBE in Germany. MIBE in
24 Germany had a full indication licence and we had thought
25 if we apply for a UK version of that we will get a full

1 indication licence. So we applied for one and the MHRA
2 came back at the end of November and said, no, you have
3 to have a reduced one for this replacement therapy in
4 Hyperplasia, which is a tiny part of the market because
5 of this orphan drug thing and so that was another issue
6 that had caused a whole load of confusion and I was
7 asked by the management team to go and check this, which
8 we did with Pinsent. As I mentioned, they came back and
9 said you cannot do anything about this orphan drug
10 thing.

11 Then on top of that there was the confusion caused
12 that when Brian had been going with the draft to
13 Auden McKenzie to say we need to document this informal
14 Agreement, it does not comply with AMCo's compliance
15 policies because it isn't in writing, he provided the
16 drafts of the Hydrocortisone and the Carbimazole
17 agreements we had supplied. Amit Patel at
18 Auden McKenzie had come back and said, well, I am not
19 particularly happy about that, but I want you to look at
20 buying my company. I think that is a far better way
21 forward. Why do you not buy Auden McKenzie or buy the
22 Hydrocortisone business?

23 So sort of a combination of all of that was what I
24 had. Dee Brian, who was head of M&A, had been asked
25 effectively to pretend we want to buy his company,

1 because we had said we absolutely need to get these
2 signed, these agreements, these informal agreements,
3 because it is a medium -- it is the only medium risk
4 compliance red flag in the business at the time and
5 I said we had to do that. We had to sort of play along
6 for a bit at looking at his company. We said fine. Let
7 us do that.

8 So she is doing this sort of project to do that.
9 A combination of all those things meant there was a lot
10 of confusion. So what I came back to was and what I was
11 seeing on emails was all of that going on and I said,
12 well, hold on a minute. We've already agreed way back
13 earlier in the summer this Aesica -- it is quite clear
14 this Aesica one is an interim supply -- sorry the Auden
15 one is an interim supply until Aesica comes online. We
16 plan to launch in February. If there is an issue that
17 is fine, but we need to carry on with that plan and that
18 is effectively what I wanted to clarify and John came
19 back, as you see there, and said that is absolutely it.
20 We are using Auden as an interim supply until we can
21 launch the Aesica product.

22 THE PRESIDENT: Thank you. Ms Demetriou.

23 MS DEMETRIOU: So there are a few things that have come out
24 of that. I want to --

25 THE PRESIDENT: Follow up if you wish to.

1 MS DEMETRIOU: Thank you.

2 On the issue of Carbimazole and I hope this also
3 helps the Tribunal, but if we can go back to the
4 document that the Tribunal took you to, which is
5 {H/554/21}. Sorry, can we go to {IR-H/554/21}. If we
6 can go to the bottom of the page or the top of page 20
7 actually top of page 20. Scroll down, so yes, at the
8 top of page 20, so 8.1.3. This is the Pinsent advice
9 and 8.1.3 says what they are instructed. That refers to
10 the arrangements about Hydrocortisone, yes? You can see
11 there the rebate arrangement. So there is a rebate
12 which we discussed yesterday. So AMCo's charged £38 per
13 pack and there is a rebate for £37 so the actual price
14 is £1, yes?

15 A. Yes, that is what we discussed yesterday. One of the
16 things we did not like about it when we discovered it.

17 Q. I do not want to get into the rebate. I am just trying
18 to show you other parts of the document so we can see
19 what we are looking at?

20 A. Right.

21 Q. Then we see at (a) there is a reference to Carbimazole
22 and those are described below.

23 Then if we scroll down, do you see 8.1.5:

24 "We note under a separate arrangement (also with no
25 written contract) Amdipharm supplies Auden with

1 Carbimazole under largely similar terms."

2 Then it explains about the MA and then do you see at
3 the bottom:

4 "The pricing under this [and if we go to the next
5 page] arrangement is that Amdipharm supplies Carbimazole
6 to Auden at a 'slight discount' from its usual sale
7 price (£37 in place of £38)."

8 So it was very different from that in perspective,
9 was it not, the discount was very small?

10 A. No, so that change in price had come about once
11 Amdipharm had switched ownership. So there was less
12 concern about it, because the concern that Pinsent
13 raised and that we had was on this rebate idea, but
14 the -- as I understand it, the price before Amdipharm
15 was acquired by Cinven was £2 or £3 and I think there's
16 references in some of the drafts, because there was some
17 confusion when we were drafting the first set of
18 agreements, as to, is the price £2 or £3 or is it drug
19 tariff less a percentage and it was drug tariff less
20 a percentage. But it apparently had started off as £2
21 or £3 and once Amdipharm was acquired by Cinven it had
22 been changed.

23 Q. So at this stage once -- when you are concerned about
24 it, so you are not -- the supply at this stage there is
25 a slight discount as opposed to the 97% discount for

1 Hydrocortisone, yes?

2 A. Yes, yes.

3 Q. That is why you are saying that is?

4 A. Exactly. So when I am instructing Pinsent in the summer
5 of 2013, I am saying this is the price that it is.

6 If that helps, that is why the focus was on this
7 Hydrocortisone one. Is there an issue with the rebate,
8 which we think there is. Yes, let us get rid of that
9 and is there a wider issue we are missing.

10 Q. Thank you. You then said a lot of things about Aesica
11 and so on and I cannot hope to unpack all of them,
12 because you said quite a lot in answer to the question,
13 but I just want to pick up one thing and ask you if this
14 is what you really meant. You said that
15 the October 2013 batch of the Aesica product failed
16 stability tests and that is not right, is it? It is not
17 what Mr Middleton says in his statement. Do you
18 actually remember that it failed stability tests or is
19 that is a misstatement by you?

20 A. No, I remember that the October 2013 batch failed
21 stability. There was a big palaver. That is why
22 Mike Stokes got involved. Nick Thornton, who was global
23 head of quality. The regulatory people. I mean, that
24 is why it became this big drama. Just before Christmas
25 in December 2013 the product we were hoping to launch

1 shortly was failing stability.

2 Q. Let us look at what Mr Middleton says. If we go to
3 {B2/5/7} and it is paragraph 22. He says that:

4 "On 2 October 2013, Aesica manufactured the batch
5 ordered by AMCo in March 2013, but informed us that all
6 validation batches from the July 2010 production were
7 failing stability studies ..."

8 Yes. Says then further down:

9 "This meant the product Aesica had manufactured for
10 us was not ready for release ..."

11 And it says:

12 "The batch manufactured in October 2013 would highly
13 likely also fail stability studies, but that batch was
14 placed on hold pending resolution of the stability
15 issues."

16 Yes? So you understand -- so you would accept you
17 are wrong to say that the batch was tested for stability
18 issues and failed them?

19 A. If he is right, yes. He was closer to the project.

20 I had understood that is -- I do not know why the
21 validation batches from July 2010, I mean, they are
22 three years old by now, would still -- but I had
23 understood at the time that the batches they just made,
24 which they were hoping to launch, had failed and that is
25 why there was this big drama. I may be wrong, you know,

- 1 if he's right.
- 2 Q. So you would accept that Mr Middleton is closer to the
3 technical detail, so these are points I should follow up
4 with him?
- 5 A. Yes, I think that is right. I am reporting on what has
6 come to me, which is that there are all these problems
7 and I had understood that.
- 8 Q. All right, thank you. I am going to now move on to
9 orphan designation. I just want to make sure first that
10 we are on the same page about the effect of the fact
11 that Plenadren was given orphan drug status
12 in November 2011, yes, and so the effect from
13 a regulatory perspective was that no product could be
14 granted an MA between November 2011 and November 2021,
15 with the orphan drug protection, which included an
16 indication for adult adrenal insufficiency, yes?
- 17 A. That is what we understood and we took advice on it and
18 that is what we understood.
- 19 Q. Thank you. And that was because of a branded product
20 called Plenadren, which was a modified release form of
21 Hydrocortisone, yes?
- 22 A. Yes, that is what we found out, yes.
- 23 Q. And Plenadren was given orphan drug status?
- 24 A. Yes, I believe in 2006, but I do not quite know why
25 there was the gap from 2006 to 2011, but, yes, it was

- 1 a Swedish product.
- 2 Q. I think the status was conferred in 2011. I think you
3 are probably aware, are you, that it was that drug,
4 itself, Plenadren was actually sold in very, very low
5 volumes? Did you know that that?
- 6 A. The modified release?
- 7 Q. Yes.
- 8 A. So we found that out when we thought about buying
9 Plenadren in 2014. It was one of the sort of ways we
10 tried to get around the orphan drug issue, was to
11 consider buying Plenadren and we found it was small
12 volumes and a high price.
- 13 Q. So we agree, do we not, it was not the Auden product
14 itself that had the orphan drug status?
- 15 A. Yes, we do. That was one of our huge frustrations, as
16 I mentioned yesterday.
- 17 Q. I understand. But Waymade -- so Waymade's 10mg MA was
18 granted by the MHRA in September 2012, yes?
- 19 A. Yes.
- 20 Q. And so the MHRA could not grant that authorisation, that
21 MA, with an indication for adult adrenal insufficiency,
22 that is right, is it not, because of the orphan drug
23 status?
- 24 A. That is right. So effectively that orphan drug status
25 in November 2011 had sort of put this hard line in the

1 sand. Anything that already had adrenal insufficiency
2 for adults was entitled to carry on, but nothing new
3 could and, hence, as you say, the 10mg Aesica, Waymade
4 10mg line extension, had this very reduced indication.

5 Q. And so it was called a skinny label product, because it
6 had the reduced indication?

7 A. Industry terminology.

8 Q. Coming back to what you just said, you just said that
9 anything granted before the orphan drug status could
10 have the full indication and so Auden's MA had been
11 granted before the orphan designation for Plenadren, had
12 it not? So its 10mg product was indicated for adult
13 adrenal insufficiency, yes?

14 A. It was and it could -- the way it works is it could
15 continue to have adult adrenal insufficiency. It was
16 not sort of taken away, but nothing new could have that.

17 Q. So in other words, it was a full label product?

18 A. Yes, the Auden line was a full label, a full indication
19 product.

20 Q. I want to look now at the practical effect in terms of
21 how the product was marketed. If we go to your witness
22 statement at paragraph 33.1 and 33.2, which is
23 {B2/2/10}. Here you are listing -- you are talking
24 about what the MHRA has told you and you make two points
25 at 33.1 and 33.2 and you have listed them as separate

1 points. But I think it is right, we can see from the
2 footnote, that they actually both come from the same
3 communications from the MHRA. There is an email of
4 26 November and a letter of 27 November 2013, which both
5 made the same points.

6 And if we go to the letter which is at {H/263/1}.
7 The names are redacted in this version, but you can see
8 it is from the MHRA from someone at the MHRA to someone
9 at AMCo, yes?

10 A. Yes.

11 Q. You are not in copy to the emails which attach it. We
12 can go to them if you want, but you are not in copy?

13 A. No, I would not have been.

14 Q. Would you have seen it at the time?

15 A. The letter, no, but it was -- the reason I know about it
16 was because there was a meeting, a management meeting,
17 around this time when it came up as a big issue. This
18 has come through. The MHRA have said you cannot have
19 the full indication. You need to have this Hyperplasia.

20 Q. So when was the first time you saw the actual letter, do
21 you think? Was it when you were preparing your evidence
22 for this?

23 A. It would have been in the investigative stage. It was
24 before then, but the actual letter I would have seen at
25 the investigative stage.

1 Q. If we have a look at the letter. So the first paragraph
2 we can see if we go to the -- so we can see that AMCo
3 has applied, had applied for various changes to its
4 marketing authorisation and those had been -- those were
5 approved and then if we go to the second paragraph, you
6 can see that the MHRA had spotted that the patient
7 information leaflet, so it then calls that the PIL, do
8 you see?

9 A. Yes.

10 Q. Contained errors and so changes had been made, do you
11 see that?

12 "Unacceptable as changes had been introduced which
13 were not declared and not connected with the variation
14 applied for."

15 So they were not compliant, yes?

16 A. Yes.

17 Q. And then you see points 1 and 2, so they identify the
18 previous changes which were approved and it sets out
19 what the patient information leaflet used to say, yes?

20 A. It looks like that, yes, in point 2 I think.

21 Q. Yes. Then point 3, the MHRA is saying, if we just look
22 at that and then go over the page, that it had flagged
23 errors earlier without a response, because it says the
24 leaflet had referred to a combined -- there was
25 a combined patient information leaflet for 10 and 20mgs

1 that required correction, yes? That is what it is
2 saying at the first bit.

3 Then it says:

4 "I stated that the leaflet [do you see at (i)]
5 should concern only the 10mg strength ..."

6 Yes?

7 A. Yes, yes, sorry.

8 Q. Then you see -- that point is again made at (ii):

9 "I requested -- "

10 It is talking about the 20mg product and it says:

11 "I did not receive a reply to this request."

12 If we go on to Point 4, that explains that AMCo had
13 submitted -- had applied to change the name of the MA
14 holder and that had been granted. Do you see that?

15 A. Yes.

16 Q. Then point 5 identifies the errors in the patient
17 information leaflet and there are six points that are
18 made, you can see, (i) to (vi). And the ones that you
19 refer to are (iv) and (v), yes?

20 A. Yes, particularly (v). That is the key point.

21 Q. So (v) is the key point you say. So (v) is that the
22 part of the leaflet explaining dosages was confusing and
23 suggested that the tablets were indicated to treat
24 adrenal insufficiency, which is not authorised, yes?
25 That is what it is saying.

- 1 A. Yes.
- 2 Q. So the upshot of this is that because of the orphan
3 designation issue the leaflet, the patient information
4 leaflet, could not say, could it, that the tablets were
5 indicated to treat adrenal insufficiency generally,
6 including in adults, yes? That is the upshot.
- 7 A. Yes, effectively, it is saying -- so the 20mg was the
8 full indication. I am sorry. I just noticed I made an
9 error earlier on. I thought this November MHRA letter
10 was about the MIBE product. Actually, it was about the
11 Aesica product. So the team had tried to apply for the
12 full indication based on the fact the 20mg was a full
13 indication and I understand this to be saying the MHRA
14 has come back and said you're only licensed under your
15 MA for the point they made -- sorry -- just above, the
16 hyperplasia, so you are not authorised for adrenal
17 insufficiency.
- 18 Q. And just so that we can agree what they mean by that.
19 What they are saying here is that your patient
20 information leaflet cannot say that the tablets are
21 indicated to treat adrenal insufficiency generally, yes?
22 They are not saying that the product cannot be dispensed
23 to treat adult adrenal insufficiency, are they?
- 24 A. Yes, they say -- they are saying that. They are saying
25 your licence is not for adrenal insufficiency. Your

1 licence, which we granted to you, is for congenital
2 hyperplasia in children.

3 Q. Mr Sully, you understood, did you not, that they were
4 not saying that pharmacists were forbidden from
5 dispensing this product to treat adult adrenal
6 insufficiency. This was about what could be put on the
7 leaflet. You could not be presenting it on the leaflet
8 as authorised to treat adult adrenal insufficiency, but
9 they were not telling you it cannot be dispensed for
10 that. You knew that, did you not, Mr Sully?

11 A. No, sorry, it is much bigger than just on the leaflet.
12 So you are not allowed as a manufacturer of medicines to
13 market or promote medicines for a use that you are not
14 licensed to by the MHRA to sell. That is basic
15 pharmaceuticals. So this isn't just that you cannot
16 stick it on the PIL. It is saying you are trying to
17 suggest on your PIL that you are licensed for adrenal
18 insufficiency, but you are not. Your PIL must change
19 and you must follow the authorised MA. I mean, it is an
20 offence to try and suggest that we could have a product
21 and say: this is -- this can be used for adrenal
22 insufficiency is an offence and this is what this is
23 saying.

24 Q. I think we are agreeing it is not saying that it cannot
25 be dispensed to treat adult adrenal insufficiency. It

1 is talking about what could be put on the leaflet. This
2 is what this letter is saying.

3 A. No, sorry, it doesn't. So the letter says -- it picks
4 up the point in the PIL, because that has been the
5 attempt to see -- can we follow this through and say the
6 20mg was a full indication. This is a line extension.
7 Surely, we can sell it. It is exactly the same
8 medicine. Surely -- obviously a different size,
9 different dosage, but surely we can sell it for the full
10 point.

11 They are saying, no, because of this orphan drug
12 point, and it came up again with the German one, you are
13 only allowed to sell it for the licensed application.
14 Dispensing is different. We are not in control of
15 dispensing. That is a pharmacy point. We do not
16 dispense.

17 THE PRESIDENT: The same would apply to a doctor. If
18 a doctor decided to prescribe something which was not
19 covered by the patient information sheet, there is
20 nothing to stop the doctor doing it, but you cannot,
21 I think your evidence is, tell the doctor that it is
22 a product susceptible to that use. Have I got that
23 right?

24 A. Sir, yes. Essentially, yes, so I am not an expert on
25 this, but, as I understand it, doctors have a latitude

1 to dispense off-label -- sorry -- to prescribe
2 off-label, if they feel it is necessary to do so.
3 Pharmacists have some ability, as I understand it and,
4 again, I am not an expert here, but have some ability to
5 dispense off-label in certain circumstances. But as
6 a manufacturer, it is very strict and there is the PMCPA
7 code and there is the law on this. You should only sell
8 your medicines for licensed use. You cannot suggest to
9 anyone that a medicine can be used outside of its
10 licensed use and that is 101 of pharmaceutical
11 medicines.

12 MS DEMETRIOU: Thank you, Mr Sully. Can we go back to your
13 witness statement. So {B2/2/10} and look at 33.3 and
14 33.4. These are about -- 33.3 and 33.4 are about the
15 MHRA rejecting other applications for full label
16 Hydrocortisone on the same grounds and then going to
17 33.5, you refer there to another letter from the MHRA,
18 yes?

19 If we read 33.5, why do you not remind yourself of
20 what you have said there. (Pause).

21 A. Yes, I have read that.

22 Q. Thank you. You make it sound -- you rather make it
23 sound like the MHRA is being unhelpful to you, but let
24 us go to the letter which is at {H/708/1}. This is
25 a letter of April 2015 from the MHRA to AMCo. If you

1 look at the first paragraph, that describes the orphan
2 designation issue. Then, going to the second paragraph,
3 it is saying that a holder in respect of licences for
4 Hydrocortisone products authorised for adrenal
5 insufficiency in adults and children before the date of
6 Plenadren --

7 So that must be Auden, yes, that is the only one?

8 A. Yes, it must be. By this time, I think Auden has been
9 acquired by Actavis.

10 Q. Let us just call it Auden to keep it simple.

11 A. It works for me.

12 Q. It says they have raised with the MHRA a concern that
13 other more recently authorised Hydrocortisone tablet
14 products are being used for adrenal insufficiency in
15 adults when they are not licensed for that use. They
16 asked whether there are steps that might be taken in
17 relation to the packaging, summary of product
18 characteristics or patient information leaflet to assist
19 in addressing this concern, yes?

20 A. Yes.

21 Q. So then we go to the third paragraph, first sentence:

22 "Whilst the MHRA does not intend to take any formal
23 action to require any such changes, we are writing to
24 ask you to consider, in relation to Hydrocortisone ...
25 submitting a variation to include in the package

1 leaflet, the wording set out in the guidance on usage
2 patents, given the similarity of the issues between
3 usage patents and orphan status. The guidance can be
4 found at the link below. The suggested wording in that
5 guidance provides agreed standard text for the package
6 leaflet that explains why some therapeutic indications
7 may be missing as follows ..."

8 Then if we go down and then you can see what they
9 are suggesting. So:

10 "(Active substance) which is contained in (product)
11 (may also be/is also) authorised to treat other
12 conditions which are not mentioned in this leaflet. Ask
13 your doctor or pharmacist if you have further
14 questions."

15 So this suggested amendment is envisaging, is it
16 not, that the product is being prescribed off-label or
17 may be prescribed off-label? It is suggesting that some
18 wording is put in?

19 A. Yes.

20 Q. To explain to a patient --

21 A. This could be an off-label use.

22 Q. Yes. What they are doing, the wording that is being
23 suggested by the MHRA is intended to reassure a patient,
24 is it not? Reassure a patient who has been prescribed
25 the tablets to treat, say, adult adrenal insufficiency

1 in circumstances where that is not listed in the
2 leaflet?

3 A. Actually, I have just seen it says "authorised", but
4 that cannot be right because it isn't authorised.

5 Q. Other conditions, authorised to treat other conditions.

6 So what it is saying is that the amendment that it
7 is asking you to consider it -- so the way it would work
8 for Hydrocortisone is it would say that your product may
9 also, which is contained -- which is contained in your
10 product, so:

11 "This active ingredient, contained in your product
12 may also be authorised to treat other conditions which
13 are not mentioned in this leaflet. Ask your doctor or
14 pharmacist if you have any further questions."

15 What it is saying there -- that is a helpful
16 suggestion, is it not? It is basically there to try and
17 reassure patients who are being provided with a product
18 in circumstances where the label doesn't mention the
19 condition that they are being treated for and so it is
20 explaining to patients that that is okay, because even
21 though the product may not be authorised to treat their
22 condition, it is nonetheless being prescribed?

23 A. I mean --

24 Q. Authorised", I think you are confused about the word
25 "authorised" and I think "authorised" is being used in

1 the sense that doctors are authorised to prescribe it
2 and pharmacists can dispense it?

3 A. To be honest, I am not sure. As it was explained to me,
4 this was effectively to flag that actually we only have
5 an indication that is very reduced. I cannot see -- the
6 little I know is we certainly were not authorised to
7 treat other conditions. So I have -- reading it again
8 now, all I can say is at the time I was told this meant
9 you need to flag -- you should -- we are inviting you to
10 flag the difference and I am really not sure that is
11 what it means, but I am not an expert on the code
12 wording. But we definitely were not authorised to treat
13 things and I do not see how we could have been saying in
14 there: this product could be authorised to treat other
15 things, which are not in this leaflet.

16 That would have meant you are saying this product is
17 authorised to treat things which are not licensed in the
18 MA. That doesn't make sense to me.

19 Q. No, there is a difference between authorised -- you were
20 not authorised to promote, were you? But this
21 product -- doctors were authorised to treat and it is
22 saying "authorised to treat". Essentially, what it is
23 saying is that -- it is a reassuring thing that is being
24 suggested. It is intended to be reassuring to patients
25 and it is intended to tell them that although the label

1 may not refer to their condition, it may nonetheless be
2 a product which doctors are authorised to use in order
3 to treat their condition?

4 A. So I do not know if that is the case or not. I am not
5 an expert. That certainly isn't how it was explained to
6 me at the time and I know at the time -- this was around
7 the time that all the Pregabalin thing was happening,
8 which is what was closing down skinny use. So I just do
9 not understand if that was the case or not.

10 Q. Who did explain this to you at time?

11 A. I believe it would have been the regulatory people,
12 which came up through the head of operations, who
13 regulatory and quality and report into.

14 Q. Can we agree this much, because you refer to this at
15 paragraph 33.5 of your statement. Can we agree that if
16 this letter does mean what I say it means, then it is
17 not an unhelpful message from the MHRA? It is actually
18 quite helpful.

19 A. I do not know if that would be the case. It is
20 highlighting an issue that we thought that our licensed
21 product was only 2% of the market. Does it flag that?
22 That is certainly how we took it at the time. If it is
23 saying actually you can -- this product -- if it is
24 saying if you have been given this product as a patient,
25 even though it is not licensed for that, then I think

1 potentially it is helpful. But I do not actually -- it
2 doesn't really make sense to me to say "authorised to
3 treat".

4 THE PRESIDENT: Ms Demetriou, just so that I understand the
5 extent of any difference between your questions and the
6 witness's answers. Leave on one side whether there was
7 a helpful letter or not. You are saying that
8 "authorised to treat" means that the doctor or
9 pharmacist can legally dispense or prescribe to
10 a patient the medicament, but you are not challenging
11 the witness in his evidence that "authorised to treat"
12 does not mean authorised to promote by the manufacturer.

13 MS DEMETRIOU: Sir, I think the short point -- maybe to cut
14 through this -- is that a marketing authorisation is
15 what the name suggests. It is an authorisation to
16 market. It is not a question of the product being
17 licensed only for a particular -- to treat a particular
18 condition. And so what -- the point I am putting is
19 that it was perfectly open to doctors, as I think
20 Mr Sully has accepted -- this product could be used, in
21 a licensing sense, to treat adult adrenal insufficiency,
22 but the marketing authorisation was only concerned with
23 the marketing of the product, as the name suggests. So
24 the way -- the reason that I am picking Mr Sully up on
25 this point is that he refers to it at paragraph 33.5,

1 this letter, as being somehow unhelpful and the point
2 I am putting to him is that it is actually a helpful
3 indication from the MHRA about what could be done to
4 reassure patients.

5 THE PRESIDENT: Indeed, but the reassuring would have to
6 come from the doctor or the pharmacist. It would not be
7 permissible -- please to clarify me. I do not think it
8 is for the witness -- it would not be permissible for
9 the manufacturer to encourage doctors to use a drug in
10 this way.

11 MS DEMETRIOU: Sir, that is correct. And, in fact, what is
12 and is not permissible is going to be explored with
13 other witnesses and so I am not going to -- Mr Sully is
14 not an expert on that, as he said, so I am not going
15 to --

16 MR SULLY: I would say certainly in the industry we do not
17 understand that marketing authorisation -- I mean, what
18 you are licensed to sell for is what you are licensed to
19 sell for. It is the most important document. So I do
20 not want to disagree with counsel. I am not an expert
21 on this, but certainly it is not seen as the marketing
22 authorisation, which is the key document that then
23 allows you to launch, is only limiting your marketing
24 promotion. That is your permission, your licence, to
25 sell a medicine and you must not, as I understand it,

1 sell outside of your licensed indications.

2 Q. In fact, we know, do we not, that once -- we know, do we
3 not, what actually happened in the market once Alissa
4 and others entered with skinny label products that lots
5 of pharmacists have in fact chosen to dispense skinny
6 label products?

7 A. That is not quite how it happened, because after the
8 second agreement was signed AMCo very closely monitored
9 the market. They noticed that Alissa had got an MA in
10 late 2014 and we watched it carefully. We thought -- we
11 looked at the MA. You can see them online. You can see
12 the SPC. The SPC is a summary of product
13 characteristics which has the licensed indications and
14 the PIL and it was a skinny label. It actually did have
15 adrenal insufficiency, but only for children and we
16 monitored it. We thought maybe this is the beginning of
17 the market opening up, but, as far as we were aware, it
18 did not make any sales for a whole year.

19 Q. Mr Sully, I am going to interrupt you. You are not
20 answering my question. You are going on a huge track
21 that I just haven't asked you about and I really just
22 want you to answer the questions, please, because
23 otherwise we are going to be here much longer than we
24 need to be.

25 I am just asking this. I am asking about the point

1 that pharmacists and doctors, as I think you have
2 agreed, were able, they were not precluded or forbidden,
3 from dispensing the skinny label product to treat adult
4 adrenal insufficiency. Do you agree or disagree?

5 A. So, it isn't an agree or disagree point. I am not an
6 expert on this, but my understanding is there are
7 certain circumstances in which pharmacists can dispense
8 off-label. I understand them to be where licensed
9 product is not available or where there is a better
10 reason and I do not want to go into this, because it is
11 not my own area of expertise.

12 THE PRESIDENT: No.

13 MR SULLY: I am a bit uncomfortable. So it isn't an agree
14 or disagree point, I am afraid.

15 MS DEMETRIOU: Mr Sully, I think the only question I was
16 putting you about Alissa and others coming on to the
17 market, and this really is a yes or no, is that however
18 we got there, however we go there -- and I am not
19 interested in what AMCo was doing at that stage --
20 however we got there, where we ended up was that skinny
21 label products ended up taking a significant proportion
22 of the market, yes or no?

23 THE PRESIDENT: Ms Demetriou, I think you have put to the
24 witness the theoretical possibility of a doctor or
25 pharmacist dispensing or prescribing off-label and I do

1 not think you need press the witness any further there.

2 MS DEMETRIOU: No.

3 THE PRESIDENT: But if you are putting to him that in actual
4 fact when a skinny label product was on the market, it
5 was substantially sold for whatever use then that is
6 something I think you need to put more specifically by
7 reference to the documents.

8 MS DEMETRIOU: Sir, let us move away and we will come back
9 to that, because I think there are other witnesses we
10 can put that point to.

11 THE PRESIDENT: Okay.

12 MS DEMETRIOU: I wondered if Mr Sully knew about that off
13 the top of his head.

14 THE PRESIDENT: I do not think it is fair to him, or indeed
15 helpful to us, to say, look, there were substantial
16 sales off-label when this is on the fringes of his
17 expertise.

18 MS DEMETRIOU: No, it is a factual question which the
19 Decision covers. So I was putting to him on the basis
20 that he either knew or did not know, but I certainly do
21 not want to get into the history of market entry with
22 Mr Sully.

23 I want to go back to your witness statement and if
24 we look at paragraphs 37-38 this time so page 11
25 {B2/2/11}. You explain there that you sought external

1 legal advice on this issue from Pinsent Masons and,
2 specifically, you said you needed to understand whether
3 Plenadren's orphan designation could be challenged and,
4 if not, what the implications were for AMCo's
5 development of a Hydrocortisone product, yes? You
6 exhibit the advice. Let us go to it at {IR-H/293/1}.
7 We can see from the email that it was sent to you in
8 fact by Brian McEwan, was it not? He forwarded it on to
9 you on 20 December. That is what that looks like
10 20 December 2013?

11 A. Yes, that looks right.

12 Q. If we go down to page 5 which is where it starts
13 {IR-H/293/5} and you read the introduction you can see
14 that Pinsents were asked to advise on the legal
15 justification for the refusal by the MHRA of an
16 indication for adrenal insufficiency for AMCo's product
17 in the light of the orphan status, yes?

18 A. That is right, yes, so that has flowed out of the letter
19 we looked at, the 27 November one.

20 Q. And we do not have to read the whole advice, but it is
21 fair to say, I think, and we can maybe scroll down, that
22 Pinsent explained the relevant law and regulations and
23 then they concluded that the MHRA had got the law right,
24 did they not, when they decided that the AMCo product
25 could not have the full indication, yes?

1 A. Yes, in a nutshell, that is what we understood them to
2 be saying.

3 Q. If we go to page 7. {IR-H/293/7}. It is the bottom of
4 page 7 just above the conclusion. So you can see there
5 that -- sorry, can we just scroll -- exactly. You can
6 see there just above the conclusion:

7 "Whilst grant of orphan status ... the fact of such
8 grant and the subsequent MA for adrenal insufficiency
9 does preclude the MHRA from permitting AMCo's 10mg form
10 such an indication."

11 Yes?

12 A. Yes, I can see that, yes.

13 Q. And they said there were no grounds for a legal
14 challenge. That is right, is it not?

15 A. I think they said there were initially grounds, but at
16 that time you basically time-barred it. It expired.

17 Q. But I think it is right, is it not, they did not
18 consider wider practical questions about whether
19 pharmacists could and would dispense the product anyway?
20 That was not for them.

21 A. As far as I am aware, no, we did not ask them that.

22 Q. If we go back to your witness statement at {B2/2/21} and
23 go to paragraph 82, that says that you went back to
24 Pinsent for further advice in relation to the new
25 agreement, the new supply agreement, yes?

1 A. That is right, yes. We saw this yesterday. When we had
2 no product, no customers, we went back to them and said
3 how can we proceed at the end of May.

4 Q. When you say "no customers", Mr Sully, you are referring
5 there to the orphan designation problem?

6 A. To the fact that -- so we had received the advice from
7 Pinsent. As I explained yesterday, we had decided we
8 are going to try this anyway. We want to move away from
9 Auden. We terminated. We documented and terminated the
10 unwritten agreements at the end of March. We had lined
11 up to launch with Aesica. We had hoped Aesica would
12 deliver in April and, therefore, we had gone to the
13 customers or the commercial team had gone to the
14 customers in April and May and they had said we are not
15 interested in this product because it has got a skinny
16 label.

17 So at the end of May, as I say, as we discussed
18 yesterday, we had no product from Aesica and the
19 timeline was now July for the first delivery. We had
20 customers saying they are just not interested in this.
21 There is a compliance risk and, in fact, at the very end
22 of May, we discovered that that was because we were sent
23 this letter that a customer had been sent by Auden,
24 a threatening warning letter about off-label dispensing
25 etc. So that is when we went back to Pinsent to say

1 what do we do in this situation? What can we do?

2 Q. Mr Sully, just a very short question, I hope. You have
3 just said now our commercial team had gone to customers
4 in April and May, that wasn't you, was it? That was the
5 commercial team that did that, reporting back to you?

6 A. That is right. That is why I said commercial.

7 Q. And there is no written report that you have exhibited,
8 so that must have been a verbal communication?

9 A. Yes.

10 Q. Who would it have been that you spoke to?

11 A. Jane Hill was the one who was lined up, because she was
12 the UK commercial director, to launch the product and
13 she came -- I assume it was a discussion with Jane Hill,
14 John Beighton and me. I remember also John Beighton,
15 I think I mentioned in my witness statement, he was
16 actually really quite alarmed by this, because he had
17 always thought there must be a way around this. It
18 cannot be right that the Auden product with its
19 immediate release and its high volumes is protected by
20 this modified release, as I mentioned, and so it would
21 have been one of those two.

22 Q. Thank you. Sir, I have forgotten that we need to take
23 a break. When would you like to take it?

24 THE PRESIDENT: We are at your convenience.

25 MS DEMETRIOU: It is already 10 to 12 so shall we take it

1 now.

2 THE PRESIDENT: Yes, we'll take ten minutes until about
3 midday. We'll resume then. Thank you very much.

4 MS DEMETRIOU: Thank you.

5 (11.50 am)

6 (A short break)

7 (12.00 pm)

8 MS DEMETRIOU: Mr Sully, I want to go back to your statement
9 at paragraph 83 in the IR bundle, which is the one that
10 we have got up {B2/2/22}, so let us just read that
11 together:

12 "Pinsent Masons reviewed the situation and advised
13 that it would be compliant and permissible for Auden and
14 AMCo to enter into a new supply agreement for Auden's
15 full indication ... product: and they advised on 30 May
16 and again on 6 June that from a competition law
17 perspective, Auden and AMCo would not be considered
18 competitors whilst the orphan designation was in place."

19 In the same email chain Pinsent also noted that "as"
20 a result of the orphan designation, AMCo has decided
21 that the best commercial option is to source 10mg supply
22 from Auden whose product is capable of being marketed
23 for adrenal insufficiency."

24 Yes? So we know that you thought, because you
25 accepted this yesterday, that AMCo and Auden were

1 potential competitors at this stage, because AMCo was
2 trying to bring its own product on to the market. That
3 is right, is it not?

4 A. I am not sure I did say that yesterday. I think I said
5 initially we thought -- so we thought that once we got
6 a product which we can take to market, which we hoped in
7 early 2014 we would have in April, then we would become
8 a competitor, and we were a potential competitor up
9 until then. Then we discovered our customers did not
10 want a skinny product. None of them, as it was
11 explained to me.

12 So then we went back to Pinsent and said so what is
13 the position and they said actually, no, you're not
14 competitors. It is in a different market.

15 Q. Let me show you. That is fair. Let us go to transcript
16 page 45, line 6-9. I said to you:

17 "Whilst AMCo were trying to come on the market they
18 were a potential competitor to Auden, were they not?"

19 "Yes, a potential competitor."

20 So you accepted that yesterday.

21 A. Yes, as I just said, so whilst we thought we had
22 a product, they were a potential competitor and then we
23 assumed they would be competitors once we had a product
24 to launch, yes.

25 Q. Your position is that and your position in your witness

1 statement is that AMCo was trying throughout to come on
2 to the market, yes?

3 A. Yes, it was.

4 Q. So it was always then a potential competitor, was it
5 not?

6 A. Well, not according to the experts at Pinsent, who said
7 actually, as their email says, because of this orphan
8 designation it is an IP right. It is like a patent. It
9 is a different product market. There was a slightly
10 different point where I thought we were competitors,
11 which is after we had signed the second written
12 agreement I recognised that if we are taking supply from
13 them but we are selling to the same customers
14 downstream, then absolutely we need to make sure there
15 is no discussion.

16 Q. You dealt with the downstream point separately and
17 yesterday I put to you that whilst AMCO was trying to
18 come to the market with its own product, it was
19 a potential competitor and you said yes. You are saying
20 somehow that Pinsent Masons changed the position. Let
21 us look at the email chain -- so you exhibit an email
22 chain starting on 6 June.

23 So there is an earlier thread that I want to look at
24 first. If you go to {IR-H/490/1}. Start at page 4
25 {IR-H/490/4}. So if we go to the bottom of page 4, you

1 are asking Pinsent if they are available for a call
2 later this afternoon. You can see the date is
3 28 May 2014, yes? And then she responds saying they are
4 available for a call.

5 Then if we go to page 3 {IR-H/490/3}, you then
6 summarise the matter for discussion and do you see that
7 there?

8 So you are talking about:

9 "We have moved forward on getting our own registered
10 source of Hydrocortisone. Should be ready to launch in
11 the next few months. However, our product will not have
12 the adrenal insufficiency indication that is protected
13 by the orphan drug status. Auden has begun writing to
14 pharmacies. Brian McEwan raised this orphan drug issue
15 with Pinsents."

16 That is the earlier advice. You said:

17 "There is nothing we could do to challenge the OD
18 status."

19 A. Yes.

20 Q. "In the circumstances, we are now considering an offer
21 from Auden to be supplied with their product in order to
22 avoid a continuing battle over our product. It would be
23 on broadly similar terms to the contract we put in place
24 earlier this year to formalise the previous oral
25 agreement. I think this is fine, but would just like to

1 double check with you."

2 So that is what you are asking. Just pausing there.

3 You are recognising there, are you not, that AMCo has

4 two options: take supply from Auden or have a battle

5 with them, as you put it, over your own product, yes?

6 A. Yes, and a battle in which we just learnt over the
7 previous eight weeks customers did not want our product
8 but, yes.

9 Q. So what you are recognising, I think you would accept,
10 is that the supply agreement is instead of the battle,
11 so it is instead of entering the markets, to avoid the
12 battle that would happen if you entered the market with
13 your own product. That is right, is it not?

14 A. Yes, the way I phrased it was that. We had taken advice
15 and we were told we could not challenge the orphan drug
16 status. The customers said they did not want it, but we
17 said -- we did not want to drop out of the market, so it
18 was do we carry on -- do we take a supply from Auden or
19 do we have a battle about this? But, yes.

20 Q. So if you were going to come in with your own product,
21 you knew there you would then be a battle about the
22 orphan drug status. You were not happy about having
23 that battle, so you said let us take supply from Auden
24 instead. That is where you are at the moment, yes?

25 A. No, because we could not come in with our own product.

- 1 We tried to and the customers said they did not want it.
- 2 Q. Let us leave that to one side.
- 3 A. That is part of exactly what I was saying at the time.
- 4 Customers said they didn't want it, so there is no
- 5 option to launch. We tried to launch. We said we think
- 6 we are going to have a product soon -- the soon kept
- 7 moving back -- do you want it and they said no. So in
- 8 our eyes if there is no market, what position does that
- 9 put us in?
- 10 Q. Let us take this in stages. First of all, where have
- 11 you told Pinsent that you have no market at all for your
- 12 reduced indication product?
- 13 A. So that would have been part of the call, because we
- 14 explained to them the situation we were in and I think
- 15 we showed them the letter which arrived around this time
- 16 that Auden had sent out and said, as a result of this,
- 17 there is no customer demand. Customers are saying they
- 18 just do not want it.
- 19 Q. So can I get this right: is your position that you would
- 20 have made zero sales, zero sales, you had no market at
- 21 all or is it that the market would have been difficult?
- 22 Which is it, Mr Sully?
- 23 A. Zero sales. We had tried to sell to our customers and
- 24 they said they did not want it.
- 25 Q. So your evidence is that if you had entered the market

1 at this stage, you would not have sold a single pack of
2 your product, is that your evidence?

3 A. That is what we understood, yes, we --

4 Q. That is what you understood from --

5 A. From the discussions that I had with the commercial
6 people who said we have gone to our main customers, and
7 AMCo only sold to a few customers at this time, and they
8 said they do not want it and then they explained why and
9 so it was zero.

10 Q. Your understanding, because obviously we have
11 established you did not speak to the customers, but your
12 understanding from the commercial people is that you
13 would not be able to sell a single pack and so the
14 market was completely, completely out of the question
15 for you?

16 A. Yes.

17 Q. And so that is the basis, is it, that you went to
18 Pinsent Masons. You said we will not be able to sell
19 a single pack of this product?

20 A. Yes, we said to them, we have gone to customers, they do
21 not want this product. We still do not have the product
22 from Aesica. What can we do about it? That is where
23 the advice came back that we will see in a minute.

24 Q. Pinsent than follow up with an email and if we start at
25 the bottom -- very bottom of page 2 {IR-H/490/2}. So

1 "will follow up with an email" and you can see that is
2 timed 17.32 on 30 May and then let us go on to page 3.

3 Now, this is the associate solicitor saying -- let
4 us look at it, saying:

5 "My initial view was that as a result of the orphan
6 status of Auden's 10 and 20mg Hydrocortisone tablets..."

7 Just pausing there, they do not actually have orphan
8 status, but they have the full indication because of
9 someone else's orphan status?

10 A. Yes.

11 Q. And the fact that the orphan adrenal insufficiency is
12 the primary indication for which the product is
13 prescribed, that AMCo -- her initial view is that in
14 light of that AMCo and Auden would not be considered as
15 competitors in relation to this specific indication for
16 the 10mg Hydrocortisone.

17 "Having read Paul's note, I can see" and she talks
18 about the 20mg tablet:

19 "AMCo having an MA which covers adrenal
20 insufficiency for 20mg tablet. Unfortunately, because
21 AMCo can compete on to 20mg Hydrocortisone, potentially
22 it could also bring a 10mg product to market, the
23 competitor/not competitor analysis is not clear cut in
24 that you are competitors for some patients and not
25 others."

1 So I think what she is saying there is you could
2 compete for some patients and not for other patients.
3 Presumably she means for patients that are not being
4 prescribed it for adult adrenal insufficiency?

5 A. So, no, as and as I clarified further on up this email,
6 she had thought that the 20mg was also owned by us and
7 so I went back to us and said, no, the 20mg is a full
8 indication, as it is pointed out in the Pinsent advice,
9 but the 20mg isn't ours so we are just dealing with the
10 10mg.

11 Q. But just pausing on this question. So your product,
12 your 10mg product had -- that was authorised, so the
13 marketing authorisation covered, for example, child
14 adrenal insufficiency, yes?

15 A. No, no, so our product -- this was the big discussion
16 in January in the PPRM report. Our product was only
17 licensed for congenital -- for replacement therapy for
18 congenital hyperplasia in children and when we looked at
19 that -- there was all kinds of does it mean this, does
20 it mean that, but the conclusion that was reached, and
21 it was the conclusion that went to the board and the
22 PPRM report we looked at yesterday was that it was 2% of
23 the market.

24 So we knew that our licensed indication was
25 extremely tiny. When we -- we hoped that there would be

1 a pick up anyway and that customers would say that. But
2 the feedback we got, and I raised this in the first
3 state of play meeting is, as it was explained to me,
4 when we went to customers, they said we are not
5 interested in a reduced indication like that and part of
6 the reason we believe that was the case is it is tiny,
7 there is a risk of confusion, if it is on pharmacy
8 shelves, because they do not want to dispense off-label
9 and certainly customers aren't going to want two
10 products when only one covers 2% of the market.

11 It was explained to me customers do not want this,
12 full stop. When I said why, that was the reason that
13 was given to me.

14 Q. I think probably we are at cross-purposes, because
15 I think when you talk about adrenal hyperplasia that is
16 an insufficiency, is it not, in children?

17 A. No, as I understand it is different and you can tell
18 that because I have seen on the case file the Alissa
19 indication has adrenal insufficiency for children and
20 adolescents and hyperplasia, whereas ours just had
21 hyperplasia. I do not know the difference. I am not
22 a doctor.

23 Q. So your evidence is that you could only sell on the
24 market -- so when you say "zero packs" that your
25 evidence was that you could not sell anything, I think

1 your evidence -- is that right, zero packs? So you
2 would not be able to sell even for the indications that
3 you had?

4 A. That is the point I have just explained.

5 Q. So you --

6 A. So I say it would be zero packs, because our licensed
7 indication was only 2%. But when we had gone to
8 customers and they had said we do not want it, they had
9 said we are not interested in a product that only sells
10 to 2% of the market. Customers are just not going to
11 accept that and we said why? They said that means they
12 are going to have two packs on the shelves. These were
13 the reasons that were given to me.

14 Q. Just pausing there, because you are talking very quickly
15 and it is very difficult then to come back and unpick
16 all of this.

17 But when you say that customers are not just going
18 to accept that and you said why, because that means they
19 are going to have two packs on the shelves, just to be
20 clear, that is not a conversation you had with
21 customers?

22 A. No, I think I explained. So this is -- so the
23 commercial UK people or effectively Jane Hill and
24 John Beighton and I had a discussion and Jane said
25 I have spoken to customers. They are not interested in

1 this product, full stop.

2 Q. Just pausing one minute. Let us take it in stages. So
3 she said that to you. You are at the moment giving
4 evidence about what customers said. Is that because you
5 remember exactly what they said to her and then she
6 passed on to you or are you just recreating what they
7 must have said?

8 A. No, sorry, I thought I made it clear. I am saying what
9 I recall of the reason why when I was told customers do
10 not want this, it was a big disappointment to both John
11 and I and we said, well, why, what can we do about this?
12 I recall the reason was, and I cover this in the State
13 of Play meeting, it is in the minutes, because of this
14 effectively pharmacies have small shelf space. They do
15 not like stocking multiple products. There is a risk of
16 confusion. A pharmacist gives out the wrong product
17 that it is not licensed for. Dispenses off-label
18 unintentionally. So that was why. So to your question,
19 it is -- we -- I was told there was zero interest from
20 customers.

21 Q. Right. Okay. Let us go back to the Pinsent advice so
22 we have that on the screen in front of us. You say --
23 so this says -- we have read the first paragraph and she
24 says there "It is not clear cut" at the end of that and
25 this is her initial view and then she says:

1 "As a result, whilst it would not be out of the
2 question for AMCo to enter into a supply contract with
3 Auden, AMCo would need to be very careful as to how this
4 was done."

5 Yes?

6 A. Yes.

7 Q. So that is the advice that --

8 A. I am so sorry. But just to be clear, that is the advice
9 based on her misunderstanding that we own the 20mg,
10 which I then corrected.

11 Q. All right. Then what happens is that -- but you see
12 there that she is saying that her view, her initial view
13 is based on the fact that you would not be considered to
14 be competitors. You understood that, yes?

15 A. So --

16 Q. Her initial view that the supply agreement was okay or
17 might be okay, if you were careful, was based on, we can
18 see in the first paragraph, the fact that because of the
19 orphan designation AMCo and Auden would not be
20 considered as competitors. That was the basis for her
21 view, yes?

22 A. Yes, but she says directly there, as a result of the
23 orphan status of Auden's 10 and 20 and I then went back
24 and clarified and said, hold on, we do not own the 20.

25 Q. I am not talking about the 20. It is not connected to

1 the 20. That is a different point. Please just try and
2 listen to the question. So the first thing says:

3 "My initial view is that as a result of the orphan
4 status... "

5 Let us cut out 20, because I think it still holds
6 together with it:

7 "As a result of the orphan status of Auden's 10mg
8 Hydrocortisone and the fact that the orphan indication
9 adrenal insufficiency is the primary indication for
10 which the product is prescribed, AMCo and Auden would
11 not be considered as competitors."

12 It is nothing to do with the 20mg. She is just
13 making the same point you are making. It is not a very
14 controversial point I am putting to you, Mr Sully. She
15 is saying, based on what you told her, because of the
16 orphan designation, you and Auden would not be
17 considered as competitors, yes or no? That is what she
18 is saying.

19 A. As I said, she had asked me a question. She got the
20 facts wrong. She came back with some clear advice.
21 I understood her to be saying that it was all tied in
22 together and she had misunderstood the context so
23 I corrected it. That is -- she then said if you do not
24 own the 20, this is my advice, so --

25 Q. Let us go on to look at the email chain you do exhibit

1 on the point. It is {IR-H/501}.

2 A. Would it be possible to scroll up to make sure I have
3 not misunderstood this, because I am sure on this
4 document I go back and say hold on a minute.

5 Q. Of course. You probably do that in the next bit?

6 A. I am pretty sure.

7 Q. But have a look, yes.

8 A. Yes, thank you. So this is the email directly above:

9 "One point of clarification. We do not own it. It
10 is owned by Waymade and that is the full indication."

11 Q. That is fine, Mr Sully, but what I am trying to get
12 at -- let us leave aside the 20mg. What I am trying to
13 get at is you are saying they have given you the all
14 clear for the supply agreement. Her initial advice is,
15 well, I think it is okay, because you are not
16 competitors because of the orphan designation; yes or
17 no? That is really the simple question.

18 THE PRESIDENT: I think it probably would be helpful to see
19 if [REDACTED] corrected her advice, because I mean, the
20 witness is right. He has articulated a point of
21 clarification. Now, it may be that it is an immaterial
22 point, but he has said in terms you have got this wrong
23 and we ought to see whether the solicitor corrects her
24 advice in light of that.

25 MS DEMETRIOU: That is a fair point. I am going to move on.

1 So {IR-H/501/1}. If we start on page 2, there is an
2 email if we scroll down, {IR-H/501/2}. There is an
3 email at 6 pm, do you see, from the same solicitor to
4 you. So it is after the thread that we have just seen,
5 yes?

6 And if you look at the first three paragraphs, what
7 you see is that it is an attendance note:

8 "Formally record my attendance at your offices and
9 on the conference call during the discussion with
10 Auden McKenzie ..."

11 So there would have been a consultation at your
12 offices without Auden McKenzie being present and then
13 a call afterwards with Auden McKenzie, yes?

14 A. That is right. This is about a week further on. She
15 has come to us and we have discussed the matter in
16 detail and then we have together gone on to the call
17 with Auden McKenzie and its lawyers, which was one of
18 the points recommended: you need to make sure Pinsent
19 are on this call, because it is a sensitive issue.

20 Q. Then if we go on to the next paragraph, the largest
21 paragraph there. And then you see that summarises what
22 she says is the key concern for AMCo was Auden's ability
23 to prevent AMCo from launching its own 10mg product and
24 ensuring continuity of supply for AMCo's customers once
25 it entered into the agreement.

1 "Prior to the call, I discussed with you the extent
2 to which AMCo would be considered a competitor of Auden
3 in relation to the 10mg product (which AMCo has
4 a pipeline source): as a result of the orphan
5 designation for 10mg Hydrocortisone, AMCo cannot supply
6 its 10mg Hydrocortisone into the market in respect of
7 the main therapeutic use, ie adrenal insufficiency. The
8 orphan designation is akin to an IP right and as such,
9 from a competition law perspective in respect of this
10 product and the orphan indication, AMCo and Auden would
11 not be considered competitors whilst the orphan
12 designation was in place."

13 A. That is right, and that is the advice we understood,
14 yes. We were not competitors while it was in place.

15 Q. The orphan -- an orphan designation is not the same as
16 an IP right, is it? Do you understand that? So
17 a patent prevents competition on a particular molecule
18 for a period of time, so a competing product cannot
19 enter the market. But that wasn't the situation here,
20 was it? You were not legally precluded. No one was
21 with legally precluded from selling your product. You
22 understand the difference, do you not, as a lawyer?

23 A. I understand there is a difference, but it is akin to an
24 IP right because you are legally prevented, because you
25 are not give given a licence to sell it for ten years.

1 So you are not allowed to sell it for that indication.
2 You can sell it into the market if someone wants to buy
3 that licence indication and if they choose to do
4 something different, then that is there. But that is
5 a compliance risk and you have to be very careful around
6 that to make sure you're not encouraging that. You are
7 not marketing it for some wider use etc. It is akin to
8 an IP right, but I accept it is not. There is a
9 difference between intellectual property patent and
10 orphan designation, but it is a legal obligation. You
11 are not allowed to have that licensed indication.

12 Q. What you are not allowed to do is market the product for
13 an indication for which it isn't authorised, right? You
14 are allowed to sell the product. You just cannot market
15 it for another indication, yes or no?

16 A. No, we have covered this earlier on. It is not
17 simply -- so there are a number of obligation. If you
18 are not -- you cannot -- it is bigger than just you
19 cannot market it. You have a licence to sell
20 a medicine. You need to make sure that you and your
21 supply chain are only selling that medicine for the
22 licensed indications. You cannot market, you cannot
23 promote, you cannot suggest, no one in your supply chain
24 can suggest. So it isn't just you cannot put out
25 advertisements, but you can say this could be used. It

- 1 is wider than just --
- 2 Q. Let us say that one of your customers came to you and
3 said: we would really like to have 5,000 packs of your
4 skinny label product, yes. I am not talking about this
5 product. Let us just take another skinny label product.
6 So they came to you and they say we see you have got
7 this. If you can do us a good deal on price, we'd like
8 5,000 packs of that. So the labelling doesn't indicate
9 that it is a full label. You have complied with all of
10 your marketing organisation requirements, nothing is
11 stopping you selling those packs to the customer that
12 has asked for them, yes or no?
- 13 A. So this is exactly what we wanted to happen and this is
14 what happened in April 2016.
- 15 Q. Mr Sully, yes or no to my question? You can then come
16 back if you like. I just asked you a very simple
17 question.
- 18 A. If a customer came to us and said we want your skinny
19 label product, then that is what we were hoping would
20 happen and that is what did happen in April. If
21 a customer came to us and said we want Hydrocortisone,
22 then I would say there is a code risk, because if it was
23 subsequently discovered that they had been off-label
24 dispensing and there was a suit, they would say we
25 brought it from you as Hydrocortisone.

1 So if a customer came to us and said, as we hoped
2 they would, we want your skinny label product and that
3 is what happened in April 2016, then absolutely that is
4 what we were hoping the market would end up and do, but,
5 firstly, they had not done that when we tried in 2014
6 and, indeed, they did not in 2015, so I think that
7 answer --

8 Q. Mr Sully, you have made your points about what the
9 customers have said so the Tribunal -- you have made
10 them a number of times now. The Tribunal has heard
11 those loudly and clearly.

12 I am really just trying to ask you -- I think where
13 we got to in the end was that your answer to my question
14 I actually put was yes. I said if customers came to you
15 and said forget this product, forget the history, I am
16 just asking a question about how it works. If
17 a customer came to you and said, we want 5,000 packs of
18 your skinny label product, nothing is precluding you
19 from selling those packs, yes or no?

20 A. If it is clear it is skinny, yes.

21 Q. Thank you.

22 A. If it is skinny, yes.

23 Q. However, if somebody else held a patent and the patent
24 was in force, you could not sell a product that was
25 covered by that patent, could you? So if somebody came

1 to you in those circumstances and said, will you produce
2 X patented product at a lower price, you would be
3 precluded from doing that, would not you?

4 A. Broadly speaking, yes. It is akin to an IP right. I do
5 not think it is saying it is a patent.

6 Q. Right. There is quite a big difference and we will have
7 to agree to disagree how big the difference is, but
8 I think we have established there is a difference?

9 A. Between an orphan drug designation and a patent, yes,
10 I agree there is a difference.

11 Q. If we go back to this document to the bottom bullet, we
12 can see -- so the question from the associate is that --
13 sorry, it is at the bottom. So do you see -- if we go
14 to the very bottom of that page:

15 "Is there a risk" do we see that? So look at that.
16 So you can read the whole bullet if you want to
17 yourself. (Pause)

18 "Is there a risk of AMCo inadvertently supplying for
19 orphan designation?"

20 I think it is fair to say, is it not, that this
21 question betrays a lack of understanding of the effects
22 of the orphan designation, no?

23 A. I think it is actually a misunderstanding of the law
24 around the code on selling, but it is probably tied into
25 that. Effectively, she is saying is there a risk of you

1 supplying a product where it is not licensed?

2 Q. Right. But we are not worried about supplies. It is
3 about marketing. That is betraying some
4 misunderstanding. But let us look at your reply, which
5 is on page 1 {IR-H/501/1}. You say:

6 "Pharmacy bears the responsibility to ensure that
7 the correct product is dispensed (which is why Auden has
8 been writing to pharmacy, not us, to point out the fact
9 that we do not have this indication). So long as we
10 make sure that our product does not misrepresent itself
11 as covering additional indications that are not on its
12 licence (which will not happen), our medical team
13 consider that we would be OK. The issue would be how
14 Auden react ... I suspect we would end up in the OD
15 dispute that we are now facing, but I do not think that
16 there is much we can do about it, unless we decide to
17 abandon this product market which we really do not want
18 to do."

19 So this shows, doesn't it -- let us take the
20 propositions in turn -- you understood, did you not,
21 that AMCo's skinny label product could be dispensed by
22 pharmacists? That is what you are saying?

23 A. In some circumstances, yes, we did.

24 Q. Why are you qualifying that now, to say in some
25 circumstances?

1 A. Because I am aware of the rules on this and we looked at
2 them at the time.

3 Q. But what you are doing here is you are drawing
4 a distinction is between the dispensing of the product
5 which you say that is a matter for pharmacy?

6 A. Yes.

7 Q. And then your responsibilities, which is that you do not
8 misrepresentation yourself as covering additional
9 indications which are not on the licence. That is the
10 distinction you are drawing and it is a correct
11 distinction, is it not?

12 A. It is, exactly. That is exactly what I said to your
13 question. If a customer came to us and said we want
14 your skinny label, there is no misrepresentation. That
15 is absolutely fine. That is what we were hoping would
16 happen. But if a customer comes and says we want
17 Hydrocortisone, that is where I say which will not
18 happen, that is where you have to be really careful.
19 You need a documentary record that they want skinny.

20 Q. So you say that if we comply with our -- if we do not
21 misrepresent ourselves, which of course will not happen,
22 we are not going to misrepresent ourselves, then that is
23 okay. The issue would be how Auden react. So, in other
24 words, you are saying if you enter and you enter
25 properly without misrepresenting yourself, the key

1 question is what will Auden do and you are worried that
2 there might be a dispute if AMCo enters with its own
3 product, yes?

4 A. Yes.

5 Q. And the business didn't want to take that risk, did it?
6 Did not want to risk?

7 A. We had gone to customers. There was no demand so there
8 was no market, but certainly if we had gone into the
9 market and the customer had wanted our product, then it
10 would have been interesting to see what Auden did, but
11 that is a hypothetical because no customers did want the
12 product.

13 THE PRESIDENT: Just to understand, and I appreciate this is
14 you trying to work out what Auden would do, how might
15 they have reacted in terms of what could they have done
16 had you entered the market under the restrictions that
17 you have described?

18 A. So they had threatened earlier on that they would be --
19 there could be litigation, they would go to the MHRA and
20 require us to put a label on saying for clarity, this is
21 only effectively a tiny percentage of the market, only
22 2%, only for congenital hyperplasia. So there could
23 have been a dispute between them and the MHRA and us
24 dragged into, which would have required us to explicitly
25 label this. That was the fear. Then the concern was,

1 well, if customers already do not want it, and we
2 actually had to put a label on it, then that is going to
3 be -- there is even less chance of hitting the market.
4 So that was certainly one of the things that we were
5 concerned about that they had been threatening. I do
6 not know what else they could have done. They may have
7 taken advice on it. I do not know. But there was
8 a concern they would react to that saying this is not
9 happening properly and let us not forget that, as we
10 understood it, because we looked into it carefully,
11 because we wanted to hit the market, we wanted there to
12 be skinny sales, the rules, as we understood them and as
13 I understand them, are pretty clear that a pharmacist
14 should dispense the licensed indication, if it is
15 available, but there are then exceptions. So --

16 THE PRESIDENT: We will leave that to others to cover. Were
17 you concerned as to what might happen to your Auden
18 supply of Hydrocortisone?

19 A. So at this time we were concerned that we would have to
20 leave the market altogether and we were out of stock.
21 We had customers saying we want it. We said we got some
22 skinny coming on board, would you like that? They said
23 no. So the concern was we had customers who wanted this
24 product. We do not want to be seen as unreliable. It
25 seemed to us the only route forward is to take the

1 supply from Auden and that is in the context, of course,
2 of having been -- the MHRA had been given us no sign of
3 any optimism that there would be -- they would change
4 their position and the Pinsent advice that said you
5 cannot challenge the orphan drug status.

6 THE PRESIDENT: Mr Sully, we will obviously go back to look
7 at the precise terms of the first and second agreements,
8 but, correct me if I am wrong, under the second
9 agreement if you entered the market, did that give Auden
10 any ability to cut off the supply of full label
11 Hydrocortisone, the 12,000 units that we have been
12 talking about?

13 A. Yes, sir, it did. So what happened in that agreement
14 was for us it was imperative that we knew customers did
15 not want it at the time, but we wanted to be able to
16 monitor the market and see if something changed and if
17 it did not -- to be able to react and to sell. So part
18 of getting that in was they said, well, hold on that is
19 going to cause chaos if you just launch in the market at
20 the same time. There are firm orders in place etc. So
21 they wanted a right, which I think we looked at
22 yesterday in 17.2, to terminate on three months if we
23 launched. I cannot remember. I think we had to give
24 three months' notice, but it is in 17.2.

25 So, yes, if we had said, great, we have got sales,

1 the customer wants to buy our skinny product and we have
2 given a notice to them, they would have had a right to
3 terminate on three months' notice.

4 THE PRESIDENT: So, correct me if I am wrong, but going
5 through your mind would there have been a balancing --
6 at the moment you are without your skinny label product.

7 A. Yes.

8 THE PRESIDENT: You are selling 12,000 units of Auden's
9 product at a cost to you of £1.78 a packet.

10 A. Yes, sir.

11 THE PRESIDENT: And so you are making --

12 A. Once this is signed, yes, sir.

13 THE PRESIDENT: Sure. And you are making therefore, because
14 you are selling it at £38 a packet, a significant
15 marginal profit in each case.

16 A. Yes.

17 THE PRESIDENT: You are thinking of introducing into the
18 market your own product, which is, as you have described
19 skinny label. What you have got to ask yourself is: am
20 I going to be able to sell more than or equal to 12,000
21 units in order to make it commercially worthwhile? Is
22 that a thing you recognise or am I just barking up the
23 wrong tree?

24 A. That is a hypothetical. Our position was we wanted to
25 be able to take half the market, thinking we could

1 compete fully. We could not. Our position on entering
2 into this and my understanding was if a customer comes
3 to us -- we sign this agreement and, as I said to the
4 management team and the owners subsequently, we signed
5 it as an interim while we work out what is going on and
6 try and work out how we are going to get round this
7 orphan drug issue. If a customer had said to us we want
8 skinny label product, then the position was we would
9 have said right, well, we want to be able to sell it.

10 I do not think we would have then said is it enough
11 to justify, certainly not without going back to Pinsent
12 and saying, okay, there is a balancing act here. This
13 was absolutely in agreement where there was zero
14 interest and we wanted to put -- keep a foothold in the
15 market and supply our customers until we found a way
16 round it.

17 So no, I am not aware of ever having a discussion of
18 is there enough of an order and, indeed, when the first
19 order came through for our skinny product, I said we
20 need to take it and that is what the commercial team
21 wanted to do. We wanted to launch our own product and
22 I do not remember the volume, but it was not very big,
23 but it was this is what we have always wanted to do is
24 to launch our own product. So there was not a balancing
25 act then and there was not a balancing act earlier.

1 THE PRESIDENT: Just to be clear.

2 A. In my mind. I do not know from if my commercial
3 colleagues thought differently, but certainly that
4 wasn't the understanding I had at all.

5 THE PRESIDENT: No, that is very clear. Just to nail
6 a potential ambiguity. You have mentioned customers
7 a number of times. You are talking about pharmacies
8 when you are talking about customers.

9 A. No, so the way the supply chain works in generics and
10 the way we were geared up was we tended to sell to
11 wholesalers. We had a specific agreement. We had
12 followed what a number of companies did, which was to
13 sell -- to do what was called reduced wholesale
14 agreements. So we sold to wholesalers, in particular to
15 the two main ones, AAH and Alliance, and in fact then we
16 actually ended up in 2015, I think it was, only selling
17 to Alliance. It was a model that a lot of companies
18 followed at the time.

19 So, effectively, the wholesalers were our customers.
20 The wholesalers in turn either had their own vertically
21 integrated pharmacies. Alliance has Boots. AAH has
22 Lloyds or they were selling to other independent
23 pharmacies or other pharmacy chains, Safeway's; Wells,
24 the smaller ones. So we were not selling directly to
25 pharmacy generally.

1 THE PRESIDENT: But what -- at the end of day, it is what
2 sales are made in pharmacies that drives the whole
3 thing?

4 A. Absolutely.

5 THE PRESIDENT: So you were getting information as to what
6 would or would not happen in the pharmacies
7 intermediated through your wholesalers who were saying
8 this is what we think will happen.

9 A. Exactly, sir, and those wholesalers that we had chosen
10 to work with, Alliance an AAH, are the two big full line
11 wholesalers, which means they carry every line in the
12 country, everyone refers to them. They are effectively
13 the pedigree and number 1 and joint number 1 wholesalers
14 in the country and they had said we do not want this.
15 So in our eyes that was the entire market doesn't want
16 this, because they sell to the entire market, as far as
17 I understand.

18 THE PRESIDENT: Thank you very much, Mr Sully. I am so
19 sorry, Ms Demetriou.

20 MS DEMETRIOU: Mr Sully, you are saying here, so just going
21 back to the document that we have got on our page, you
22 are saying the issue is how Auden would react. So you
23 understood, did you not, that you were not prevented
24 from entering the market. The question is how Auden
25 would react when you were entering. The business hadn't

1 had good feedback from customers, you are saying, and so
2 did not want to take the risk of entering. That is
3 fair, is it not?

4 A. I believe I already answered this question.

5 Q. I am just asking you to answer it again. Just bear with
6 me, please.

7 A. So we had wanted to launch. Customers had said they
8 were not interested, full stop. We thought there were
9 zero sales. We thought if there were sales, and that is
10 what [REDACTED] had asked me in the email --

11 Q. Mr Sully, to be clear, I am not asking you to repeat the
12 same thing that you have now said several times. I am
13 just asking you to answer yes or no to my question?

14 A. What is the question?

15 Q. Is this a fair assessment of your evidence, that you
16 accept -- let us take it in stages. You accept that
17 nothing was legally precluding you from entering the
18 market, yes or no?

19 A. Nothing was legally precluding us from entering the
20 market with a skinny product.

21 Q. Yes, and your feedback, you say from customers, had been
22 that you would not be successful if you entered the
23 market, yes or no?

24 A. Our customers said they do not want the product. They
25 haven't commented on our ability to launch. They had

- 1 said we do not want the product.
- 2 Q. So that created a big commercial risk for AMCo, yes or
- 3 no, if you were to enter with your own product?
- 4 A. No, that meant that the market was dead. The risk about
- 5 Auden reacting is if a customer had said they do want it
- 6 and we had supplied, which is the point that is being
- 7 discussed here, then what would have happened? But we
- 8 were not in that situation, because customers as had
- 9 said they do not want it.
- 10 Q. Let us go to {IR-H/806/1}. If we go down to page 4.
- 11 {IR-H/806/4} If we go to the bottom of the previous
- 12 page, just so we can see when this was sent. So do you
- 13 see it is from Graeme Duncan -- he is at AMCo, yes?
- 14 A. Yes.
- 15 Q. December 2015 and you are in copy, yes?
- 16 A. Yes.
- 17 Q. If we then go down you see there:
- 18 "I want to keep you posted on our thoughts on supply
- 19 options for the potential hydrocortisone tablets."
- 20 Yes?
- 21 A. I am so sorry, where are you? Sorry, yes.
- 22 Q. Do you see:
- 23 "I wanted to keep you updated as to our
- 24 thoughts ..."
- 25 A. Yes.

1 Q. And then you see further down:

2 "As you are aware, the only manufacturer with
3 a product with the full list of indications is Actavis."

4 So that was Auden, yes?

5 A. Yes, that is right, Actavis had acquired Auden.

6 Q. "Therefore our first choice would be to negotiate
7 a supply agreement from them which would allow us to
8 sell the product to the entire market. If Actavis are
9 unwilling to provide this supply, we will use Lamda as
10 a supplier but this will limit sales ... for the
11 following reasons."

12 Lamda also had a skinny label, did it not? If we
13 look at what it says. It says:

14 "Only a small part of the market (less than 30%) is
15 willing to use the product, therefore potential volume
16 will be limited. To use what is perceived as an
17 inferior product due to the indications the independent
18 pharmacy sector is only buying due to the discount being
19 offered."

20 And then it says that:

21 "There is already a product being sold into this
22 limited market ..."

23 This is later on. This is in 2015.

24 A. This is 18 months after the second agreement has been
25 signed.

1 Q. I haven't asked you a question, yet, Mr Sully. I am
2 just asking you to look at it. If we go up the page do
3 you see there that it says:

4 "Thank you very much for this detail. It is
5 interesting and of course gives us very clear market
6 feedback of the issues a product without the full range
7 of indications would have. To have such a significant
8 and clear response from the two major retail chains is
9 very useful. This is in line with our own historical
10 assessments of some of the issues with this market."

11 That seems to indicate that it was not a zero
12 market, does it not, Mr Sully, that there had been
13 historical assessments indicating that there would be
14 some demand for this product?

15 A. I do not know what Mr Duncan meant. I can tell you that
16 there was zero interest when the second agreement was
17 signed.

18 Q. You can tell us because that is what you were told by
19 Ms Hill, yes?

20 A. Yes, and this was at a different position in time when
21 the market had started to open up, non-compliantly we
22 thought.

23 Q. He is talking about -- you accept he is talking there
24 about historical assessments, not 2015. He is saying
25 that what he has been told in 2015 is in line with

1 historical assessments. You accept that is what he is
2 saying. You are in copy.

3 A. So it is in December 2015 and we have been monitoring
4 this market throughout the period since June 2014. I do
5 not know what he meant by "historical assessments".
6 There were a number of discussions. I do not know if he
7 meant the discussion that took place when Alissa first
8 obtained the MA, when Alissa -- in May 2015 when we
9 looked at it again closely before the sale of the
10 company. I do not know what he means by "historical
11 assessments".

12 Q. The reality, Mr Sully, is that it would have been risky
13 to enter the market because of this product but not
14 impossible but that AMCo preferred the certainty of the
15 supply agreement to the risks of entering the market
16 with its own product, did it not?

17 A. That is not the case. So we signed the second agreement
18 because there was zero interest.

19 Q. Sorry, carry on.

20 A. So at the time we went to Pinsent and then in June 2014
21 we understood, I was instructed, that customers had said
22 they do not want this product, there is zero interest.
23 We did not have a product from Aesica and so with
24 Pinsent's advice they said you are in different markets
25 so we signed the second agreement. We kept on then

1 trying to get the product from Aesica despite a whole
2 number of issues that happened, and kept on monitoring
3 the market.

4 It is true that in December 2015, by then we
5 actually had got product so we had gone back to the
6 market again to say, great, do you want it, AAH and
7 Alliance, and they had both said no, we do not, which
8 was like for goodness sake this is completely dead this
9 market. But they raised this other small part of the
10 market, these independents that were starting to buy it,
11 and we looked into that.

12 Q. There is nothing that we have been able to see where you
13 respond saying well, those actually were not our
14 historic assessments, you cannot recall anything, can
15 you, where you said that in writing to anyone?

16 A. I do not know what he meant by historical assessments.

17 Q. You did not ask him at the time?

18 MR BREALEY: Just ask him to go a bit further down to
19 page 5, just to give the witness some help here.

20 {IR-H/806/5}. I think you need to go from the --

21 MS DEMETRIOU: Why does Mr Brealey not do this in
22 re-examination?

23 MR BREALEY: I can too but ...

24 THE PRESIDENT: I think it would be helpful, given that we
25 are on the topic, to enable the witness to see the

1 entire email chain.

2 MR SULLY: Yes. So I mean -- perhaps we could start at the
3 bottom but certainly that email on the screen now is
4 that is where we have gone back to the market, as I have
5 said, to say, we have finally got product. Do you want
6 to buy this product? Alliance and indeed AAH have both
7 said, we do not want it. I do not know if AAH is in the
8 same ... yes, and the reason they gave, it is at the
9 bottom of this screen, is so that both of them had
10 said -- they have people called chief superintendent
11 pharmacists who are effectively the ones that make sure
12 that they are doing what they should I suppose, and then
13 said the products need to have the full indication,
14 which is the feedback we consistently got.

15 Q. And those are two of the full line wholesalers, yes?

16 A. They are two biggest full line wholesalers. I do not
17 know if there other full line wholesalers. They are the
18 two big wholesalers in the UK.

19 MR BREALEY: Can you just -- on page --

20 MS DEMETRIOU: I am sorry, this is really not appropriate.

21 Mr Brealey can deal with it in re-examination. I have
22 no idea what is in his mind. I have a series of
23 questions I want to ask. If he thinks it is misleading,
24 he can deal with it.

25 THE PRESIDENT: I made clear at the beginning that I do not

1 want witnesses to be disadvantaged by seeing a snapshot
2 of a picture. I appreciate that Mr Brealey can take
3 matters in re-examination but if there is material here
4 that enables the context to be understood, then I do
5 think the witness needs to look at the whole document.

6 MS DEMETRIOU: Sir, I am very happy for him to go to the
7 material but Mr Brealey just said to me: can you put to
8 him that, and I have no idea what is in his head so ...

9 MR BREALEY: I will explain. If one goes to page 4,
10 {IR-H/806/4}, Ms Demetriou was asking the witness:

11 "Hi Roland.

12 "Thank you very much, it is interesting and of
13 course gives us a very clear market feedback of the
14 issues a product without the full range of indications
15 would have. To have such a significant and clear
16 response from the two major retail chains is very
17 useful. This is in line with our own historical
18 assessments of some of the issues with this market."

19 The reason that I refer to the bottom of the email
20 chain is because that relates to the two major retail
21 chains which is -- maybe the witness --

22 THE PRESIDENT: Mr Brealey, I am very happy for you to point
23 out what the witness should read but I think that is as
24 far as it should go.

25 MR BREALEY: I am sorry.

1 THE PRESIDENT: But I am grateful for that. Anything else
2 by way of direction is for re-examination.

3 MR BREALEY: Of course.

4 MS DEMETRIOU: I think the witness has now read everything
5 Mr Brealey wants him to read.

6 THE PRESIDENT: I hope so. Mr Sully, are you comfortable
7 that you have got the context?

8 A. Yes, and actually looking at that bit, the second
9 sentence does appear to be what the historical
10 assessment is, so, as I said -- I said before, I am not
11 aware of any sense that there was appetite for the
12 skinny product before this late period in late 2015 and
13 actually I now see I think that that historical
14 assessment is the fact that the two major wholesalers
15 have again given a very unequivocal no to the product.

16 MS DEMETRIOU: Mr Sully, your evidence is that there was
17 zero appetite for the product but your evidence is also
18 that AMCo continued to develop the product. Why did
19 they continue to develop it if there was no appetite for
20 it at all?

21 A. So that was the whole reason for signing the second
22 agreement was. We had already -- we had a Mercury
23 product with MIBE. We had the Amdipharm product with
24 Aesica. Then the orphan drug issue came out and we
25 said, we have got to find a way around this. Let us see

1 if we can buy Waymade's full indication product. That
2 did not work. Let us look at the Plenadren product. We
3 were determined to come to market with the product but
4 when customers said they did not want it, we said, okay,
5 well, our customers want a product. They do not want
6 the skinny. Let us sign the second agreement provided
7 that it is compliant, which we were told it was, and we
8 will keep monitoring the market and we will keep
9 bringing these products through and we will hope that
10 something changed.

11 What that led to was we carried on with Aesica, we
12 carried on with MIBE. We subsequently acquired
13 a company called Focus Pharma and they had a 10 and a
14 20 skinny product, and we said, great, let us do those
15 too. We could not buy Plenadren. It did not work for
16 the reasons I explain in my statement. But we were
17 determined if any opportunity came up to sell the
18 product we would be able to take it, subject to it being
19 compliant.

20 Q. Mr Sully, it is a very short question I asked you.

21 A. I am so sorry.

22 Q. Let me take you to your witness statement, paragraph 98.

23 {B2/2/26}

24 A. I think that is what I have just been saying.

25 Q. You say there AMCo never stopped pursuing independent

- 1 entry via Aesica and these are the routes, yes?
- 2 A. Yes.
- 3 Q. So my confined question, I am not asking about the
4 history of this, I am just asking you why AMCo never
5 stopped pursuing these options if you were clear that
6 the demand was zero, there was zero market for it. Why
7 would you have invested money in pursuing these options
8 when there was no market?
- 9 A. Because we hoped things would change. We had always
10 thought this seems like a bonkers situation where the
11 Auden immediate release product is being protected by
12 this small volume modified release product and we were
13 hoping that something would change.
- 14 Q. When you say you were hoping something would change, you
15 were not anticipating challenging the orphan designation
16 because you have had had advice that was not possible.
17 So what were you hoping would change?
- 18 A. We were hoping that the MHRA would, to be polite, look
19 at it again and go actually this is bonkers and that is
20 why we went back to the MHRA I think shortly after the
21 second agreement was signed, we went back to the MHRA
22 and we tried to get a full indication for an injectable
23 to see is there a route to -- and again we got
24 a definitive no. So we were hoping the MHRA would
25 change.

1 Q. Change what, Mr Sully? What were you hoping the MHRA
2 would change? You had received definitive advice from
3 Pinsent which you told us you accepted that you could
4 not challenge the orphan designation and therefore you
5 could not market your product as having the full range
6 of indications. So what were you hoping the MHRA would
7 do in relation to that? I am not interested in
8 injectables. That is different.

9 A. We were hoping they would step in and do something. We
10 did not know what that would be.

11 Q. What? You are a lawyer, what were you asking them to
12 do?

13 A. We wanted to be able sell to that part of the market.
14 We were hoping they would do something. We did not know
15 what it was. That is why we kept on it.

16 Q. Mr Sully, come on, you are committing funds to carry on
17 developing a product and you are saying that is because
18 you were hoping the MHRA would change its mind, but you
19 know the MHRA is not going to come to you changing its
20 mind unless you ask them to do something. What were you
21 asking them to do?

22 A. So we kept asking them: can we get full indications?

23 Q. Where do you ask them that?

24 A. I am not a regulatory expert on the MHRA but we were
25 hoping there would be some change in the market. Or

1 indeed, as well as other changes, was we kept a close
2 eye on what people -- is there any interest in the
3 market? Because the other change that could have
4 happened was either the MHRA sorts out this situation
5 that we felt was deeply unfair or that customers said,
6 actually we want to buy skinny product.

7 Q. Can I just pause there because you have mentioned two
8 things. You were hoping the MHRA would do something but
9 you are not able to recollect asking them to do anything
10 in particular?

11 A. If I had known what to ask them that would have made
12 a difference, I would obviously have done it but we did
13 not know.

14 Q. But you did not?

15 A. We were hoping there would be a change because it was
16 important for us to launch.

17 Q. You were hoping they would unilaterally approach you
18 with a change?

19 A. No, we were hoping there would be something that -- that
20 when they looked at it, for example, when we applied on
21 the injectable or if there were other MAs that were
22 granted they would look at it and say, actually this
23 does not make sense. They did not but that was the
24 hope.

25 THE PRESIDENT: You were not engaging in a form of

1 communication inviting them to reconsider?
2 A. That had already happened really. So that had happened.
3 Waymade had done that in 2012 we learnt. We had done it
4 in 2013, in 2014 and again with the injectable
5 in September 2014. So we were -- they were not open to
6 persuading but that did not mean that someone else might
7 have succeeded in changing them or they might have had
8 some wholesale review. I think right now they are
9 actually looking at this whole area of orphan drug rules
10 and where it has gone wrong. So that was a change, the
11 sort of thing we hoping. They might it and go, actually
12 the legislation is not doing what it is intended to do
13 which is to protect.

14 THE PRESIDENT: Let us leave what the legislation is
15 supposed to do to one side. You were hoping for
16 a spontaneous change on their part, not one, as it were,
17 induced by further communications from you.

18 A. Well, no, one or the other because we did try again with
19 the injectable thinking if they had not accepted the
20 tablets on three occasions, let us try the injectable
21 and if we had won that you could try to morph it across
22 or something. But we did not know what to do other than
23 we wanted to keep trying and we wanted to have product
24 there in case our customers said, actually, we do want
25 a skinny product.

1 MS DEMETRIOU: When you brought Aesica to market eventually
2 nothing had changed as regards the MHRA. That is
3 correct, is it not? The regulations had not changed,
4 the orphan designation was the same, there was still the
5 same issue, yes?

6 A. That is right, it was the same. So then it was
7 a customer came to us and said, we specifically want
8 your skinny. Great, we supplied it.

9 Q. And a customer came to say, we specifically want your
10 skinny, because by that stage there was already another
11 skinny label product on the market, was there not?

12 A. So there was, and that is what we were monitoring
13 carefully from those emails we just looked at
14 in December 2015.

15 Q. Mr Sully, it is unlikely is it not -- if there is no
16 skinny label product already on the market, you are
17 unlikely to see customers come and ask you for a skinny
18 label product if they do not know that one exists, yes?

19 A. They did know it exists because we had gone to customers
20 in April/May and said, we have got a skinny product
21 coming to market, do you want it, and they said no. We
22 went again in December so they did know there was a
23 skinny product there.

24 In addition, Alissa launched -- it got an MA at the
25 end of 2014 which we were like, maybe this is some

1 movement. It did not sell for a year and we were
2 watching, so we thought they have run into the same
3 problems that we have but then some sales did start
4 coming through so of course we watched it carefully. It
5 appeared to be non-compliant as I have said but we
6 watched it and we said, the position is always the same.
7 If a customer comes to us and says, we want your skinny
8 product, we want to be in a position to sell. We want
9 stock on the shelves so could do so. That is why we
10 pursued all those projects and invested a lot of money.

11 Q. So the position is that Alissa appeared to have
12 stimulated a demand for skinny label product and at that
13 stage the company took the view that they would incur
14 the risk of entering the market, yes?

15 A. No, that is not what I said. So what I said was Alissa
16 got an MA and for a year it could not sell. So we
17 assumed they were not able to. Then there was the
18 talk -- it is in the email we just looked at, that there
19 seem to be some independent pharmacists prepared to take
20 a compliance risk and so we understood there
21 was effectively a bit of a misrepresenting of this is
22 a product that can be used in place of the full product.
23 We said we can't do that. That is against all of the
24 code and the law. But if a customer comes to us and
25 says he wants skinny, which did happen in April, we want

1 to be ready to supply them.

2 Q. What happened, Mr Sully, is that you did not want to
3 test the market yourself in 2014 because you had a much
4 more lucrative supply deal from Auden. The business did
5 not want to take the risk of entering the market itself
6 so it entered into the agreement to take supply from
7 Auden instead of entering the market itself, and both
8 sides knew the score, did they not?

9 A. I hope I have explained clearly but we did test the
10 market in April and May 2014. We tested it again
11 in December 2015 when we finally had product from
12 Aesica. On both times our customers said they did not
13 want the skinny product. But we carried on, as
14 I believe I said, investing, making sure we were ready
15 so if a customer wanted to give us skinny product we
16 were ready to do so because that was always the plan, to
17 have our own product with our own IP on the market, and
18 when that finally happened in April 2014 we supplied
19 them.

20 THE PRESIDENT: Just to be clear about what is meant by
21 "knowing the score". I will say what I get from that
22 and Ms Demetriou can correct me if I am wrong and then
23 you can answer the question.

24 What I think is being suggested is that at the time
25 of the second agreement both Auden and your company were

1 agreeing, and I am not saying or suggesting a legal
2 agreement, I am suggesting an understanding that you
3 would get the product, the Hydrocortisone full label
4 at £1.78 a packet which you would sell or be able to
5 sell for far higher price, thereby making a marginal
6 profit which was substantial and in return for that you
7 would not enter the market with your own product,
8 whatever that might be.

9 Have I got that right, Ms Demetriou?

10 MS DEMETRIOU: Sir, yes.

11 THE PRESIDENT: Very good. Would you mind answering our
12 question.

13 A. I can tell you absolutely definitively that was not the
14 agreement. As far as I was aware, I never saw anything
15 to suggest that was the case. On the contrary, we
16 wanted to enter the market. We could not. We wanted to
17 keep supplying customers and keep a foothold in there in
18 the hope that something changed. We carried on pursuing
19 all of these projects and investing money to be ready
20 and as soon as we could enter the market, because
21 a customer said we want your skinny product, we did.

22 There was no agreement, no understanding to stay off the
23 market.

24 THE PRESIDENT: Mr Sully, you will know this because you are
25 a lawyer but counsel is obliged to put her case and I am

1 just making sure that you have the opportunity, as she
2 does, to put it in the clearest possible way so that
3 your answers are on the record so you know where we are
4 all coming from.

5 A. Thank you, sir.

6 MS DEMETRIOU: Thank you, Mr Sully. I do not have any
7 further questions for you. Thank you very much.

8 THE PRESIDENT: You can think over the short adjournment
9 whether there is any further questions you have or
10 indeed anyone else has to ask but is there any need for
11 us to resume early or shall we resume at 2 o'clock?

12 MR BREALEY: I think 2 o'clock is fine.

13 THE PRESIDENT: Very good. In that case we will resume at
14 2 o'clock.

15 (1.02 pm)

16 (Luncheon Adjournment)

17 (2.00 pm)

18 Re-examination by MR BREALEY

19 MR PALMER: Having reviewed my notes, there is nothing
20 further beyond what Ms Demetriou has already asked that
21 I wish to ask.

22 THE PRESIDENT: That is very helpful. Mr Brealey. Unless
23 there is anyone else?

24 MR BREALEY: I have asked.

25 THE PRESIDENT: I am grateful.

1 MR BREALEY: Quite briefly, Mr Sully, could we go, please,
2 to document {IR-H/368/1}. It is a document you saw
3 yesterday.

4 A. Yes, I can see it on the screen.

5 Q. And that is the PPRM recommendation for board approval
6 and then you were shown page 3.

7 A. Yes.

8 Q. The rationale. I will read it out:

9 "Back up product to ensure continuity of supply in
10 case our existing distribution agreement with
11 Auden McKenzie for Hydrocortisone is not renewed. Also
12 more beneficial to be the IP owner versus rely on
13 a distribution agreement."

14 So we can put that away, but I would like you to
15 take you to the transcript, please of yesterday and that
16 is page 115. {Day1/115:1}. So yesterday's transcript
17 at 115. While we are waiting for it to come up, this
18 was a recommendation for the board approval. We saw
19 that on the first page, yes? I am only interested in
20 the first two lines, because it is identifying the date
21 of the board meeting on 29 January 2014. I am going to
22 come to that in a moment, because you were not taken to
23 that document. You were referred to the board approval.

24 Could we then go to page 118 of the transcript
25 {Day1/118:19} So if you could read page 118, line 19 to

1 119, line 18 and just say when you need to flip the
2 page, Mr Sully?

3 A. Okay, sir.

4 Q. So it starts at line 19:

5 "Can you explain this: why does this say ..."

6 So this was the passage you were referred to.

7 (Pause).

8 A. Yes, please could we go to the next page, thank you.

9 Q. Just to line 18 of 119.

10 A. Yes, I have read that.

11 Q. So two things I would like to ask about this. The first
12 is at the top you refer to the Aesica IP agreement being
13 more beneficial to the IP owner. So that is the
14 sentence that comes from that. Do you see that?

15 A. Yes.

16 Q. So we launched the Aesica product and it says here,
17 "more beneficial". Could you just explain why it would
18 be more beneficial to be the IP owner rather than have
19 a distribution agreement?

20 A. Yes, sir, so for a number of reasons. So, as
21 I mentioned, the majority of the companies' products
22 were our own IP. That meant you had full control of the
23 product. You could arrange for whoever you wanted to
24 manufacture it for you and you were not beholden to
25 somebody else who ultimately had control. So clearly

1 the opposite is if it is someone else's IP and they
2 dictate the terms effectively on which you get the
3 product and how long you get the product for and at what
4 cost etc.

5 So we wanted to be fully in control of this product,
6 because this was a product we wanted to launch. As
7 I mentioned, it was one of our big new launches for
8 2014.

9 Q. Thank you. Then the second point relates to, if one
10 goes to line 8 and 9, Ms Demetriou refers to this going
11 to the board and at 11 you say:

12 "I was there at the time [and we will see the
13 minutes in a minute] and I recall at all times time
14 Aesica -- sorry, Auden, was an interim supplier until we
15 could bring Aesica online and that was exactly what was
16 agreed at the board meeting ..."

17 You were not taken to the board meeting, the
18 minutes, so could I please take you to document
19 {IR-H/346/1}. Just to confirm at the top, as you said
20 in evidence, you were in attendance?

21 A. Yes, I was.

22 Q. Then could you go to page 3, please {IR-H/346/3}. These
23 are the minutes of the board meeting of 29 January 2014.
24 Halfway down you see that:

25 "Mr Beighton confirmed that negotiations with

1 Auden McKenzie to agree formal written contracts for the
2 supply of Hydrocortisone and Carbimazole had proved
3 difficult and that signed contracts had still not been
4 achieved. However, Mr Beighton was hopeful that
5 contracts would soon be signed. It was noted that, as
6 a result of a more positive outlook on the group's own
7 Hydrocortisone product that is being developed by Aesica
8 for Amdipharm, it was hoped that the group would be able
9 to obtain its own fully compliant product in the next
10 four months and thereby move away from sourcing
11 Hydrocortisone from Auden under the legacy arrangements
12 that had been inherited from the merger with Amdipharm.
13 Mr Beighton explained that the issue with the AMIL
14 development was that Auden had obtained orphan drug
15 status for their product in relation to the adrenal
16 insufficiency indication, which AMIL and AMCo were
17 currently investigating. It was currently thought that
18 AMIL's own version would be able to compete with the
19 Auden product even if it does not have this indication,
20 but investigations continue as this is a £30 million
21 EBITDA market and so there is much at stake."

22 I have read it out and we can read it, but can you
23 assist the Tribunal as to what was decided by the
24 company at this meeting?

25 A. Yes, so that was a discussion that took place and the

1 decision was taken that we will continue to formalise in
2 writing the informal agreements with Auden, bring them
3 to a close at the end of March 2014, and then move to
4 taking supply from Aesica which was our preferred route
5 forwards. We understood at the time at the end
6 of January that Aesica will be able to deliver product
7 in April 2014.

8 Q. Just to be crystal clear, and this is something that the
9 Tribunal has asked, just to be crystal clear, did the
10 board at this meeting approve an agreement with Auden
11 which allowed AMCo to develop and to manufacture 10mg
12 Hydrocortisone, but then not sell it and only have it as
13 back up?

14 A. Absolutely not.

15 Q. Thank you. I have no further questions.

16 THE PRESIDENT: We have no further questions for you,
17 Mr Sully. Thank you very much for your time and
18 efforts. You are released from the witness box.
19 Thank you.

20 A. Thank you very much.

21 (The witness withdrew)

22 MR BREALEY: I next call, sir, Mr Beighton.

23 MR JOHN BEIGHTON (affirmed).

24 Examination-in-chief by MR BREALEY

25 THE PRESIDENT: You will get some questions, but what I said

1 to Mr Sully, I think you were in court when you heard
2 it, but if you want to see any other parts of documents
3 which come up on the screen, you only ever get to see
4 a fraction, but if you want to see any other bits let
5 counsel know and we will arrange for that to be done
6 because you will want to know the context. This is not
7 a memory test.

8 Mr Brealey, over to you.

9 MR BREALEY: Mr Beighton, you have had handed up to you,
10 I think, your witness statements. Can you just confirm
11 it is your statement, yes?

12 A. It is.

13 Q. I understand that you just wanted to make a small change
14 to your present occupation?

15 A. Yes, I am no longer chairman of Acino. That was the
16 only change.

17 Q. So which paragraph is that?

18 A. Paragraph 1.

19 Q. You are no longer chairman of Acino. Subject to that
20 change, if you go to the end of this statement, can you
21 see your signature?

22 A. Yes.

23 Q. Can you confirm that the contents of this statement are
24 true to the best of your knowledge and belief?

25 A. I can confirm that.

1 Q. Thank you very much. I think it is Ms Demetriou who
2 will have some questions for you, but I will give her
3 the ...

4 Cross-examination by MS DEMETRIOU.

5 MS DEMETRIOU: Good afternoon, Mr Beighton. You are
6 familiar, are you not, already with the Tribunal's
7 procedure because you very recently gave evidence to the
8 Tribunal in Liothyronine, did you not?

9 A. Yes.

10 Q. And I think you also gave evidence to the Tribunal in
11 Phenytoin?

12 A. Yes, I did.

13 Q. Have you been in court while Mr Sully has been giving
14 his evidence?

15 A. Yes, I have. For most of it. I think I missed the
16 first half hour or so when you were having the technical
17 problem.

18 THE PRESIDENT: The IT problems, but you did not miss much.

19 MS DEMETRIOU: You have said, Mr Beighton, in your witness
20 statement that you have been in the pharmaceutical
21 industry for a long time, for about 39 years, and that
22 includes managing -- being managing director of Teva for
23 seven years, that is right, is it not?

24 A. Yes.

25 Q. Then you were CEO of Goldshield. So you have got,

- 1 I think it is fair to say, is it not, that you have
2 a huge amount of experience in this industry?
- 3 A. Yes, that is right.
- 4 Q. So you have experience developing product and what is
5 involved in developing a product?
- 6 A. Most of my experience is in the commercial world, but
7 I have some experience of product development too.
- 8 Q. You understand how the supply chain works?
- 9 A. I do, yes.
- 10 Q. And you have got experience of what happens to market
11 after generic entry?
- 12 A. I certainly have that.
- 13 Q. And you must have plenty of experience negotiating
14 supply deals with contract manufacturers, for example?
- 15 A. Not so much. As I have said, I am a commercial guy so
16 I have usually been the salesman, but I have had some.
- 17 Q. And you have seen how those work anyway?
- 18 A. Yes, I have definitely seen how they work.
- 19 Q. And also you have seen how negotiations work in terms of
20 deals with wholesalers to sell products on?
- 21 A. Yes.
- 22 Q. You explain in your witness statement that you joined
23 Goldshield Group as CEO in May 2010. That is correct,
24 is it not?
- 25 A. That's correct.

- 1 Q. And Goldshield was re-branded as Mercury Pharma Group?
- 2 A. Yes.
- 3 Q. And then Mercury was acquired by Cinven, which is
- 4 a private equity firm and that was in August 2012?
- 5 A. Yes.
- 6 Q. And at paragraph 12 of your witness statement, do by all
- 7 means look at it if you want to, but I think this is
- 8 going to be controversial, you say following the
- 9 acquisition of Mercury by Cinven you were asked to help
- 10 Cinven acquire the Amdipharm pharmaceutical business?
- 11 A. Yes, that's correct.
- 12 Q. And Amdipharm was part of Waymade Healthcare?
- 13 A. It was.
- 14 Q. And so in doing this you were reporting to Cinven
- 15 presumably?
- 16 A. I was, yes.
- 17 Q. And you were involved in the acquisition of Amdipharm
- 18 from the outset of the acquisition of Mercury, which was
- 19 in August 2021 -- sorry 2012.
- 20 A. Could you just say that again?
- 21 Q. Yes, so Mercury was acquired by Cinven in August 2012
- 22 and from more or less that time you were involved in the
- 23 acquisition of Amdipharm?
- 24 A. Yes.
- 25 Q. You say at paragraph 16 of your witness statement that

1 in the run-up to Cinven's acquisition of Amdipharm you
2 learned from Cinven that it was acquiring some Waymade
3 assets?

4 A. Yes.

5 Q. And that included Waymade's Hydrocortisone business?

6 A. Yes.

7 Q. And you thought, I think, I think it is right, is it
8 not, that at that stage you thought it was the entirety
9 of the Hydrocortisone business, including 20mg as well
10 as 10mg?

11 A. Yes.

12 Q. But it turned out not to be so, so it turned out to be
13 the 10mg business?

14 A. Yes, that is right. 20mg was removed or we chose not to
15 have it, yes.

16 Q. I just want to look at the final due diligence report
17 which is at {H/150/1}. You can see the date on this is
18 23 October 2012. Project Ampule refers to the
19 acquisition of Amdipharm, does it not?

20 A. Yes.

21 Q. And you would have seen this document at the time?

22 A. I would.

23 Q. Do you recognise it?

24 A. Yes.

25 Q. If we turn to page 9, {H/150/9}, we see from the heading

1 that:

2 "Management's forecast growth is primarily focused
3 on price increases across a number of SKUs."

4 Can you just help the Tribunal with what SKU stands
5 for?

6 A. Stock keeping unit. It means the individual line of
7 product, individual pack.

8 Q. "And one significant new product launch", yes?

9 A. Yes.

10 Q. Then we see that the product launch is Hydrocortisone,
11 yes?

12 A. Okay, yes.

13 Q. If we look at that, so you can see -- if you look at the
14 blue, do you see the blue left-hand column, so you see
15 there that says, it is through the launch of
16 Hydrocortisone tablets in the UK?

17 A. Yes.

18 Q. You see on the right-hand side:

19 "Hydrocortisone is planned to be launched in the UK
20 in 2013, taking market share from the incumbent
21 supplier."

22 Yes and you understood that was Auden?

23 A. The incumbent supplier was Auden, yes. The incumbent
24 supplier to the UK market, yes.

25 Q. That is right. If you go to page -- can we please go to

1 page 12 of this document {H/150/12}. If we look at
2 Hydrocortisone, we see there that the current market --
3 I am looking at the Deloitte comment in the third
4 column. Do you see where I am looking?

5 A. Yes.

6 Q. "The current market for Hydrocortisone is supplied
7 solely by Auden McKenzie. Management plan to launch
8 their new product to take a share of this market... "

9 But then it is recognised that there would be --
10 there is a high risk of other new competitors coming in,
11 which might take potential market share but the idea is
12 to get in to the market earlier, yes?

13 A. Yes.

14 Q. We then see, if we look at the last bullet:

15 "Cinven's sensitivity lowers management's volume and
16 price assumptions by 30% to reflect the scenario of
17 several players in the market rather than two as
18 management assume. This is a reasonable reflection of
19 the impact of additional competitors entering the market
20 at a similar time to Ampule."

21 So you believed, did you not -- so this reflects
22 your belief that other competitors, or at least the
23 business's belief, that other competitors would enter
24 the market for Hydrocortisone?

25 A. This does not reflect my view. This was the view of

1 Deloitte. However, I think that we knew from other
2 sources that other people were developing this product
3 at the same time, so we did expect competition on
4 Hydrocortisone in due course, but you never really know
5 when it is going to come.

6 Q. Thank you. Now, Waymade owned the original marketing
7 authorisation so did you understand -- where it says --
8 so even though Waymade had the original marketing
9 authorisation, do you see where it says there:

10 "Products. You can get to market earlier than other
11 suppliers because they own the original marketing
12 authorisation for this product."

13 I am just looking at those words. It is at the end
14 of the second bullet. Do you see that? I am looking at
15 the second risk:

16 "There is a high risk of other new competitors.
17 However, Ampule may be able to get to market earlier
18 than other suppliers because they own the original MA."

19 Did you understand that to be a reference to
20 Amdipharm being the first business to have a 10mg MA
21 apart from Auden?

22 A. "Ampule may be able to get to the market earlier than
23 other suppliers because they own the original MA for
24 this product."

25 I do not actually understand what that means. They

- 1 own an MA. I assume the original MA is the Auden MA.
- 2 Q. I suppose it might be a reference to the 20mg MA, but
- 3 you are not able to help us as to what it means?
- 4 A. No.
- 5 Q. A marketing authorisation is a licence to market
- 6 a medicine, is it not?
- 7 A. Yes.
- 8 Q. And to market a product in the UK you need a marketing
- 9 authorisation from the MHRA?
- 10 A. Yes.
- 11 Q. In order to obtain -- there is an application process,
- 12 is there not, to obtain a marketing authorisation?
- 13 A. There is.
- 14 Q. And that is only something that you can do only once you
- 15 have product which is sufficiently developed for
- 16 validation purposes?
- 17 A. Correct.
- 18 Q. You understood that the 10mg MA was a recent acquisition
- 19 because it had been conferred, had it not, in
- 20 mid September of 2012?
- 21 A. Granted you mean? It had been granted by MHRA.
- 22 Q. Granted is a better word.
- 23 A. Yes.
- 24 Q. So you understood when you were looking at this -- when
- 25 you started looking at this acquisition, you understood

- 1 that it had recently been granted the 10mg MA?
- 2 A. To be honest, I am not 100% sure that I did, because
- 3 there were so many other things that I was taking care
- 4 of at the time, but it is not unreasonable.
- 5 Q. All right, thank you, that is understandable. It is
- 6 a long time ago. Presumably, I think we can take it
- 7 that the plan to launch, which we see in this document,
- 8 the plan to launch was off the back of this new
- 9 marketing authorisation?
- 10 A. Absolutely, yes.
- 11 Q. If we go to page 32 of this document {H/150/32}. So
- 12 there we can see the heading:
- 13 "Management's strategy in the UK is to increase
- 14 prices on generic drugs and debrand selected PPRS drugs
- 15 to enable price increases, in markets with little or no
- 16 competition."
- 17 That is the heading. Hydrocortisone was a generic
- 18 drug, was it not, it was not a PPRS drug?
- 19 A. Yes, that is right.
- 20 Q. The table shows, you see the heading above the table:
- 21 "UK growth products -- key drugs."
- 22 I think it is fair to say these were the products
- 23 which were key to the Amdipharm strategy or portfolio?
- 24 A. Yes.
- 25 Q. So you would have been particularly interested in these

- 1 products as opposed to others?
- 2 A. Yes.
- 3 Q. We see Hydrocortisone in the second row and you can see,
4 I think, if you go across to the fifth column,
5 "Management revenue uplift" it is the second highest
6 revenue uplift in the table, yes?
- 7 A. Yes.
- 8 Q. We can see that this strategy focuses on the 10mg
9 product and it says that Auden is the sole supplier and
10 we see that in the third column under "Competitive
11 Environment"?
- 12 A. Yes.
- 13 Q. Then we see in the next column across the price, which
14 would have been the market price at that time, which was
15 £35 and the volume, which is said to be 160,000 by 2015.
16 But then we see in the final column that there is a high
17 risk of new competitors which would affect market prices
18 and also which would impact market share.
- 19 That follows, does it not, Mr Beighton? So if there
20 are new competitors coming in the market for generic
21 drugs the price tends to drop?
- 22 A. It does, yes.
- 23 Q. I think you would have been aware that the price, the
24 market price for Hydrocortisone that we are seeing here,
25 which was £35 then, had risen significantly since it had

- 1 been debranded in 2008?
- 2 A. Yes.
- 3 Q. If we -- we have seen that -- we see that these
- 4 forecasts here are based on a market price of around £35
- 5 per pack and I think you have already confirmed that
- 6 would have been the market price at that time?
- 7 A. I do not know if it was, but it is kind of familiar.
- 8 Q. That would be the logic of this document?
- 9 A. Yes.
- 10 Q. Now, the due diligence material does not, as far as we
- 11 have seen, refer to any supply agreement with Auden and
- 12 I think that is because the focus at this stage was on
- 13 the launch of a new product; is that right?
- 14 A. Yes, this was what we intended to do with the Amdipharm
- 15 business once we bought it.
- 16 Q. You say in your witness statement that you became aware
- 17 of the deal with Auden around the time that the
- 18 acquisition completed?
- 19 A. Yes.
- 20 Q. Just to confirm, you do not recall being aware of the
- 21 supply agreements before the time of the acquisition
- 22 completing?
- 23 A. No, I was not.
- 24 Q. The acquisition completed on 31 October 2012. That is
- 25 right, is it not?

- 1 A. Yes.
- 2 Q. We know that Cinven did not acquire Waymade's 20mg
3 business, but it did get Waymade's 10mg business as part
4 of the acquisition of Amdipharm?
- 5 A. Correct.
- 6 Q. What that meant was that it inherited the supply
7 agreement with Auden for 10mg tablets, yes?
- 8 A. Yes.
- 9 Q. Amdipharm had not yet transferred -- the MA had not yet
10 been transferred to Amdipharm at that point. It was
11 still with Waymade, yes?
- 12 A. Yes, though I think that Amdipharm was getting the
13 benefit of the sales from that period.
- 14 Q. That is right. I think you explain that in your
15 statement. So from 31 October 2012 proceeds from the
16 sale that were made by Waymade were transferred to
17 Amdipharm so, as you say, they were getting the benefit
18 of the agreement. In effect, would this be fair:
19 Waymade were selling the 10mg agreements in effect as an
20 agent for Amdipharm at that point in time?
- 21 A. Yes.
- 22 Q. And that arrangement continued in that way
23 until May 2013 when the marketing authorisation was
24 formally transferred to Amdipharm?
- 25 A. I am sorry. I was not listening carefully.

- 1 Q. So sorry. I was going fast. So that arrangement of
2 selling as agent continued until May 2013 when the
3 marketing authorisation transferred to Amdipharm, so
4 then it was selling it in its own right?
- 5 A. And then Amdipharm within the AMCo group can sell it in
6 its own right, yes.
- 7 Q. After the acquisition, Cinven merged Mercury and
8 Amdipharm to form a new company and that was called
9 Amdipharm Mercury Company Ltd, which you refer to as
10 AMCo in your statement?
- 11 A. Yes, that is right.
- 12 Q. And you took up the post of chief executive of AMCo that
13 newly formed company?
- 14 A. Yes.
- 15 Q. But you explain that even before that you started to
16 familiarise yourself with the Amdipharm business?
- 17 A. I did.
- 18 Q. Because you had been made responsible, I think, for the
19 integration of the two companies?
- 20 A. Correct.
- 21 Q. You would have paid attention, would you not, to those
22 parts of the business which were key to future growth,
23 like Hydrocortisone?
- 24 A. Yes.
- 25 Q. Presumably during this process you had discussions with

- 1 senior people at Waymade to try and understand the
2 business that you were now taking over?
- 3 A. Yes.
- 4 Q. Including Mr Vijay Patel, who owned and managed Waymade,
5 would you have spoken to him?
- 6 A. Yes.
- 7 Q. You would have also -- there were some people, were
8 there not, who came over from Waymade with Amdipharm and
9 they included Mr Brian McEwan?
- 10 A. Yes.
- 11 Q. And so you would have spoken to him as well about the
12 business?
- 13 A. Yes.
- 14 Q. He was the Amdipharm group's managing director, I think
15 that is right, is it not?
- 16 A. I think that is what he became when he joined in the
17 Amdipharm Mercury Group. I think before that he was
18 working as general manager for either Waymade or
19 Amdipharm. I cannot remember which.
- 20 Q. Thank you, but he had a senior executive position?
- 21 A. He did.
- 22 Q. He continued working for AMCo until the end
23 of April 2014?
- 24 A. Yes.
- 25 Q. Mr McEwan was responsible initially, was he not, for the

- 1 relationship with Auden in relation to the supply of
2 10mg Hydrocortisone?
- 3 A. Yes, that is what Vijay Patel told me.
- 4 Q. And you were made aware of -- when the acquisition was
5 being -- had been completed?
- 6 A. Yes.
- 7 Q. I think it is right, is it not, that Mr McEwan also had
8 oversight of the strategy for the development of AMCo's
9 own 10mg product with Aesica?
- 10 A. He had some influence over it. I think eventually it
11 was transferred to the supply chain team in AMCo.
- 12 Q. But he was involved?
- 13 A. But he was involved, yes, sure.
- 14 Q. So he would have been quite an important port of call
15 for you in understanding this product?
- 16 A. Exactly.
- 17 Q. During this period of familiarising yourself with the
18 Amdipharm business in late 2012, I am looking at now,
19 you also met with Amdipharm's main contract partners,
20 did you not?
- 21 A. Yes, or spoke to them on the phone.
- 22 Q. They included Amit Patel of Auden and I think you met
23 him in November of 2012?
- 24 A. Not sure if I met him then, but we certainly would have
25 had a conversation.

1 Q. That conversation presumably would have included
2 a discussion about the 10mg Hydrocortisone supply
3 agreement?

4 A. I guess so, yes.

5 Q. That would have been the main reasoning to talk to him,
6 would it not?

7 A. Yes.

8 THE PRESIDENT: Just so I understand the quality of your
9 recollection, you do not have an actual recollection.

10 A. I definitely met Amit Patel from Auden. I do not
11 remember the exact dates and whether I met him
12 in November or -- but I met him two or three times
13 during this period and spoke to him on the phone
14 a number of times.

15 MS DEMETRIOU: I think in your witness statement you say you
16 recollect you were introduced to him in November 2012,
17 but I guess that is not being specific as to whether you
18 were introduced to him in person.

19 A. I think on the phone. I do not think I actually met
20 him.

21 Q. You would have known at that time that the supply
22 agreement was profitable for AMCo. I am going to call
23 it AMCo just to avoid getting into terminological
24 issues.

25 A. Okay, yes.

1 Q. You would have understood it was a profitable supply
2 agreement?

3 A. Yes.

4 Q. Now, we have seen that the focus in the due diligence
5 documents was for independent entry with AMCo's own
6 product and, in fact, I think pretty much straightaway,
7 just in terms of the product and the supply agreements,
8 you were involved -- in the autumn you were involved in
9 discussions about the supply agreement with
10 Mr Vijay Patel and Mr McEwan.

11 Let us just look at some of that. I think you have
12 agreed some of that already. But if we go to some of
13 the documents {H/160/1}. This is an email from
14 Brian McEwan to Vijay Patel and it is November 2012:

15 "Brian.

16 "I one to [I do not know - phoned] John Beighton

17 "I told him you are handling Hydrocortisone 10mg
18 with Amit at Auden McKenzie. He was very happy about
19 that. I told him that we will be looking to receive
20 15000 packs per month on a supply agreement."

21 Do you think that was a mistake 15,000? Maybe you
22 are not able to help on that.

23 A. I do not know if it was a mistake.

24 Q. Anyway, we see that?

25 A. This is between Brian and Vijay, is it not? I think

1 this is explaining that Vijay had spoken to me and
2 I think "I one" to John Beighton probably means I spoke
3 to John Beighton and I told him that you were was
4 handling Hydrocortisone with Amit at Auden.

5 Q. So at this stage, I think, as you said before, Mr McEwan
6 was handing the Hydrocortisone relationship with Auden
7 and you were fine about that. That made sense to you?

8 A. Yes, so I cannot remember how Vijay told me. I think
9 maybe he sent me a text message or spoke to me and said
10 that Brian is dealing with -- which was absolutely fine
11 for me.

12 Q. Thank you. If we go to {H/163/1} this might just help
13 us on whether you met or spoke to Mr Patel. I do not
14 think it terribly matters, but just in case it helps.
15 You see further down there is an email from you, do you
16 see, 29 November and it is to Amit Patel, because you
17 can see the email address Auden McKenzie:

18 "Good to speak to you.

19 "As discussed let's you Brian and me meet up asap.

20 I have copied Julie... "

21 Would Julie have been your PA?

22 A. Yes.

23 Q. "To suggest some dates."

24 And then:

25 "Hi John.

1 "Would you now be looking to have this meeting in
2 Basildon?"

3 Presumably that is your PA?

4 A. Yes.

5 Q. And then you have then asked to try and find out when
6 Amit Patel is free in the next week or so?

7 A. Yes.

8 Q. So by this stage you had already spoken presumably on
9 the phone to Amit Patel?

10 A. Yes, so that was the introduction meeting, phone meeting
11 that I had with him.

12 Q. Okay, thank you. If we go to {H/170/1} and if we go to
13 the bottom of the page. This is December and there is
14 an email from Vijay Patel at Waymade to you:

15 "Dear John.

16 "I am taking the liberty to ask you to make sure
17 that the above ... "

18 The "above" presumably being 10mg Hydrocortisone
19 tablets, because that is in the subject line:

20 "...is sorted today, otherwise there will be no
21 stock in January."

22 "He may try and put you off until February."

23 Then we see you say:

24 "Hi Vijay.

25 "Yes, we were meant to meet Amit yesterday but he

1 called in sick. Brian and me are now meeting him first
2 week of January."

3 So you had already presumably had some discussion
4 with Vijay Patel about the issue he is identifying,
5 because there is not much context in the emails?

6 A. Sorry.

7 Q. Presumably this came in a context where you had been
8 having some discussions already with Vijay Patel about
9 these issues, because if you go to the bottom email from
10 him to you, it says:

11 "The above is sorted today".

12 A. Yes, it was referring to the supply agreement on
13 Hydrocortisone, which I knew by this time he had running
14 with Auden McKenzie and I think he thought that maybe
15 Auden McKenzie would cancel the supply agreement because
16 we have changed ownership or -- I do not -- yes.

17 Q. Okay, thank you. It is discussing a meeting. You are
18 saying that you are now going to meet Amit Patel in the
19 first week of January. Do you remember if that meeting
20 went ahead?

21 A. I do not know. There was definitely meetings with Amit.
22 I do not know if it was at that time.

23 Q. But you would -- before meeting him or talking to him
24 about the supply agreement, you would have tried -- you
25 would have sought, would you not, to have understood the

1 relationship between Waymade and Auden by speaking to
2 Mr McEwan?

3 A. Yes.

4 Q. So you would have tried to understand the context from
5 him?

6 A. Yes.

7 Q. Now, you say at paragraph 25 of your witness statement
8 that you were told that the price that had been agreed
9 was £1 per pack, yes?

10 A. Yes.

11 Q. So presumably you were told that, were you, by
12 Mr Vijay Patel or Mr McEwan?

13 A. One or the other, yes.

14 Q. And that would have been presumably around the time of
15 the acquisition when you first learned about the supply
16 deal?

17 A. I do not know when, but it would have been during that
18 period towards the end and the beginning of that year.

19 Q. So you understood then at some point during that period
20 that AMCo got a certain volume of packs from Auden of
21 Hydrocortisone and it paid £1 per pack for them and then
22 it sold them on to its own customers at market price.
23 You understood that?

24 A. Correct.

25 Q. Did they at the same time -- do you remember if they

1 told you about the rebate system where Auden were
2 invoicing at £38 a pack and then paying a rebate of £37
3 a pack back?

4 A. It is funny, because I only actually remembered that
5 when it was raised yesterday. To be honest, I always
6 thought it was just being invoiced at a pound a pack,
7 but I have a vague recollection of that sort of slightly
8 strange rebate arrangement.

9 Q. So does that mean that you probably did know about it at
10 the time?

11 A. Yes, I am sure I did. I am sure I would have done.

12 Q. So you knew what the market price was, more or less,
13 because you had seen that in the due diligence
14 documents. You would have known what the market price
15 was?

16 A. Yes, yes.

17 Q. And so you were aware, were you not, of the scale of the
18 discount that was being given to AMCo?

19 A. Yes.

20 Q. And that as a result you would have known that this was
21 therefore a very valuable supply agreement for AMCo?

22 A. Yes.

23 Q. Did you know that Auden had started supplying the 10mg
24 product to Waymade in July 2011? Did you know that?

25 A. I did not know about the exact date, but I think I knew

- 1 that there was a deal already ongoing where I think
2 2,000 packs were sold to Waymade every month.
- 3 Q. Yes. Let us look at the Decision. If we get that up,
4 the CMA's Decision. So that is {A/12/716}. If we just
5 look at 6.562. Do you see that just above the bottom of
6 the page?
- 7 A. Yes.
- 8 Q. So between July 2011 and September 2012, Waymade
9 purchased an average of 1500 packs per month at the
10 prevailing market rate, which was between £31.50 and
11 £34.50. So at that stage for that period they were
12 paying market price. Did you know that at the time?
- 13 A. No.
- 14 Q. And then what happened was that it was only then
15 in October 2012 that the price went down to £1, which is
16 the price that you had been told about, but you were not
17 aware of that history at the time?
- 18 A. No.
- 19 Q. Now, you understood, did you not, that Auden was
20 supplying pharmaceutical wholesalers directly? It was
21 the only supplier of 10mg Hydrocortisone in the market
22 at that point in time?
- 23 A. Yes.
- 24 Q. And those wholesalers would have been paying market
25 price?

- 1 A. Yes.
- 2 Q. So you would have understood that Auden could have
3 supplied these tablets that it was selling to AMCo
4 direct to the wholesalers instead and received a lot
5 more money for them?
- 6 A. Yes.
- 7 Q. So, to put it simply, if I am Amit Patel at Auden and
8 I can either sell a packet of 10mg tablets to AMCo at 1
9 pound per pack or I can sell them to Alliance at £34
10 a pack, you would imagine you would choose Alliance at
11 £34 a pack?
- 12 A. You would for sure.
- 13 Q. So actually in choosing to sell these volumes to AMCo
14 that translated, did it not, into a substantial loss of
15 profit for Auden? You understood that?
- 16 A. Yes.
- 17 Q. In effect -- you understand that the effect of it was
18 that those profits that Auden was losing it was in
19 effect transferring to AMCo, because it was able to sell
20 the product on at market price to its own customers?
- 21 A. We were.
- 22 Q. When you first became aware of this arrangement, and in
23 particular the price, did you ask Mr McEwan or
24 Mr Vijay Patel why Auden had been prepared to do the
25 deal?

- 1 A. I do not actually remember having that conversation.
2 I assume I did and I assume that Vijay probably would
3 have said I persuaded him to do so. I do not actually
4 specifically remember that conversation.
- 5 Q. So you do not remember a conversation, but you assume
6 that you would have wanted to have understood why Auden
7 was prepared to do this deal?
- 8 A. I wanted to -- I wanted to understand that the deal was
9 going to continue. That was my main --
- 10 Q. Sorry, you would have wanted to understand that the deal
11 was going to continue?
- 12 A. Yes.
- 13 Q. As part of that, would you not have wanted to understand
14 why Auden was prepared to sell -- to enter into such an
15 arrangement where it was losing money and effectively
16 transferring profits to AMCo?
- 17 A. At the time, I was intrigued by it, but, as I said,
18 I did not delve any further. I accepted it on face
19 value from what Vijay had told me that the deal had been
20 done.
- 21 Q. Presumably it would have been obvious to you would it
22 not, that Auden was only offering this price because
23 Amdipharm had a marketing authorisation for a 10mg
24 product?
- 25 A. No, I do not think so. I really did not know why he was

1 doing it. There were some strange things going on at
2 that time in the relationship with that -- between those
3 two companies. There was also another deal which was
4 going the other way on Carbimazole, which looked as if
5 we were kind of doing the same as what Amit Patel was
6 doing with Waymade.

7 Q. So is this the position? Is this right: I think you
8 have accepted already that this was an important product
9 for you?

10 A. Yes.

11 Q. That you would have spoken to Vijay Patel and also to
12 Brian McEwan to try and understand the nature of the
13 supply deal, yes? You knew the price?

14 A. Yes.

15 Q. You understood that the implications of the price were
16 that Auden was losing a lot of money and effectively
17 transferring it to AMCo?

18 A. Yes.

19 Q. But you do not recall asking anyone at the time why they
20 might have decided to do that?

21 A. Now I do not remember having that discussion.

22 Q. It would have been obvious to you, would it not,
23 Mr Beighton, that they were only real willing to do that
24 because they knew you had your own market authorisation?

25 A. No, I do not think so. I do not know what the

1 relationship between Amit and Vijay was, but he
2 persuaded him to do this deal and I took it on face
3 value.

4 Q. Is that normal in your experience for one company to
5 effectively transfer a lot of its profits to another
6 company for nothing in return?

7 A. I thought it was very odd, very odd.

8 Q. You thought it was very odd?

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

12 Q. I would like to show you a transcript of the CMA's
13 interview with Mr McEwan. Let us go to {H/950/1}. Have
14 you -- what have you looked at? Have you been provided
15 with a pack of documents in preparing to give evidence?
16 Have your solicitors given you a pack of documents?

17 A. They have, yes.

18 Q. How many documents? What are we talking about? Lots of
19 files or?

20 A. Lots of files. I have to confess I have not looked at
21 them all, but --

22 Q. Does it include transcripts of CMA interviews?

23 A. I think so, yes.

24 Q. This is an interview of Mr McEwan and if we go to page 9
25 {H/950/9}. Let us have a look from lines 13 onwards.

1 The CMA are there saying that the supply to Waymade of
2 10mg product was market price at that point. That is
3 the point that I just showed you in the CMA Decision, so
4 from July 2011 through to September 2012?

5 A. Yes. Actually, I have seen this fairly recently.

6 Q. Okay, that is helpful. So we can take it more quickly.

7 Then my next question was: do you recollect why it
8 was at that point in time, so prior to 2012, why Waymade
9 was not also receiving a discounted rate for the 10mg
10 but was only receiving it for the 20mg and then the
11 response is:

12 "Because for the 20mg, Auden was supplying the 20mg
13 to Waymade on the basis of it being a contract
14 manufacturer as opposed to Waymade buying from Aesica,
15 or whoever."

16 And then "Okay" and then Mr McEwan:

17 "Until the point that Waymade had a marketing
18 authorisation for the 10mg, then I guess it was just
19 another customer for Auden."

20 So I think we can see what he is saying there, can
21 we not? He is saying that as regards the 10mg product,
22 until it had -- until Waymade had a marketing
23 authorisation for it, it could not -- it did not have
24 its own product. It could not bring its own product to
25 market so it was just another customer and that is why

1 it was being charged market price?

2 A. Oh, I see, yes.

3 Q. But once it had the marketing authorisation, then it had
4 much more leverage, do you see that?

5 A. I can see that is what Brian is saying, yes.

6 Q. Then if we read -- if we look from page -- sorry, if we
7 go over the page:

8 "Until you've got the marketing authorisation, you
9 don't have the choice as to ... you know, to place an
10 order on your own contract manufacturer or to source it
11 elsewhere."

12 And so that is the point he is making, is it not,
13 that when you have got your marketing authorisation, you
14 have got a choice, you can bring in your own product or
15 source it from someone else?

16 A. That is the point he is making, yes.

17 Q. Then if we go to page 13, {H/950/13}, and if we read
18 from line 8, so that is the CMA interviewer saying:

19 "I can see why it's a good deal for Waymade.
20 I suppose, in getting that price, what are you offering
21 to Auden? What does Auden get in return?"

22 Then Mr McEwan:

23 "I guess you'd have to ask them that -- you know,
24 maybe it is dangerous to try to put myself in their
25 shoes."

1 Further down it says, if we carry on -- if we carry
2 on going so you see:

3 "But you are getting a £1 supply price"

4 Then further down the question:

5 "So obviously it has the ability to price at the £34
6 or the £37 [that is the market price] whatever it is at
7 the time, but it's giving you a £1 supply price, so what
8 are you offering?"

9 Then McEwan:

10 "I wasn't offering anything. I was asking if they
11 could supply us and they agreed to."

12 Then he is asked:

13 "Was there a condition attached to getting that?
14 price?"

15 "No, I wanted to get as good a price as possible."

16 "I suppose at that stage you have to tell them that
17 you are now a marketing authorisation holder."

18 "Yes, they can see that. That is in the public
19 domain."

20 Then the question is:

21 "That is different from being a wholesaler, what you
22 were in the past, and you make that part of your
23 negotiations, I guess."

24 "Well, in requesting whether they would supply or
25 not, I would say, you know, I have a licence for this

1 period, I am, you know, looking to come to the market
2 with it. Would you be interested in supplying us?"

3 That is what he is saying. Then if we carry on and
4 at the bottom of the page he says:

5 "And clearly, what -- I mean maybe the inference
6 from me is that, you know, he can supply me or I'll get
7 someone else to supply me. And if he wants to retain
8 the manufacturing volumes, then he might agree to supply
9 me, and you know, we were lucky that he did, because
10 that is before we even got to the indications."

11 Then carrying on:

12 "Would Auden have been aware of the difficulties
13 that you had on the Aesica side?

14 "No."

15 And then:

16 "No, and it would have been foolish of us to tell
17 them."

18 "Yes, so it is basically for Auden a question of
19 either Aesica is going to be the supplier or I am going
20 to be the supplier of Waymade as Auden McKenzie."

21 So then she says:

22 "Well, I do not know if they knew who our potential
23 manufacturer was."

24 So you have seen what he says. Did Mr McEwan tell
25 you that he negotiated with Auden on the basis that he

1 had a licence for the product and was looking to enter
2 into the market with it?

3 A. No, we did not discuss the origin of the deal as it was
4 handed over to me.

5 Q. Did you and Mr McEwan discuss the inference that either
6 Auden could supply -- could make the supply or AMCo
7 could get someone else to supply? Did you discuss this
8 point that Mr McEwan has talked to the CMA about?

9 A. No.

10 Q. Did you and Mr McEwan discuss whether the upside for
11 Auden of this supply arrangement was that it could
12 retain its manufacturing volumes?

13 A. No.

14 Q. Auden would only retain, this is right, is it not, would
15 only retain its manufacturing volumes if someone else
16 did not come into the market such as AMCo?

17 A. Yes.

18 Q. Because it was the incumbent, had 100% of the market?

19 A. Yes.

20 Q. Let us have a look at what Mr Vijay Patel said. This is
21 at {H/1148/1}. Is this a document that you read in
22 preparing to give evidence?

23 A. No.

24 Q. If we go to page 137 {H/1148/137}. Then let us look
25 towards the bottom of the page, so line 25:

1 "So, our understanding from the evidence that
2 Waymade has given us so far is that you get the MA on
3 27 September 2012, and then from October, so a few days
4 afterwards, the supply price under the Auden arrangement
5 drops from market rate, which is about £34 to £1 per
6 pack. Can you explain what the reasons were for that
7 change?"

8 "They gave us the product. Our product would not
9 have come to the market for a further two-three months,
10 because we have just got the licence, right?"

11 "But you are already taking supply before that, so
12 the only thing that changes is the price."

13 And Vijay Patel says:

14 "It is because of the licence and he can see that."

15 And then the CMA say:

16 "Right, so let us unpack that a bit more. So, you
17 have got the licence. How does that enable you to
18 achieve the 90% reduction in price?"

19 "Because as far as he is concerned, I have got the
20 licence and I have got another source. I won't
21 necessarily tell him it will take me six weeks to get
22 it.

23 "So he believes that you will launch?"

24 "Yeah, of course we will launch, of course we will
25 launch."

1 "Hence he reduces your price."

2 You can see what Mr Vijay Patel is saying is the
3 same as what Mr McEwan said?

4 A. I can, yes.

5 Q. So his understanding of this very beneficial
6 advantageous deal is that Auden believes that if they do
7 not provide all this money to AMCo, AMCo will launch its
8 own product. They both thought that?

9 A. So it seems.

10 Q. If we go in the same document to page 139 {H/1148/139},
11 and if we look at line 23, so if we just scroll a bit,
12 please:

13 "But if the understanding on both sides is that you
14 will enter anyway, why would they drop the price to £1?"

15 Then the question:

16 "Why would he drop the price."

17 "They are expecting something in return, presumably
18 ..."

19 "Yes, his volumes would go down, then, eventually.
20 His volumes would start dropping, once we fight him in
21 the market, which we would."

22 Just pausing there, that is in fact what happened,
23 is it not, when there was generic skinny label entry to
24 the market in 2015, Auden's volumes dropped?

25 A. I assume so, yes.

- 1 Q. They must have done, must they not?
- 2 A. Yes, yes, unless somehow they expanded the market, but
3 I do not think it did.
- 4 Q. It was a stable market, was not it?
- 5 A. Yes.
- 6 Q. Mr Patel, Mr Vijay Patel's understanding at the time, we
7 can see from this, was that Auden had offered this very
8 low supply price of £1 per pack to protect its volumes,
9 yes?
- 10 A. Sorry. Could you say that again?
- 11 Q. Yes, that Mr Vijay Patel's understanding at the time was
12 that the reason Auden had offered or was giving this
13 very low supply price of £1 per pack was to protect its
14 volumes, because it knew that otherwise Waymade could
15 enter the market independently?
- 16 A. Yes, well, is that what he said? I think it was that he
17 said because Waymade had got an MA at the time.
- 18 Q. The implication of that being they can enter the market
19 independently, yes?
- 20 A. He says the volumes would go down.
- 21 Q. Yes. Let us go back to the previous page just to look
22 at that again, page 139 {H/1148/139}. We see at the
23 top -- if we go to 137, please. We have just looked at
24 this, but I just want to remind you {H/1148/137}. If we
25 look at the bottom of the page. So our understanding

1 from the evidence that Waymade has given us so far is
2 that you get the MA on 27 September and then
3 from October, the supply price drops.

4 Then he is pressed on why did that happen? Then
5 further down "Let us unpack that". Then Patel says:

6 "Because as far as he is concerned, I have got the
7 licence and I have got another source."

8 What he is saying there is that the reason the
9 supply price was so low is because he knows that
10 otherwise --

11 A. He would go somewhere else.

12 Q. With his own product, because he would go to another
13 contract manufacturer or go to a contract manufacturer,
14 yes. The reason why Mr Patel understood and Mr McEwan
15 understood, we have seen from this, that the reason why
16 Amit Patel was willing to transfer so much money to AMCo
17 was because he did not want that to happen? That is
18 right is it not?

19 MR BREALEY: Sorry, to interrupt. But that is speculating
20 what this gentleman said and asking Mr Beighton to
21 either agree with it or disagree with it. That is not
22 evidence. What Ms Demetriou can say is: was this
23 discussed with him? But to go through an exercise of
24 what does this man mean in an interview is not evidence.

25 THE PRESIDENT: No, I agree.

1 MS DEMETRIOU: Of course, there is no reason we know of why
2 Mr McEwan -- Mr McEwan could have been called presumably
3 and has not been called. We do not have him here.

4 THE PRESIDENT: I anticipate we are going to have a lot of
5 discussion in the course of Closings about the weight
6 that is to be attributed to these transcripts. Contrary
7 to the situation that sometimes pertains, this is
8 a case, it would appear, I will hear what everyone has
9 to say about it, it would appear that parties other than
10 the CMA could have called these people and have not.

11 So that if -- if that is the case then that will
12 affect the weight we attach to these documents. But
13 I do not think it is the time now to have that argument
14 about what we can properly infer or properly not infer
15 from the absence of certain witnesses. But we would
16 certainly encourage all of the counsel team to add that
17 to their list of things that we need to think about in
18 due course.

19 But to set Mr Brealey's mind at rest, we have well
20 in mind that Mr Beighton is not a mind reader and he
21 cannot tell us what Mr Patel meant by what is said in
22 the transcript, beyond incidentally, in terms of the
23 fact that he dealt with him during these transactions.
24 But it is helpful to have this material drawn to our
25 attention and we take it in that spirit.

1 MS DEMETRIOU: Sir, I understand and I am not -- if -- I am
2 not proposing to ask Mr Beighton to mind read, but he is
3 very experienced in the industry and where certain
4 statements are made about protecting volume then it is
5 helpful to understand what Mr Beighton understands by
6 that. I do not think there is anything improper in
7 asking him that.

8 THE PRESIDENT: Yes.

9 MS DEMETRIOU: Mr Beighton, the understanding that
10 Brian McEwan and Mr Vijay Patel appeared to have at the
11 time, which was that it all changed when the marketing
12 authorisation was granted, that is why the price dropped
13 from market price to £1, and that is because the
14 marketing authorisation enabled Waymade to bring its own
15 product on to the market. You understood that at the
16 time too, did you not?

17 A. Oh, no, I wasn't involved at this time.

18 Q. Okay.

19 A. As I said, I inherited this deal and I did not delve
20 into it. I spoke to Mr Sully about it and all the deals
21 that Waymade and Amdipharm had got and he went away and
22 investigated them.

23 Q. Let us look at your witness statement, please,
24 Mr Beighton and let us go to paragraph 23. So that is
25 at {B2/1/9}. Do you want to just remind yourself of

1 what you have said there.

2 A. Remind me of the paragraph.

3 Q. Paragraph 23. (Pause).

4 A. Yes.

5 Q. You describe there the arrangement between Auden and
6 Waymade as an own label supply agreement and then when
7 we look at paragraph 24 you expand on that a bit. You
8 say there that:

9 "[Own label supply] agreements were a relatively
10 common occurrence in the UK pharmaceutical industry at
11 the time, particularly when supply or development issues
12 emerged (as here) and where a manufacturer offered to
13 act as a CMO to other MA-holders in order to keep its
14 own CMO costs of goods down by ensuring higher
15 manufacturing volumes, or where a large pharmacy chain
16 such as Boots wanted supply in its own label livery."

17 Then you say at paragraph 25:

18 "Under this OLS arrangement Waymade had negotiated
19 a price in of £1 ... on a CMO basis."

20 I just want to break all of this down a little bit.

21 So let us start with what you mean by OLS agreement.

22 You give the example of an OLS agreement where a product
23 would be supplied to Boots in its own label livery.

24 Just to be clear, Boots is vertically integrated
25 with Alliance is it not, the pharmaceutical wholesaler?

- 1 A. Yes.
- 2 Q. So you might have a product supplied by, say, Auden to
3 Alliance in Boots livery for onward sale to Boots. They
4 are vertically integrated?
- 5 A. That is an own label supply agreement.
- 6 Q. For Boots that would be Almus branding?
- 7 A. Exactly.
- 8 Q. And that would be an own label supply agreement because
9 the product is supplied to the pharmacy in Boots livery,
10 but Auden did not supply a 10mg Hydrocortisone to AMCo
11 in AMCo livery, did it?
- 12 A. No, and I think that own label supply agreement is
13 generally used as a shorthand for manufacturer to
14 manufacturer deals.
- 15 Q. Is that how you are using it here?
- 16 A. Apart from the example of Boots, but, yes.
- 17 Q. So what you mean is a manufacturer to manufacturer deal?
- 18 A. Yes.
- 19 Q. Just so we are clear about this, the fact that you
20 describe a supply agreement as an own label supply
21 agreement doesn't tell you anything about the price that
22 you can expect for the deal, does it?
- 23 A. No, no, it doesn't.
- 24 THE PRESIDENT: Just to be clear, it doesn't tell you
25 anything about the price, but also it doesn't tell you

1 anything about how it is going to be packaged on your
2 understanding.

3 A. It doesn't, it doesn't, but I said it is from
4 manufacturer to manufacturer or actually probably better
5 to say from IP holder to IP holder, because a lot of
6 these companies including ours use contract
7 manufacturing organisations, but if the deal -- if the
8 OLS agreement is going to go for a long time then you
9 would usually try to get the product in your own
10 packaging because that adds brand value. In this case,
11 which was meant to be a very short term bridging
12 activity, there was probably no point in using --
13 persuading them to put it into our own label.

14 THE PRESIDENT: Would you say -- just so I get my
15 terminology right -- that if you have an OLS arrangement
16 of any duration, own label will mean what it says on the
17 tin?

18 A. Own label, yes.

19 THE PRESIDENT: And you would have a difference,
20 a differentiation between a product of the supplier and
21 product of the purchaser of the supply?

22 A. Yes, sir.

23 MS DEMETRIOU: Thank you, sir. The other thing that you
24 talk about we have seen you talk about in paragraphs 24
25 and 25 of your witness statement are CMO arrangements

1 and CMO, we have established, means contract
2 manufacturing organisation, yes.

3 A. Yes.

4 Q. So in other words, what we are talking about is a third
5 party company that manufactures a product on behalf of
6 the holder of the marketing authorisation?

7 A. Yes.

8 Q. So Tiofarma is a CMO, yes? You might not know.

9 A. I do not know.

10 Q. So Tiofarma was Auden's CMO for the manufacture of
11 Hydrocortisone. So Auden held a marketing authorisation
12 for 10mg Hydrocortisone, yes, and it had a contract with
13 Tiofarma who manufactured those tablets for Auden and
14 that would have been of course in accordance with
15 Auden's marketing authorisation, yes?

16 A. Yes.

17 Q. Then Auden sold those tablets, did it not, to
18 pharmaceutical wholesalers like Alliance?

19 A. Yes.

20 Q. Or perhaps directly to larger pharmacies or hospitals?

21 A. I do not know but definitely they will have sold it to
22 wholesalers.

23 Q. So you have a situation where the CMO Tiofarma
24 manufactures the product for Auden but Auden supplies
25 the product onto the market?

- 1 A. Yes.
- 2 Q. We know that Waymade and then later AMCo also held
3 a marketing authorisation for the 10mg tablets, and the
4 manufacture of 10mg tablets in accordance with the
5 marketing authorisation was done, at around that time
6 was being done by Aesica; that is right, is it not?
- 7 A. Yes.
- 8 Q. So Aesica was AMCo's CMO, yes?
- 9 A. It was.
- 10 Q. And if AMCo had entered the market with the product
11 manufactured by Aesica, it too would have sold that
12 product to pharmaceutical wholesalers, would it not?
- 13 A. Yes.
- 14 Q. That product would have been in competition with the
15 Auden product?
- 16 A. That was the plan, yes.
- 17 Q. So again Aesica is manufacturing the product, supplying
18 it to AMCo and AMCo is then supplying it to the market?
- 19 A. Yes.
- 20 Q. As you say, that is what happened eventually when other
21 generic suppliers entered the market and when AMCo
22 eventually entered the market in 2016?
- 23 A. Yes.
- 24 Q. So it is right then, is it not, that AMCo and the other
25 skinny label entrants when you are looking at 2016 were

1 at the same level of the supply chain, they are
2 competing directly with each other?

3 A. I think so, yes.

4 Q. Before they enter they are potential competitors?

5 A. Yes.

6 Q. So they are all competing to supply 10mg tablets to
7 pharmaceutical wholesalers. I think you said "yes" to
8 that.

9 A. Yes.

10 Q. This is the transcript.

11 What happened under the deal with Auden was that
12 instead of the product going from Tiofarma to Auden to
13 the wholesaler it went from Tiofarma to Auden to AMCo
14 and then to the wholesaler, yes?

15 A. It did, yes.

16 Q. So the move from Auden to AMCo was essentially an
17 unnecessary move, was it not, from Auden's perspective?

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

23 Q. We will come on to that. If we go back to paragraph 24
24 of your witness statement you say that the rationale for
25 an MA holder entering into this kind of arrangement

- 1 would be to keep its own CMO costs of goods down by
2 ensuring higher manufacturing volumes, yes?
- 3 A. Yes.
- 4 Q. And that is based on your experience in the industry?
- 5 A. Yes.
- 6 Q. That is because in general terms asking a CMO to
7 manufacture higher volumes will help the MA holder
8 secure a better price?
- 9 A. Yes.
- 10 Q. It is economies of scale, yes?
- 11 A. Yes.
- 12 Q. But it is not your evidence, is it, that Auden wanted
13 the deal with Waymade and then with AMCo to increase its
14 volumes of 10mg tablets and therefore secure a better
15 price from Tiofarma. That is not your evidence, is it?
- 16 A. I am not saying that, no.
- 17 Q. In fact it would not make sense, would it, because Auden
18 was the only supplier of 10mg tablets so it was
19 supplying the whole market anyway?
- 20 A. Yes.
- 21 Q. So what you are saying is a hypothetical. It does not
22 fit the facts of this case, yes?
- 23 A. Hypothetical? If a manufacturer's volumes drop for
24 whatever reason then probably their costs per unit will
25 go up.

1 Q. But I think you have agreed that that does not fit the
2 fact pattern of this case so that would not have been
3 Auden's interest in supplying this product because it
4 was already supplying the whole market so it did not
5 need to --

6 A. I see. If Tiofarma's volume stays the same, then the
7 costs will stay the same.

8 Q. Yes, so -- sorry --

9 THE PRESIDENT: I think what counsel is putting to you is
10 that what you are here saying whilst it might in other
11 cases hold true is not a sufficient explanation for
12 Auden's conduct in this matter.

13 A. Sorry, for Auden's conduct, no, I agree, sorry.

14 MS DEMETRIOU: So you are unable, are you, to point to any
15 explanation why Auden would have entered into the supply
16 contract?

17 A. (Inaudible).

18 Q. Just a short question, I think I know what the answer is
19 going to be, but we know that Mr McEwan was also
20 responsible when he was at Waymade for negotiating with
21 Auden the 20mg agreement. Did he talk to you about that
22 agreement at the time?

23 A. Not that I remember.

24 Q. I thought it would be a short answer. We can move on.

25 THE PRESIDENT: Are you moving on to a different topic,

1 Ms Demetriou?

2 MS DEMETRIOU: Well --

3 THE PRESIDENT: I appreciate that is a hard question.

4 MS DEMETRIOU: It is quite a hard question, because there

5 are lots of -- I am not leaving the topic of price

6 totally, no, but I am moving on a bit in the chronology.

7 THE PRESIDENT: It is just the reason I ask is -- we have

8 some questions, which I think we ought to put at some

9 point regarding the enquiry or absence of enquiry into

10 the arrangement that existed with Auden and I do not

11 want to cut across any questions that you have got so it

12 is a question of when we put those questions.

13 MS DEMETRIOU: Sir, I think if you would -- it is probably

14 a good time to take a break soon anyway for the

15 shorthand writer. I think, if it is all right, I would

16 quite -- I will have in mind that the Tribunal wants to

17 put those questions, but if it is okay for me to carry

18 on with where I am going first.

19 THE PRESIDENT: Of course.

20 MS DEMETRIOU: Then I think that might be easier for me, if

21 that is all right.

22 THE PRESIDENT: We really do not want to interrupt your

23 flow.

24 MS DEMETRIOU: Okay, such as it is.

25 THE PRESIDENT: Is now a convenient moment to rise?

1 MS DEMETRIOU: It is for me if it is for the Tribunal.

2 THE PRESIDENT: Of course. We will resume then at 20 past

3 3. Thank you very much.

4 (3.11 pm)

5 (A short break)

6 (3.20 pm)

7 MS DEMETRIOU: Mr Beighton, I think when I asked you one of
8 the questions before I misspoke and I think we are on
9 the same page, but just for the transcript I just want
10 to go back to it. So it is transcript page 145, the
11 bottom of the page, and it is when we were talking about
12 the CMO situation and Tiofarma and all of that. We will
13 get there in a minute. So bottom of 145, please. So do
14 you see that I was asking you -- so if we go up a bit.
15 So if Aesica is manufacturing the product, supplying it
16 to AMCo and AMCo is then supplying it to the market and
17 you agree and then "that is what happened when generic
18 entry happened" and then at 21 I say:

19 "So it is right, then, is it not, that AMCo and the
20 other skinny label entrants, when you are looking at
21 2016, were at the same level of the supply chain?"

22 I should have said "as Auden". So at that stage
23 they are all competing at the same level of the supply
24 chain, yes? Shall I take that a bit more slowly?

25 A. Let me just read it again. You have just added "as

1 Auden."

2 Certainly as far as the supply chain at that stage
3 they were at the same level as Auden. I think there was
4 obviously a difference in terms of how they were
5 competing, because Auden was able to offer the full
6 indications, but that is the only difference from
7 a supply chain perspective.

8 Q. So subject to that point about the orphan designation,
9 which we will come to, you accept they were competing
10 with Auden. But you say that the type of competition
11 was a bit different because of the orphan designation,
12 but they were keeping with one another to supply product
13 to the market?

14 A. Yes, I think -- it does skew things a little bit having
15 that orphan indication thing, because it means there is
16 not equal competition. Clearly, Auden have a huge
17 advantage in this situation.

18 Q. Okay. So let me accept, for the time being -- I am
19 going to come on to talk about this -- but let us accept
20 for the minute that the competition is not equal. So
21 I am accepting that bit, but, subject to that, so
22 accepting that, you agree that they are competing with
23 Auden?

24 A. Yes, the prescriptions that Alissa and maybe now Advanz
25 are taking are and AMCo is taking, they are taking from

1 Auden.

2 Q. And before the skinny label entrants come on to the
3 market, they are potential competitors with Auden? You
4 would accept that I think it follows?

5 A. For those specific indications, yes.

6 Q. We will come on to talk about that later?

7 A. Yes, but it is kind of my point. For those indications,
8 those products, that is all those produces are able to
9 compete in.

10 Q. So you are saying that the competition was inhibited
11 because of the skinny label, but they were, nonetheless,
12 competing?

13 A. They were taking --

14 Q. Market share?

15 A. -- prescriptions from Auden, yes.

16 Q. Okay. Thank you. That is helpful.

17 Now, I want to go to {H/919/1}. I want to look at
18 the first page first, because it sets out how -- I am
19 going to go to another page further down in a minute,
20 but it sets out how this is shown. It is data provided
21 to the CMA by Auden, okay. So it is not data you
22 provided, but I just want to ask you to look at it.

23 It is data provided by Auden on sales of
24 Hydrocortisone to Amdipharm and Waymade in that period
25 that you can see above, January 2007 to June 2010, and

1 then different periods -- there are then different
2 periods which are then set out for the boxes underneath.
3 Do you see how it works?

4 What I want to be looking at in a minute is the
5 sales volume of 10mg, the 10mg product. So if you just
6 look at the first box, because all the boxes are
7 structured in the same way, it is the fourth row down
8 after the date.

9 In fact, let us look at -- so there is nothing in
10 that box, but that is where it would appear, yes? It is
11 the fourth row we are looking at under the date and if
12 you read across, that is the monthly sales volume for
13 10mg. Do you see how it works?

14 I am going to take you to another date at the
15 moment, but I just want you to see, because they do not
16 have the headings, the other boxes, so I want you to see
17 how it is put together.

18 If we go to page 5 {H/919/5}, we can see there the
19 dates, the numbers for late 2012 and early 2013, yes,
20 and if we take the fourth row down under the date, those
21 are the monthly sales volumes for the 10mg product,
22 okay?

23 A. Starting 3,000, 2,000?

24 Q. Exactly that.

25 A. Yes.

1 Q. So when you look at October 2012, which is when you
2 first became involved, yes, it is 2,000 and reading
3 across to December it is 2,000. Then in January we see
4 it is 7,000 packs and then we have got February, March
5 and April, it is 6,000 packs for each of those months?

6 A. Yes.

7 Q. That is because -- so what happened in January is that
8 you were able to renegotiate or rather AMCo was able to
9 renegotiate higher volumes with Amit Patel
10 from January 2013. That is right, is it not?

11 A. Yes.

12 Q. Now, there is not any written record of that negotiation
13 at all in all of the documents that the CMA found, but
14 you were involved in it personally, were you not?

15 A. I do not know. I cannot -- I do not think I was.
16 I definitely was involved in the negotiation for the
17 higher volumes later on, but I think that this must have
18 been managed by Brian, Brian McEwan.

19 Q. Let us just go back to -- we have seen it already, but
20 let us go back to {H/170/1}. This is the email that we
21 have seen already from Vijay Patel and he is saying --
22 you see at the bottom of the page:

23 "Dear John.

24 "I am asking you to make sure that the above is
25 sorted today, otherwise there will be no stock

1 in January."

2 That is in December 2012?

3 A. Yes.

4 Q. What you are being asked is to sort out the situation
5 because the concern was that Auden might not continue to
6 supply the 10mg product?

7 A. Yes.

8 Q. So you were aware of the concern, because you were
9 obviously aware about it?

10 A. And it seems from another document you showed me that we
11 were expecting to get 15,000 packs as well.

12 Q. You had been planning to meet Amit Patel to sort it out?

13 A. Yes.

14 Q. Then we see he called in sick and you were planning to
15 meet him in the first week of January instead. We see
16 that from this. We have seen from the data we just
17 looked at from January, indeed, Auden did start to
18 supply three times as many packs as before, so it jumped
19 from 2,000 to 6,000?

20 A. Correct.

21 Q. That was presumably agreed when you and Mr McEwan met
22 Mr Patel in January, it must have been, must it not?

23 A. I do not know. Really, I do not actually remember the
24 event. I was obviously aware of discussions going on,
25 but I do not think that I had them myself with Mr Patel.

1 Q. But there is no reason that -- you say here that you
2 meant to meet him and he called in sick and that you
3 were rearranging the meeting. You do not recall whether
4 you did or did not meet him?

5 A. No, I do not.

6 Q. But --

7 A. In fact, I have a recollection that I wasn't involved in
8 those discussions. I have a very clear recollection of
9 discussions on the second deal and the higher volumes,
10 but not on this.

11 Q. Is that because your recollection is hazy as to that
12 period generally?

13 A. It definitely is, but -- yes, I just do not remember.

14 THE PRESIDENT: When you say the second deal, Mr Beighton?

15 A. The second contract.

16 THE PRESIDENT: It is the first written contract or have
17 I got that.

18 A. This is the first written contract volumes. What
19 I really mean in my head is when we moved from 6,000
20 packs to 12,000 packs and the discussions that I had
21 with Mr Patel at that point.

22 MS DEMETRIOU: But you would have been -- so even if you
23 were not directly involved, you would have been told,
24 would you not, that the volumes had gone up from 2,000
25 packs to 6,000 packs?

- 1 A. Yes.
- 2 Q. We have already agreed, have we not, that Auden was
3 better off selling its 10mg product to wholesale
4 customers rather than to AMCo?
- 5 A. Yes.
- 6 Q. So this increase, threefold increase in the supply, was
7 obviously contrary to Auden's commercial interest, was
8 it not?
- 9 A. Look, I think I have suggested this before. If I had
10 been Mr Patel, I would not have done this, but he did.
11 It was an arrangement, as you can see from previous
12 documents, that somehow Vijay had persuaded Amit to do
13 this deal. We inherited it. As I think I have said,
14 I asked Mr Sully to investigate, to check that
15 everything was okay with it and we just continued with
16 it.
- 17 Q. So you inherited the deal, but then at this stage you
18 are very much in charge, are you not, Mr Beighton? This
19 is the stage where the deal is under your watch?
- 20 A. Yes.
- 21 Q. And it has increased from 2,000 to 6,000 packs?
- 22 A. Yes.
- 23 Q. So at this point you must have been addressing your mind
24 to why on earth Auden would agree to something like
25 this, no?

1 A. I think I was actually in charge later on in March when
2 AMCo was formed, but I did have some involvement at that
3 time.

4 Q. You say in your witness statement that you were in
5 charge of integrating the two companies and that you
6 were aware of this supply agreement?

7 A. Yes, no, no, that is true. Absolutely true I was --
8 I knew about most things that were going on at that
9 time.

10 Q. But we can also see, can we not, from this email from
11 Vijay Patel that you are directly involved on the
12 ground, as it were, because he is asking you to sort out
13 the supply issue today?

14 A. He asked me to. Whether I actually was or not, I do not
15 know, because I definitely was relying on Brian McEwan
16 at this stage. This is not to say I did not meet
17 Amit Patel at some stage, because I did on two or three
18 occasions, but I do not remember specifically discussing
19 6,000 packs.

20 Q. But you would have been -- so you were being asked to
21 make sure it was sorted so you would not have ignored
22 that instruction, you would have made sure it was
23 sorted, would not you? Whether you were doing it
24 personally or whether you were making Mr McEwan was did?

25 A. I think Vijay would have called it a request rather than

- 1 an instruction.
- 2 Q. But you were not someone who would just ignore
3 a request, particularly when there was a risk of losing
4 a very lucrative supply deal?
- 5 A. No, no, for sure. But then it is also true, which is
6 probably why I cannot remember specifics of this period,
7 there was loads going on. We were integrating two
8 companies. I definitely had many other things to think
9 about at this time, some of which were preying on my
10 mind more than this.
- 11 Q. Although Hydrocortisone, you have accepted, was an
12 important product, so you would have been focusing on
13 that as well?
- 14 A. Sure, it was an important product, whether I was
15 focusing is another matter.
- 16 Q. Let us put it --
- 17 A. I am not trying to get away from taking responsibility
18 for this by the way. It is just, as I have said, there
19 was a lot going on at this time.
- 20 Q. Let me ask you this: so you would have known at the time
21 that the issue had been -- the issue that Mr Patel
22 raised was sorted and in fact sorted in a very
23 beneficial way for AMCo, because of the threefold
24 increase in volumes, yes?
- 25 A. Yes.

- 1 Q. So even if you didn't take part in the negotiation
2 yourself, you would have known that Mr McEwan had
3 negotiated that increase in volumes?
- 4 A. Yes, yes, sure, yes, I mean, it was -- it looks as if we
5 then continued to buy these 6,000 packs a month until
6 the increase.
- 7 Q. Mr Beighton, the way that a negotiation works is that
8 there is give and take, that is right, is it not? There
9 is give and take in a negotiation. So Mr Amit Patel
10 would have needed some advantage to him, would he not,
11 to agree to a threefold increase in the volumes?
- 12 A. You know it is a funny thing, my experience of working
13 with Mr Patel was that -- sometimes you just asked and
14 he said yes. You know, and that it was not a classic
15 negotiation where you are horse-trading and --
- 16 Q. Mr Beighton, I can understand that might be true of some
17 things, but here he was giving away a huge amount of his
18 profit to AMCo?
- 19 A. As I have said before, it is not something that I would
20 have done.
- 21 Q. He is not a man that had some kind of death wish, was
22 he? I mean he was an intelligent man who was experience
23 indeed the industry?
- 24 A. It is interesting because if you look at it -- you use
25 the word "death wish" which is a bit extreme -- but if

1 you look at this thing and if what the CMA is asserting
2 is that somehow we had gone into some pay for delay
3 discussion, it really kind of does not make sense to me
4 or to him, because he is supplying me with 6,000 packs
5 per month for a bridging period and, as counsel rightly
6 says, he is effectively losing that money himself and
7 I am developing and getting ready to launch my
8 competitive product, which will not be 6,000 packs
9 a month, it will be -- the market I think was something
10 like 80,000 or on that -- so I would have been able to
11 launch 40,000 packs a month.

12 So the whole premise of this case just does not make
13 sense. It -- why would I -- why would I accept any
14 delay to my product for this measly amount of stock?
15 Albeit he is -- what is in his head I really do not
16 know, but --

17 Q. Mr Beighton, I want to ask you what -- Mr Sully
18 yesterday speculated as to what might have been in
19 Mr Patel's head so he had various things that he shared
20 with us. Are you saying that you just did not give it
21 any thought at all?

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

1 Q. When you say you gave it thought, what you would have
2 thought at the time was that the reason that Mr Patel
3 was willing to do this was because he was concerned that
4 if he did not, you would enter the market with your own
5 product because you had an MA?

6 A. No, I actually think that he was making a terrible
7 mistake, because of the reasons I have just explained.
8 Because even though we had an MA, we had not launched.
9 We obviously would have launched when we had the MA.
10 Why on earth -- I guess this is -- it was an OLS
11 agreement. It was typical in that sense, but, as I have
12 said, it is not something I would have done.

13 Q. Typical in what sense?

14 A. That it was own label supply, generic companies
15 supplying each other. It is a done thing.

16 Q. We have established it is not -- that it is not typical,
17 right, because he was not doing it to increase the
18 volumes that he was able to get from his own --

19 A. No, it is slightly less typical, which is why -- I am
20 sorry. I did not want to repeat myself, but I actually
21 think that -- sorry, sir, I actually think that Mr Patel
22 made a mistake in doing this deal with us in hindsight.
23 I did not particularly think too much of it at the time.

24 Q. But when you did give it some thought at the time --
25 I know you are saying now you think it was a mistake on

1 his part, but when you did give it some thought at the
2 time, you would have known, would you not, that the
3 reason he was doing this was because he knew you had an
4 MA and could launch a product?

5 A. No, my point is, why would that make any difference?

6 Q. Mr Beighton, it would make a difference, would it not,
7 because as soon as there is generic entry into the
8 market, prices would collapse so this is a way of
9 keeping -- for Auden to keep volumes and to keep prices
10 high?

11 A. Yes, but unless he thinks I am completely bonkers, why
12 would I not launch my product as soon as I got access to
13 40,000 packs a month? I promise you that the economics
14 of this I would have -- are hugely in favour of
15 launching my own product.

16 Q. Mr Beighton, we will take that in -- we will come on to
17 that. I want to take that in sequence, because we will
18 look at whether the economics would have been beneficial
19 for you in launching your own product a little bit
20 later.

21 What I want to do is go back to the document showing
22 the volumes, so {H/919/6}. What we can see here, so
23 this is the next page, and what we can see here is that
24 Auden continued to supply 6,000 packs per month on
25 average at 1 pound per pack through 2013 and the early

1 part of 2014. What you see there is you see sometimes
2 it is 12,000, but then for the previous month there is
3 nothing and so that explains -- so what you have is
4 6,000 a month, but for June 2013, for example, you have
5 12,000 and there is nothing for May, so that is an
6 average of 6,000. Then you see the same in September
7 and October, yes?

8 A. Yes. I assume these numbers -- you say they come from
9 Auden. They have been rounded somehow, because I do not
10 think we got exactly these amounts every month.

11 Q. Why do you say that?

12 A. My memory is that there was slightly less than 6,000,
13 slightly more.

14 Q. Is there --

15 A. Not that it matters, but this was the sort of general.

16 Q. This is their data?

17 A. Okay.

18 Q. Then what we see is?

19 A. I guess we can check our data as well. That will
20 presumably correspond.

21 Q. Then we see -- in 2014 we see 12,000 packs, if we go on
22 to the next page, please {H/919/7}. We see it is 6,000
23 in January 14, 6,000 in February, 6,000 in March and
24 then it goes up to 12,000?

25 A. Yes.

1 Q. Nothing in May and then a sustained supply of 12,000
2 from June 2014 and then you also see that the price is
3 higher, so it is a higher price from July.

4 I am going to come back to this, but just to
5 clarify. That is after the deal was renegotiated,
6 correct?

7 A. Yes, that will be why the 12,000 -- and you can see
8 these numbers are rounded, because it was not £2 a pack.

9 Q. Then if we go to the Decision again at {A/12/711} and
10 6.552. This says that:

11 "Auden paid Waymade around 70,000
12 during October 2012, and AMCo around £20.6 million over
13 the three and a half years between 31 October 2012 and
14 24 June 2016 by way of heavily discounted supplies of
15 10mg Hydrocortisone tablets."

16 That by any measure is a very large sum of money,
17 20.6 million, that Auden paid AMCo. You understand that
18 that is the amount that was transferred under this
19 supply deal?

20 A. I understand these numbers. I do not agree with what
21 they are suggesting from this that we were somehow paid.

22 THE PRESIDENT: I think what you are getting is a foretaste
23 for the submissions that counsel will be making in
24 Closing. So what is being put, is that there was a pay
25 for delay and pay, therefore, is the appropriate verb to

1 use, but I anticipate, and do correct me if I am wrong,
2 I anticipate that you would say, no, you made a profit
3 at Auden's expense, because they sold to you for a low
4 price that which you then sold at a much higher price,
5 which Auden could have done itself.

6 A. Thank you. That is -- yes, I would say that.

7 MS DEMETRIOU: But your evidence is this, is it: that
8 despite Auden agreeing to forego £20.6 million worth of
9 profit and instead let you earn that money from its
10 product, you did not give any real thought to why they
11 might want to do it. That is your evidence to the
12 Tribunal, is it?

13 A. That is my evidence and my evidence is also that this,
14 whatever the number we made in profit from
15 Hydrocortisone, would have been hugely exceeded by
16 launching our own product with our own lower costs of
17 goods and our own unlimited supply.

18 Q. We will have a look at that when we come to it. We will
19 have a look at what actually happened when you entered
20 the market and whether you succeeded.

21 I want to ask you now about -- the 6,000 packs, so
22 going back to the 6,000 packs which was agreed
23 in January 2013, that was recorded in a written
24 agreement. Do you remember that?

25 A. Yes.

1 Q. You were in court when we looked at this yesterday, but
2 you probably did not have a screen in front of you?

3 A. I did not have a screen, but I got the gist of it.

4 Q. Let us just pull it up again. So it is the first
5 written agreement at {H/172/1}. If we go to page 21
6 {H/172/21}. That is the schedule that sets out
7 the price and the volume, yes?

8 A. Yes.

9 Q. The purpose of this agreement was to record the volumes
10 that had actually been supplied since 1 January 2012,
11 because it was a retrospective agreement, yes?

12 A. Yes.

13 Q. You understood, did you not, that when this agreement
14 had been reached in January 2013, the 6,000 packs --
15 I am sorry. I think I said January 2012. It
16 is January 2013. You understood, did you not, that
17 6,000 packs, once that had been agreed that it was
18 highly, highly unlikely, that Auden was going to sell
19 you more than 6,000, yes?

20 A. Yes, as Mr Sully explained this morning. However,
21 I think on a number of occasions our supply chain team
22 did try to order more and we got 6,000 packs.

23 Q. You were not successful?

24 A. We were not successful.

25 Q. That is because they were making a loss, yes, on those

- 1 products?
- 2 A. I do not know why. I really do not know why, but
- 3 I did not expect to ...
- 4 Q. Let us think about why you did not expect it. You did
- 5 not expect it because Auden, in selling you those 6,000
- 6 packs for £1 a pack, was losing out on a lot of profit
- 7 it would have made if it had sold them at £34 a pack to
- 8 the market?
- 9 A. Those things are in Auden's mind. Look, we wanted more
- 10 than 6,000 packs, as Mr Sully explained this morning.
- 11 We would have wanted, as I have said earlier, 40,000
- 12 packs a month, but this was the amount that we were able
- 13 to negotiate.
- 14 Q. When you say that is in Auden's mind, but I did not know
- 15 anything about it, I mean, that cannot be right, can it,
- 16 Mr Beighton?
- 17 A. It is absolutely right. I have no idea what was in that
- 18 man's mind.
- 19 Q. But you would have tried to understand, would you not,
- 20 because if you are trying to negotiate with someone and
- 21 you are asking for more product, you would want to know
- 22 what is driving them, would you not? You do not
- 23 negotiate in a vacuum.
- 24 A. As I have said previously, this particular deal was set
- 25 up by Vijay. When I came to negotiate the new volumes

1 for the second supply agreement, which he asked for,
2 I asked him for more and he gave me more.

3 Q. All right. Let us go to H -- we have seen this as well
4 with Mr Sully. Let us go to {H/368/1}. This is the
5 recommendation for board approval. You have probably
6 heard the discussion about page 3, the rationale. So
7 let us get that up {H/368/3}. The Aesica product -- so
8 this is board approval for development and supply of the
9 Aesica product, yes, and the launch date is at that
10 point expected to be April 2014. Do you see that?

11 A. Yes.

12 Q. Then the rationale is that it is a:

13 "Back-up product to ensure continuity of supply in
14 case our existing distribution agreement with
15 Auden McKenzie for Hydrocortisone is not renewed. Also
16 more beneficial to be the IP owner ..."

17 You can see it is right -- just in terms of the
18 chronology, it is right that at this point in time you
19 did not have any confidence that there would be
20 a further supply deal. That is correct, is it not?

21 A. From Auden McKenzie?

22 Q. Yes.

23 A. Yes, we did not have full confidence -- in fact, from
24 week to week, month to month, I did not have confidence
25 that we were going to get product delivered.

1 Q. You say in your witness statement that the Aesica
2 product was not a back up, but that is not how you saw
3 it at the time, was it, because we can see that here,
4 that the rationale was that it was a back up in case the
5 supply contract falls through?

6 A. No, that is not what I wrote. I did not write that it
7 was a back up product. This was submitted by somebody
8 else in the team. This product was the key product, as
9 I have said -- explained earlier. Instead of the 6,000,
10 we would have been able to sell 40,000 packs.

11 Q. Mr Beighton, you would have seen this document, would
12 you, before the board?

13 A. Yes, and actually the term back up at that time, if I
14 had thought it was a back up product, it would not have
15 had the implications that we are trying to understand
16 now. It was -- the reason it was called a back up
17 product then is we -- sorry, the reason that this person
18 described it as a back up, I am assuming, is that we
19 already had a product on the market, even though this
20 was the one that was the prime product that we wanted to
21 launch.

22 Q. Mr Beighton, the reason why suddenly this was going to
23 the board was because your negotiations were not going
24 very well with Auden. You thought you were not going to
25 get a supply agreement and so let us push the Aesica

1 product forward. That is right, is it not?

2 A. We had pushed this product forward for -- we never
3 stopped pushing this product forward for the -- I mean,
4 again, the reason we wanted this product is that we
5 would get more volume. Not the only reason, but there
6 were many reasons why we would want this product instead
7 of the Auden McKenzie distribution deal, not least we
8 would be making more money on an ongoing basis, but we
9 would be launching a product with our own IP and then
10 being able to prove -- if you think about this, if we
11 had at some point, which we were considering at some
12 time, to sell the business, if we had got a very flimsy
13 unreliable distribution deal, then you would not get the
14 value for that from a prospective buyer.

15 If you have got your own product with your own sales
16 with a CMO that is under your own control, that product
17 would be given much more value by a potential buyer.
18 A number of different reasons -- and including some of
19 the reasons that Mr Sully explained this morning or
20 earlier this afternoon --- just complete control over
21 your own product is worth a lot.

22 Q. Mr Beighton, let us go to {H/831/1}. This is a document
23 from later on. These are messages between Mr Thornton
24 and Karl Belk and Mr Thornton was the director of global
25 quality, was he not, at AMCo?

1 A. He was.

2 Q. And Mr Belk was your COO was he not?

3 A. He was.

4 Q. So they are both two very senior employees, yes?

5 A. Yes.

6 Q. And they have been involved in the project for a long
7 time?

8 A. The product -- the Aesica product.

9 Q. Yes, for a long time, yes?

10 A. Yes.

11 Q. If you look down the page, read the middle of the page:
12 "That is correct. Ours ... "
13 So Nick Thornton:
14 "Thought we may have said not to release ours while
15 still selling Auden stock???"
16 "That's correct. Ours has always been merely a back
17 up until now."
18 We can see that is what was being said then and we
19 know that both Mr Thornton and Mr Belk are involved in
20 the project in 2014. Let us have a look at H --
21 A. Sorry. Before you do that, can I just read this.
22 (Pause). This is 2016.
23 Q. That is right. But what he is saying is that our
24 product, the Aesica product, has always been merely
25 a back up until now?

1 A. Sorry, where does he say that?

2 Q. In the middle of the page. That is Mr Belk.

3 A. Okay, well --

4 Q. So you are saying -- you are disagreeing with him, are
5 you?

6 A. Absolutely.

7 Q. Is Mr Belk still employed by Advanz?

8 A. Yes.

9 Q. So there is no reason that you know of why he could not
10 have come to give evidence to the Tribunal on this?

11 A. I do not even know that -- no.

12 Q. Not that you know of?

13 A. There is no reason why he could not give evidence.

14 Q. If we go to {H/302/1}. We are back in January 2014. Do
15 you see that is an email from Mr Clark and both Mr Belk
16 and Mr Thornton are in copy, as are you. Do you see
17 that at the top?

18 A. From Guy Clark.

19 Q. Just have a look at the top. It is from Guy Clark,
20 2 January 2014 and it is sent to Nicky Pattrick and
21 Nick Thornton and Mr Belk and you are in copy along with
22 Mr McEwan?

23 A. Yes.

24 Q. This says again:

25 "We need to be in a place to be able to supply the

1 market ASAP in the event that other supply sources fail
2 us, for whatever reason."

3 Again, what they are saying there is that we need to
4 be in a position to launch Aesica in case our Auden
5 supply fails us. That is what they are saying?

6 A. We are jumping about a bit here. This is now 2014. So
7 we are two years before the last document you showed me,
8 yes.

9 Q. Yes. This is back in January 2014. I showed you the
10 2016 message where they said:

11 "This has always been a back-up option."

12 We have got the same people copied in on this email
13 from Mr Clark and he says that:

14 "We need to be able to supply the market ASAP in the
15 event that other supply sources fail us."

16 What he is saying is we need to be able to supply
17 the market with our own Aesica product in case the
18 supply agreement fails us, yes?

19 A. Well, that and other reasons, but I guess there was --
20 there must have been at that time a fear that we were
21 not even going to get any stock.

22 Q. If we look at what is in red, I do not know who added
23 that in red, we see --

24 A. Guy.

25 Q. "Your teams' full support" -- would you have added that?

- 1 A. No, Guy, he just changed the font.
- 2 Q. So he is emphasising it and that is why it is in red.
- 3 A. Yes.
- 4 Q. "Your teams' full support to help get this ready for
5 market ASAP would be much appreciated. It's a very
6 important product to protect in our 2014 budget plan,
7 and there is real risk around continuity of supply from
8 the current source (Auden McKenzie), so we need to be
9 able to supply the market as quickly as we can."
- 10 So when I asked you a moment ago, I asked you
11 whether or not this product was being pushed forward
12 because you were concerned the supply agreement would
13 not be renewed and you said, no, no, we were always
14 trying to push it forward?
- 15 A. Yes, we were.
- 16 Q. Do you agree, looking at this, that actually there was
17 a relationship -- that the fact that the negotiations
18 were not going well on the supply agreement was really
19 what caused you to push the Aesica product forward?
- 20 A. This is Guy's opinion at the time and he probably knew
21 that we were potentially struggling with the supply
22 agreement, but I do not want to repeat myself again. It
23 was really important that we got this product for
24 financial reasons.
- 25 Q. So you disagree with Mr Belk who said it was always

1 a back up product and you disagree with Mr Clark, yes?

2 A. I disagree with Mr Belk that it was always a back up
3 product. I do not disagree with Mr Clark trying to
4 chivvy people along to get this product launched.

5 Q. But you disagree with the connection he is making, do
6 you, between the supply agreement perhaps drying up and
7 the need to get the Aesica product --

8 A. I do not even disagree with that. If there is a supply
9 agreement that is about to expire and we are not going
10 to be able to sell 12,000 packs, it adds even more
11 urgency to this.

12 Q. So you would accept that this was pursued with more
13 urgency, because the supply agreement might be about to
14 dry up?

15 A. No, I think -- I do not want you to put words in my
16 mouth. This was a very important project to the
17 organisation and it strikes me that it was very -- it
18 was important all the time, but at this particular time
19 it became even more important.

20 Q. So it became even more important at this particular
21 time. Okay. Going back to these negotiations at the
22 end of 2013, beginning of 2014, you explain at
23 paragraph 49 of your witness statement that Amit Patel
24 at Auden was keen for AMCo or for Cinven, I guess, to
25 buy Auden from him at that point, yes?

- 1 A. Yes.
- 2 Q. What you decided to do was to show interest in acquiring
3 Auden whilst trying to agree a supply agreement?
- 4 A. Yes.
- 5 Q. But in fact, Cinven was not interested in buying Auden.
6 That is right, is it not?
- 7 A. That is not strictly true. There was -- we were
8 intrigued by the business and we did actually start out
9 with a very serious plan to acquire it. It was kind
10 of -- it had a range of products as well as
11 Hydrocortisone that were just in our sweet spot, so we
12 started seriously. We lost interest when we realised
13 that effectively the company was very concentrated in
14 that one product, but we kept the discussions going.
- 15 Q. Would it be fair -- that is a helpful clarification,
16 Mr Beighton. Would it be fair to say then that by the
17 time you got to very early January 2014 you were clear,
18 or Cinven was clear, that it did not in fact want to buy
19 Auden, but you kept the impression you might in order to
20 get the supply deal over the line?
- 21 A. Yes, to be fair, I do not want to put -- particularly
22 put any of this on Cinven, because they usually would
23 respond to our recommendations. I do not think we will
24 have told them that we were having these discussions
25 with Auden McKenzie, but I do not think we ever put

1 a recommendation to them to --

2 Q. That is a fair point. Let us keep Cinven out of it.

3 A. Yes.

4 Q. Just in terms of the chronology, because I think you are

5 agreeing with me that, as far as you were concerned,

6 when it came to very early January, by that stage you

7 were not really interested in buying Auden?

8 A. That is right.

9 Q. But you did not want to tell them that, because you

10 wanted to get this supply deal over the line?

11 A. That was one reason, yes.

12 Q. Let us go to {IR-H/303/4}. Actually, let us start at

13 the bottom of page 3, very bottom, {IR-H/303/3}. Do you

14 see that it says "from Guy"? I just want to show you

15 who the email is from so I am going to look at the

16 email. At the bottom it says "From Guy Clark to

17 John Beighton, 2 January", yes?

18 A. Yes.

19 Q. That is the email I am going to show you on page 4.

20 So what Guy Clark says to you -- he was, we have

21 established, the chief strategy officer, and he says:

22 "FYI ... Amit seems keen to push this through, for

23 some reason. How far do we continue to dig on this,

24 when we have other realistic projects to look at? Brian

25 was supposed to have the supply agreement finalised by

1 now. Need to discuss/agree how we we push ahead on this
2 one.

3 "Rob - how likely is that we will get the agreement
4 signed? Why would he sign an agreement when he is
5 thinking he's going to sell the whole product.

6 "My worry about buying it (if we were thinking about
7 it) is that we could be preparing a generic in the
8 background and we couldn't keep him on a noncompete for
9 long enough, and he has enough other people that he
10 could use as a vehicle anyway."

11 So there Mr Clark is saying to you that he has
12 a worry about buying Auden, which is that Mr Patel could
13 be preparing generic entry of his own, yes?

14 A. Yes.

15 Q. Then if we go to page 3, {IR-H/303/3}, we see your
16 response. So you say:

17 "We aren't thinking of buying it."

18 So this accords with what you just told me just now
19 that by this stage you had lost entry, you did not have
20 interest:

21 "I think that thing is a big risk for us and if
22 I were him I would him to ... off and stop supplying us.
23 I really wish we could find a way to put our own product
24 on the market even without the indication. Trouble is I
25 bet loads of people are trying to get on to the market

1 too."

2 If we look at the response from Mr Clark. He says
3 in the first paragraph he says:

4 "Having spoken to Brian we need to look interested
5 to close the deal."

6 Then if we look at the next paragraph:

7 "Brian asked for the information that Amit had sent,
8 but I said that Rob had suggested it was more
9 appropriate and compliant if we keep Chinese walls for
10 now. He also said that we need to get our back-up
11 option moving, which has been a bit of a ham fisted
12 effort to date, and I have just asked Nicky to chase
13 up."

14 The back up option that he is referring to, that is
15 the Aesica project, that is what that must mean, yes?

16 A. Yes, I assume that is what he means.

17 Q. So that is another reference to it being another person
18 so Mr Clark --

19 A. The same person.

20 Q. So Mr Clark, Mr Belk and Mr Thornton, we have got three
21 now?

22 A. I do not think Mr Thornton was there.

23 Q. He was. He was in the text exchange?

24 A. He was in the text exchange, but he did not refer to it
25 as a back up.

- 1 Q. We see here that AMCo wants to get the project moving,
2 so Aesica, he says "has been a bit of a ham fisted
3 effort to date". The reason he is telling you "we need
4 to get it moving" is because you were concerned about
5 the situation with Auden and the fact you might not be
6 able to get the supply deal done, yes?
- 7 A. Sorry. Can you just slow down a bit. What did you say?
- 8 Q. Yes. So here Mr Clark is saying to you, "we need to get
9 the Aesica project moving" and the reason he is saying
10 that --
- 11 A. Where is he saying that?
- 12 Q. If we look at the second paragraph, he says:
13 "We need to get our back up option moving, which has
14 been a bit of a ham fisted effort to date".
15 So he is saying the Aesica project has been a "ham
16 fisted effort to date", but we need to get it "moving"
17 and the reason, I am putting to you, that he says we
18 need to get this ""ham fisted"" effort moving" is
19 because everyone is concerned that Auden is not going to
20 do the supply deal. That is correct?
- 21 A. Yes, I also think that Mr Clark had his opinions about
22 how the operations guys were dealing with this at the
23 time and was not terribly impressed with it.
- 24 Q. Your operations guys?
- 25 A. Yes.

1 Q. But this is an email to you and to Mr Sully, so he is
2 not playing to any wider audience?

3 A. No, he is trying to -- having a moan at us.

4 Q. So you think the backdrop is he is concerned that your
5 operation guys were being "ham fisted" about the Aesica
6 project?

7 A. Yes.

8 Q. If we go to page 1, {IR-H/303/1}, Mr Clark then comes
9 back to you. If we go down. Can we scroll down,
10 thank you. So he comes back to you with some more
11 positive news and he says that:

12 "This is information -- "

13 I am not going to read out the name in case it is
14 sensitive, but you can see the name. Then he says:

15 "However, I have just received the prescribing data
16 for Hydrocortisone from [D]. It shows that only 22% of
17 prescriptions are specified as adrenal, and there are
18 multiple other indications widely in use, not the 90
19 plus per cent for adrenal insufficiency that Brian was
20 once referring to. That means labelling should not be
21 that important, hopefully. [Then there is a smiley
22 face.] Pharmacists will dispense our product,
23 regardless of label, and Amit's claim that we have an
24 inferior product is irrelevant anyway, when it can be
25 shown to be bioequivalent. It just does not have the

1 labelling for one protected indication. Therefore
2 I think we can push back a bit harder! I have sent an
3 email to Brian suggesting the same."

4 Pausing there. Let us just unpack this a bit. So
5 when he is talking about the 22% of prescriptions that
6 are specified as adrenal and therefore -- he means that
7 78% are open prescriptions, does he not? That is what
8 he thought at that stage? That is what he is telling
9 you then?

10 A. I think so.

11 Q. So the implications of that are that only 22% of the
12 market is closed off to you, yes?

13 A. Yes.

14 Q. So he is saying there pharmacists will -- that is why he
15 is saying pharmacists will dispense our product
16 regardless of label, yes?

17 A. That is what he is saying. I do not agree with him,
18 but ...

19 Q. We will come back to that.

20 A. Yes.

21 Q. Let us look at the email for now. Then he says:

22 "Therefore I think we can push back a bit harder."

23 What he means is push back a bit harder in the
24 negotiations with Amit Patel at Auden, does he not?
25 That is the only thing he can be referring to?

- 1 A. I have no idea what he is referring to. On who? On
2 Amit? I do not know.
- 3 Q. Let us look at the chain again. This chain of emails we
4 are looking at -- if we go back down again to?
- 5 A. I suppose my general point on these is that it is
6 actually quite difficult to really understand what
7 meaning somebody had when they were writing an email all
8 those years ago.
- 9 Q. Mr Beighton, it was an email to you and we will look at
10 your response in a minute. But this was an email chain
11 which was looking at the -- was directly talking about
12 the negotiations with Mr Patel and the fact that he
13 wanted you to buy Auden?
- 14 A. Yes.
- 15 Q. You then respond and say, well, we are not interested in
16 it. Then what is being said here by Mr Clark is:
17 "Good news. A large part of the market is
18 contestable with our own product so we can push a bit
19 harder."
20 He must mean, must he not, push a bit harder in the
21 negotiations for the supply of it?
- 22 A. As I said, I do not know.
- 23 Q. Mr Beighton, you are in the best position really. We do
24 not have Mr Clark here.
- 25 A. But I would have to interpret it and speculate as to

1 what he meant.

2 Q. Can you do your best to speculate, because you were
3 there at the time. There was an email to you. What do
4 you think? What is your best attempt to help the
5 Tribunal with what is meant by "I think we can push back
6 a bit harder"?

7 A. I am sorry. I have said, it would be not fair on
8 Mr Clark for me to try and interpret his words.

9 Q. Let us have a look at what else he said. Just to be
10 clear, what we say this means is push back a bit harder
11 in the negotiations with Auden, with Mr Patel. We say
12 that is the obvious meaning of this. Just so you know
13 what the CMA's case is.

14 We say that the reason he is saying that, the reason
15 he is making a connection between, well, this is good
16 news, 78% of prescriptions are open and the market is
17 contestable with their own product is that this gives
18 you stronger commercial leverage. The leverage being,
19 the leverage being in the supply negotiations that AMCo
20 can enter the market with its own product and be
21 a competitive threat. That is the obvious
22 interpretation of this. That is the CMA's case?

23 A. Okay, I understand.

24 Q. And you cannot help us with that?

25 A. I am sorry. What do you want me to say?

1 Q. You were the one that was engaging in these discussions
2 at the time and I want you, to the best of your ability,
3 to try and put yourself back in the shoes that you were
4 then and reconstruct events.

5 A. Let me try and do that. I definitely remember that it
6 was good news. It was a little bit of a roller coaster
7 at the time with this limited indication issue that we
8 had got and at one stage we thought we'd only got 2% of
9 indications of prescriptions that we could go for. This
10 suggested -- this different work suggested something,
11 some better news, and then it fell back and we thought
12 we'd got worse news.

13 This was obviously good news for us.

14 Q. You cannot help us with push back a bit harder?

15 A. Maybe Guy meant that we could use that in negotiations
16 with Auden McKenzie to get that deal signed, because
17 I think that that is what we were trying to do at the
18 time.

19 Q. Yes.

20 A. But I really do not know.

21 Q. All right. Let us look at your response. If we just go
22 above that. You say -- if we scroll up, you say:

23 "Very interesting, thanks [and a smiley emoticon]."

24 A. Yes.

25 Q. So that suggests, does it not, that you understand

1 exactly -- you understood at the time exactly what
2 Mr Clark was saying to you?

3 A. Yes, it was good news.

4 Q. What he was telling you was that this is a helpful piece
5 of information that will enable you to push back a bit
6 harder in the negotiations with Auden?

7 A. No, I think the reason I felt it was good news at the
8 time was that we'd have less of an issue -- what date is
9 this? 2014? -- less of an issue with this lurking or
10 I think we had just found about this issue of adrenal
11 insufficiency.

12 Q. Let us look at what he says at the end. Just go down
13 again to look at his email again. So he says:

14 "Therefore -- "

15 So this information is leading up to a conclusion:

16 "Therefore I think we can push back a bit harder!

17 I have sent an email to Brian suggesting the same."

18 Let us look at that. That is at {H/300/1} and this
19 is Mr Clark's email on the same day to Brian McEwan.

20 Let us go -- so he says -- he gives the same information
21 about the IMS data:

22 "According to the data on IMS, only 22% of

23 prescriptions are specifically identified as adrenal,

24 with a long list of others. That gives us a bit more

25 strength to say to Amit that we do not mind

1 having limited labelling. Pharmacists will use it
2 anyway, regardless of labelling. Therefore, we should
3 still be arguing using 100% of the market as our
4 negotiating position for supply volumes! [Smiley
5 face]."

6 A. Okay.

7 Q. So he is making the same point to Mr McEwan about the
8 22% and he is saying there clearly, is he not, this
9 gives us more strength in our negotiations with Amit,
10 yes?

11 A. He is, yes.

12 Q. And he is saying that we should still be arguing about
13 using -- still be arguing about using 100% of the market
14 as our negotiating position and you will accept, would
15 you not, that the word "still" that that is what you had
16 been saying so far to Mr Patel, Mr Beighton?

17 A. What is clear is that we have always wanted to achieve
18 as much volume as we can from Mr Patel. Notwithstanding
19 that, we have always -- we thought the best route to
20 that was launching our own product.

21 Q. The way that you tried to -- the way that you tried to
22 achieve as much volume as you could from Mr Patel was by
23 arguing that if you brought your own product on the
24 market, you could contest 100% of the market. That is
25 right, is it not? That is what Mr Clark is getting at

- 1 and that is what you were doing.
- 2 A. That is what Mr Clark is suggesting to Mr McEwan.
- 3 Q. You knew that that was what you were doing. You knew
4 that was the leverage that Mr McEwan was using in these
5 negotiations. Of course you knew that, Mr Beighton?
- 6 A. Really, I think that what we were trying to achieve by
7 getting this deal signed was a stopgap position so that
8 we could launch our own product. We always wanted more
9 volume.
- 10 Q. I go back to it. Where he says, "we should still be
11 arguing using 100% of the market as our negotiating
12 position", you knew full well that that is the argument
13 that had been used in the negotiations. Mr Patel came
14 back and said, well, yours is a skinny label product,
15 and there was a negotiation, but the leverage you had,
16 the only leverage you had, was the ability to come on
17 the market with your own product and steal volumes and
18 you knew that, Mr Beighton?
- 19 A. As it happens, we had no leverage. We did not have a
20 product. We hoped we would have a product. We had no
21 leverage and, as I have said before, if I was Mr Patel,
22 I would have told us to ... off, but --
- 23 Q. You may have thought you had no leverage, because you
24 say you did not have a product, but that certainly is
25 not the impression you were conveying to Mr Patel, was

1 it?

2 A. I have no idea what Mr Patel was thinking. As I have
3 repeated and repeated, I just do not get why he did this
4 deal with us.

5 THE PRESIDENT: I think the question is slightly different,
6 Mr Beighton. It is more what you would have sought to
7 withhold by way of information from Auden. Presumably
8 you would not have gone out of your way to advertise the
9 difficulties that you were having with your alternative.

10 A. No, exactly. No, exactly. Or the fact that we were
11 worried about the skinny label and how that would have -
12 the manufacturing difficulty. We would have wanted him
13 to think that -- we certainly would not have wanted him
14 to think that we had got problems.

15 MS DEMETRIOU: And the reason for that, Mr Beighton, was
16 because you wanted him to think that you could enter the
17 market easily, because that was the best way of
18 negotiating more volumes from him, yes?

19 A. We were intending to enter the market. We were -- we
20 wanted him to supply us with more volume.

21 Q. Let me just ask the question again.

22 A. We felt at the time -- I felt personally at the time
23 that we did not have leverage and in the end, as I have
24 said before, I phoned him up and I said, part of the
25 supply agreement, could you give us 12,000 packs a month

1 and we will sign it and he said yes.

2 Q. Mr Beighton, your leverage, you understood, so when you
3 said -- I am just looking at your answer to make sure
4 I've got it right. So you say -- you said we would have
5 wanted him to think -- you would not have wanted him to
6 think that we had problems and the reason that you would
7 not have wanted him to have thought that you had
8 problems is because what you wanted him to think was
9 that you could enter the market easily, because that was
10 the best way of negotiating more volumes. That is
11 correct, is it not?

12 A. We wanted him -- we bluffed him. We definitely had
13 a strategy of bluffing Auden McKenzie that we were ready
14 to launch our own product and we were hoping that he
15 would respond by giving us product.

16 Q. Right, so you say that was a bluff.

17 A. Yes.

18 Q. But in this bluffing that you were doing, you were
19 conveying to him -- I think I understand you correctly.
20 Your evidence is that you were conveying to him that you
21 were ready to enter, because that was your best way of
22 getting more volumes, but that that was a bluff because
23 you really were not ready to enter. Is that your
24 evidence?

25 A. We really were not ready to enter. We were worried

1 about the adrenal insufficiency issue. We wanted -- he
2 wanted another supply agreement with us. I asked him if
3 he would agreed to a new supply agreement with 12,000
4 packs a month and he said yes.

5 Q. But the bluff that you were conveying to him was that
6 you were ready to enter, yes?

7 A. Yes, we definitely gave him that impression.

8 Q. Right. Okay. Let us go to {H/316/1}. If we go to the
9 bottom of the chain at page 4. This is an email chain.
10 I just want to go to the bottom of page 4 {H/316/4}.
11 There is an email of 13 January. Do you see that? It
12 has all been blacked out so I can't see on this who it
13 is to.

14 Let us go to -- if you just bear with me a minute,
15 because I do not think it is fair to show it to you
16 without looking at who the recipients were.

17 So if we can go to the IR-H bundle. Let us go to
18 {IR-H/316/4}. Let us go to the bottom of -- this is the
19 bottom of page 4. What we see here, so this is -- do
20 you know who these people are?

21 A. I do not know who -- I know Vaibhav.

22 Q. Do you know the top name, the person who it is from?

23 A. Yes.

24 Q. That is someone at AMCo, yes?

25 A. Yes.

1 Q. You can see they are emailing Auden McKenzie, Auden, and
2 they are asking for the audit quantity -- I am looking
3 at the second paragraph -- for a particular PO, 7108, to
4 be increased, revised from 6,000 to 7,000 packs, yes?

5 A. Yes.

6 Q. And then at the top of page 3, If we go to page 3
7 {IR-H/316/3}., you see that there is an email saying:
8 "In regards to your request to revise the order from
9 6,000 packs to 7,000 packs has not been authorised."

10 Yes, so it is back to 6,000 packs.

11 Then if we go to page 2, {IR-H/316/2}, you ask
12 whether we normally receive 6,000 and you are asking
13 that to Jane Hill, amongst others?

14 A. Mm-hm.

15 Q. Then she confirms:
16 "Yes, it is always been 6,000 but the new agreement
17 is 7,000 from this month."

18 Then if we go to page 1, there is an email from
19 Mr Clark, Guy Clark to you, amongst others, and he
20 refers to a call that he got from Amit that day:

21 "I received a call from Amit today, and he says he
22 was not happy with the higher order being sent before
23 the agreement is signed (by him) and without having
24 given an indication whether we are going to buy the
25 product or not."

1 Then if you read (a) to (c):

2 "I think Rob will cover this off by separate email,
3 but his main points were [so Amit Patel's main points] [
4 (a)] why was an order sent for the higher amount?
5 I said that I believed it was in anticipation of the
6 newly agreed volumes. He said that he had explained to
7 Brian that agreement on these volumes was contingent on
8 our interest in acquiring the product and giving him an
9 offer. I said that I had no idea about this and that we
10 were keeping the two activities separate within AMCo."

11 Then he says:

12 "[(b)] I have a very big company interested in
13 buying me."

14 And then he goes on to say at (c):

15 "If we do not make an offer to buy the product, and
16 thus he implied that he would not therefore sign the
17 supply agreement, he would take action to protect his
18 product by advising all parties that our product should
19 not be dispensed against generic prescriptions."

20 Yes?

21 Q. At this stage Amit Patel is saying that higher volumes
22 are contingent on you buying Auden, yes?

23 A. So it seems.

24 Q. And he is saying at (c) that if Cinven doesn't make him
25 an offer for Auden he will take action to make sure that

1 the skinny label issue is highlighted, as it were, so
2 that AMCo's product is not dispensed against generic
3 prescriptions.

4 Presumably that is in response to the fact that your
5 team has been, as we have seen in the previous emails,
6 leveraging the threat posed by your own product in the
7 negotiations, yes?

8 A. I do not know.

9 Q. In response to the bluff presumably he is saying well it
10 is not much of.

11 A. I do not know what he said to Guy. Maybe you should ask
12 Guy or Amit.

13 Q. Then what we see is that Auden's refusing to increase
14 the volumes from 6,000 to 7,000 without getting
15 something in return, and that makes sense, does it not,
16 because otherwise he is just transferring even more
17 profits to AMCo, yes?

18 A. As I have said, I do not -- if I had have been him
19 I would not have done it.

20 Q. But you agree with me that --

21 A. If --

22 Q. -- he is transferring even more profits to AMCo if he is
23 selling you 1,000 more packs?

24 A. I do not know If he is transferring -

25 Q. He is losing profit that you are making?

1 A. -- profit.

2 Q. We see the thing that he was interested, the thing he
3 wanted in return at this stage, at the beginning
4 of January, was that Cinven buy his company, yes?

5 A. Yes.

6 Q. Cinven was not interested in that and so negotiations
7 broke down at that stage. That is what happened, is it
8 not, in terms of the chronology?

9 A. I think so, yes.

10 MS DEMETRIOU: Sir, I am looking at the time. I am about to
11 go on to a different subject and so -- it is not
12 actually a different subject, it is all one subject but
13 I was going on to a different strand of documents and so
14 I do not know if this is a good time for me to stop. It
15 is nearly 4.30 or whether I should go on. I do not know
16 what time you are sitting until. I am in your hands.

17 THE PRESIDENT: How are we doing for time is the first and
18 most important question. It looks like we are doing
19 quite well.

20 MS DEMETRIOU: I think we are all right for time.

21 THE PRESIDENT: In that case it seems to us that we should
22 rise now and resume at 10.30. That clearly seemed to
23 work.

24 A. Yes, that is fine.

25 THE PRESIDENT: Mr Beighton, I probably should have said

1 this during one of the ten-minute breaks but I will say
2 it now. Please do not talk to anyone, and I do mean
3 anyone, about your evidence and we will see you tomorrow
4 morning at 10.30.

5 Ms Demetriou, two points. One if there are
6 documents relating to the Carbimazole agreements
7 I wonder if you could give us the references just so
8 that we can catch up on the reading. It may add nothing
9 to the sum of human knowledge but we would like to be
10 able to read them if such documents exist.

11 Secondly, we indicated earlier that we might have
12 some questions on what you have been putting to the
13 witness. Would tomorrow morning be a convenient thing
14 before we start or do you want us to hold off until
15 you've reached the conclusion of a different segment?

16 MS DEMETRIOU: Because I have not quite finished this train
17 of -- would it be inconvenient to the Tribunal if
18 I carried on for a while tomorrow?

19 THE PRESIDENT: Not at all. We do not want to interrupt
20 your flow. That is our --

21 MS DEMETRIOU: I am very grateful. If there comes a point
22 obviously where you think well, we really want to ask
23 our questions now then please say.

24 THE PRESIDENT: We will certainly say so but we are not
25 going to discombobulate your questioning.

1 MS DEMETRIOU: Thank you.

2 THE PRESIDENT: Thank you all very much. We will resume at

3 10.30 tomorrow.

4 (4.28 pm)

5 (The hearing adjourned until Thursday, 24 November at

6 10.30 am)

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