**IN THE COMPETITION APPEAL TRIBUNAL**

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

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")**

# A P P E A R AN C E S

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)

Friday, 16 December 2022

(10.30 am)

Closing submissions by MR BREALEY (continued)

THE PRESIDENT: Mr Brealey, before you begin, just two points not quite of housekeeping but of -- first of all, you very helpfully indicated that the parties would try to answer questions about pricing that we might have. It is, I am sure, not going to be the only question but I think we would be assisted in understanding with a high degree of granularity how, for example, one month's version of the drug tariff actually is calculated, because we have been talking about the drug tariff here and there and I just feel I do not actually understand how it works.

Given what we have been talking about in terms of lags or non-lags between prices in the market and the drug tariff I think it behoves us to understand just how it is put together in case it elucidates. It may not, but I think that is something that we would want to know about.

Secondly, I think it would be helpful to have a basic understanding, and I think this is going to be quite simple, a basic understanding of how the ultimate consumer, the patient, pays for drugs. I mean, obviously there is the prescription, but I think we

would quite like to know what the prescription charges were and, roughly speaking, what the exemptions were in terms of prescribed drugs. That, I suspect, can be done in a couple of sentences because we do not need to know the granularity of it, but I think we would like to have chapter and verse in case we need to use it.

That was in response to your very helpful suggestion yesterday.

It is really, I think, a question for Ms Ford, and I apologise for not raising it with her, but I only stumbled across it when I was reading the Decision for other purposes this morning. I wonder if we could bring up page 41 of the Decision, paragraph 3.5 {A/12/41}.

You all see the content of paragraph 3.5, and what I want to throw out for answer is what it is we are to make of points like this. I mean, it is clearly something or -- well, one infers it is something that the CMA have relied upon in order to reach elements of their Decision, because it must be in for a reason. So the question that I have got is: what, if anything, are we to make of it? I mean, it comes very close, Ms Ford, to the similar fact debate that we had in relation to the 20mg, 10mg agreement, and speaking entirely without assistance from you, my inclination would be that one does not allow prejudicial material like this in unless

it meets the similar fact level.

But it may be, Ms Ford, you can address it in reply --

MS FORD: Sir, I am happy to do that.

THE PRESIDENT: -- and we can see what the CMA tell us to make of these. There is more, there is 3.8 as well, but 3.5 was the bit that made me sit up and think, and I think we do need a steer because, I mean, the parties are all labouring under the problem that there is a great deal in this Decision which no one, with the best will in the world, is going to be able to touch upon completely even in written submissions.

So when we see something that we feel we might be addressing, well, we will obviously raise it, and perhaps that can be dealt with in the course of next week and then you can reply.

MS FORD: Yes.

THE PRESIDENT: Mr Brealey, I apologise for interrupting you with points that are not really your business, but thank you very much.

MR BREALEY: I notice that it is in another investigation, yes, so that is what we mean by "similar fact". It is not admitting -- I looked at the footnote and it is --

THE PRESIDENT: It is from another investigation, but I mean, that fact cannot make it or unmake it similar

fact, if that is the right test to apply.

MR BREALEY: I think it might be.

THE PRESIDENT: But, so anyway, thank you for your indulgence.

MR BREALEY: So, I mentioned there were six issues that I was going to deal with. Can I turn to the third one, and that is the question of back-up, but this is more from AMCo's perspective, Project Guardian is more from Auden's perspective. So I would like to just look at some of the evidence from AMCo's perspective on the question of back-up.

We deal with this at annex 7 to our closing, and again, I think all the references will be IR. So {IR-L/8/228}. Just to flag where we are going, there is a box there at annex 7 and there are eight bullet points. I am going to touch on the first four, and then Mr O'Donoghue will essentially deal with the second four because that concerns the supply agreement and Aesica. So I will deal with the first four.

The first one we touch on at paragraph 3, which is the Deloitte due diligence report. Just to scoot around on this, because we saw this yesterday, so I do not want to labour it, but it is relevant. Just to put it in context, could we go back to {L/8/212}, which was paragraph 6 of annex 6. There at the bottom we have the

quote from the Deloitte report:

"'The current market for Hydrocortisone tablets is supplied solely by Auden McKenzie. Management plan to launch their product to take a share of this market. There is a high risk of other new competitors in addition to [AMCo] which would impact market prices and market share. However, [AMCo] [and this is the reason I am going back to this] may be able to get to market earlier than other suppliers because they own the original MA for this product.'"

So I just want to emphasise the word "earlier" there.

Then if we go to our closing, {L/8/228}, we saw this yesterday. This was by context. This is, when you go over the page:

"Question: ... the due diligence material does not, as far as we have seen, refer to any supply agreement with Auden and I think that is because the focus at this stage was on the launch of a new product; is that right?"

Mr Beighton says:

"Answer: Yes, this is what we intended to do with the [AMCo] business once we bought it."

Then finally, can I go to our closing at paragraph 40, which is {L/8/20}. So {IR-L/8/20}.

Again, this will be something for Mr O'Donoghue to expand on, but I just want to emphasise paragraph 40 because these refer to emails at the beginning of 2013:

"There are clear references in the documents to 'as quickly as possible', 'as soon as possible', 'fraught at this end, we need to place orders', to 'expedite where possible' ..."

I would like, if you could, to just remember:

"'Appreciate your efforts to expedite', 'as fast as we can'."

We say this evidence is entirely consistent with the evidence given by Wayne Middleton and Kelly Lifton that there was no untoward delay suggested for the corporate desire not to launch.

Now, the reason I do that is because the reference to "appreciate your efforts to expedite" comes from Mr McEwan, and that leads me to the second bullet point on our box, so we go back now to {L/8/229} and at paragraphs 5, 6, 7, 8, 9, 10, 11 -- we will come on to some of these in a moment -- we deal with some of the involvement of Mr McEwan, because we actually rely on the contemporaneous evidence relating to Mr McEwan to say there was no plan to have this as back-up.

But rather than go through all of this, what I would like to do is refer to essentially two documents,

because it relates to his state of mind. The first document is {IR-H/177/1} which we deal with at paragraph 6, but we will look at the document. This is from Brian McEwan to Wayne Middleton, but if you just go down, so it starts from Wayne Middleton, 13 February 2013. Brian McEwan is a recipient, "Production of new products":

"Dear All, Further to our meeting at Aesica last week.

We requested commencement of production for 1 batch of Hydrocortisone + 1 batch of each strength for Morphgesic.

Rather than simply raising Purchase orders we requested they check what their earliest production date would be. Initial feedback is not great.

Due to the length of time since original purchases of raw materials many have now expired and will need to be replaced with fresh stock. Some of the items have up to 149 day lead time!

[John] is pushing the suppliers to improve on their lead times and when he has answers will allocate slots for production."

So I emphasise the words "slots for production".

"After which we will know approx. when we could expect deliveries."

So this email from Wayne Middleton is looking at production slots which is then going to lead in, when could we expect deliveries?

So this is at the beginning. If we just go up to see the response from Brian McEwan:

"Wayne, Many thanks. Appreciate your efforts to expedite. Brian."

So in my submission this desire to expedite with an expectation of deliveries is entirely consistent with AMCo's focus at the time to launch the product as envisaged in the Deloitte report. So we have the Deloitte report, the emails about as quickly as possible, expedition, all with the endgame of having deliveries, but it is important that Brian McEwan is saying within the team, "appreciate your efforts to expedite".

Now, can I go on to the second document which records, in my submission, what Mr McEwan, what his state of mind was, what Mr McEwan stated to the external solicitors in 2013.

Now, on this, could we go to page 230 of the closing, to paragraph 7. So we are going back to {L/8/230}. This is just to set the scene. This is in the context of the Pinsent Masons compliance report. So in paragraph 7:

"On 2 July ... Mr Sully provided information to AMCo's external solicitors, Pinsent Masons, on the 10mg hydrocortisone tablet supply agreement with Auden (itself an odd thing to do if there was a covert market sharing agreement). The supply agreement with Auden had been referred to Pinsent Masons from a competition law compliance perspective. Mr Sully was cross-examined on the information that Brian McEwan supplied to the external solicitors as part of the information gathering exercise."

I would just look at the question and answer and then look at the final document, but the question and answer was, referring to the July document, the document says:

"'Please see comments below from Brian, who has been the most closely involved in the Amdipharm business in recent years'. Yes, and that is Brian McEwan, yes?"

The answer is "yes".

So we see here that Brian McEwan is within management providing information to Pinsent Masons, and then I will leave the Tribunal at its leisure to read paragraph 7 and what was supplied.

But I would like to essentially go to paragraph 8. This is at {L/8/232} of the closing, because there was a continuous flow of information from the management to

Pinsent Masons. So paragraph 8:

"There was a further flow of information from Mr McEwan to Pinsent Masons which culminated in the Pinsent Masons 'AMCo Competition Audit report' dated 27 January ... Mr Sully was also cross-examined on this document."

So the question was, and the critical paragraphs we will come to in a moment are paragraphs 8.1.3(a) and (b):

"... that records information provided by AMCo management."

The question is:

"Presumably that would have been you, yes?"

Answer from Mr Sully:

"So this is information I had given to Pinsents, but I think when they say when questioned 'the management of Amdipharm'. I think that would be Brian McEwan plus the people I have spoken to, to check what is going on behind him, if you like."

The question:

"What this explains is that the strategy is to continue to source from Auden until Amdipharm has its own supply source, yes?"

"Answer: Yes."

Now, we have set out the passage, but I think it is

important just to have a look at the document, and the document is at {IR-H/554/1}. This is not necessarily relevant to what I am going to say, but I would ask the Tribunal to note the first three paragraphs. This is something that Mr O'Donoghue will, I am sure, expand on because it shows Pinsent Masons all over the hydrocortisone agreements and in particular the new agreement with Auden in June 2014.

So, for example, the third paragraph in yellow:

"You will note that section 8 deals with the informal cross-supply agreements that legacy Amdipharm had with Auden McKenzie. As recommended by Pinsents, we have ended these informal relationships (contracts were put in place and then the arrangements were terminated). Pinsents have been fully involved in the new hydrocortisone supply agreement with Auden, which arises out of the orphan drug status issue."

I will just mention that because it is relevant, but the point that I want to refer to, if we go to page 19 {IR-H/554/19}, and I just ask the Tribunal to note the heading, "Supply arrangements of Hydrocortisone tablets and Carbimazole tablets with Auden McKenzie."

8.1 sets out a factual background.

If you can please then go to page 20 {IR-H/554/20}, and we see there 8.1.3 and then we have (a) and (b).

Mr Sully was asked about the strategy but was not taken expressly to these two passages, but they are relevant to see what Brian McEwan has told Pinsent Masons. So after the first sentence:

"When questioned, the management of Amdipharm has explained that the rationale for Amdipharm to continue to source hydrocortisone 10mg supply ... is twofold: first, because Amdipharm does not yet have a supply of its own, and secondly, Amdipharm is not convinced that Aesica will be able to manufacture the product according to specification and/or consistently. We understand that Aesica has been developing this 10mg formulation for Amdipharm for some time, but has not yet produced any compliant batches."

Now, the next bit I do emphasise:

"The development project is still underway, and the management of Amdipharm have explained that the strategy is to continue to source from Auden until Amdipharm has its own supply source, when it will switch over to that source and be able to act independently."

So "Switch over to that source and be able to act independently." It goes on:

"Second, because Amdipharm has not been able to assess whether its Aesica 10mg hydrocortisone line extension, if successfully manufactured and capable of

being marketed, would be able to compete with the Auden product in circumstances where the Aesica-developed Amdipharm product does not have the key adrenal insufficiency indication due to the OD status issue. Therefore, Amdipharm has been selling Auden product in order to maintain a foothold in the hydrocortisone market while it creates a validated supply source of its own and while it assesses how to deal with the OD issue."

So that is what essentially Brian McEwan and the management told Pinsent Masons, the external solicitors.

If I go back to our annex 7 at page 233, {L/8/233}, we try and draw this together. So we start at paragraph 10:

"The CMA in its Defence at [81] expressly denies that 'the parties' lawyers were involved in a conspiracy to create documents that misrepresented the bargain or that correspondence and meeting notes were fabricated.'"

So that is relevant to any innuendo about a sham:

"Indeed, this memorandum from Pinsent Masons was put to Mr Sully on the basis that it represented the company's (the management's) strategy."

So:

"The words highlighted in bold [so "switch over to that source and be able to act independently",

"marketed", "compete", "foothold", we say] contradict the CMA's case that the Aesica product was back-up in the sense that it would not be sold and there would not be any independent entry. Quite the reverse, the memorandum records that the management's strategy was to switchover to the Aesica source and to be able to act independently."

The word "independently" comes from this memorandum. Then we go on:

"The contemporaneous AMCo internal correspondence also contradicts the CMA's case. In an email from Wayne Middleton to Kishor Karande and Paul Frankland dated 27 September 2013, he states that the Aesica 10mg hydrocortisone tablet 'is expected to be in direct competition to another product on the market [ie Auden's]'. On 17 October 2013, in an email from Jane Hill [she is the commercial person] to Brian McEwan she tells him, 'I believe we may be getting our own stock from Aesica in February 14 so would then terminate the agreement with Auden.'"

On December -- it may be the 4th, on December 2013, in response to a question she says, this is Jane Hill, there is a question:

"'are we going to compete with Auden M?"

And Jane Hill says:

"'Yes there will be two of us in the market.'"

That is dated 4 December.

So that September, October and December exchange clearly supports what Brian Middleton [sic] was saying to external solicitors throughout 2013 and as recorded in the memorandum, and there is no suggestion that this has been fabricated or is in any way a sham. It is compelling contemporaneous evidence of no promise of the sort alleged by the CMA in this case.

Before I move to the next item, the next bullet which is the involvement of senior management, can I please just give the Tribunal my five reasons why the CMA is wrong to ask for adverse inferences to be drawn.

THE PRESIDENT: Yes.

MR BREALEY: I have listed five. First, Mr McEwan, as the CMA admit, was under the supervision of Mr Beighton. The CMA's case is that Mr Beighton was aware of, and consented to, the alleged promise. It is AMCo's consent that must be proved and we have called the persons of the right seniority. That is our first point.

Second, Mr McEwan left his employment in early 2014, over eight years ago. There is no property in a witness and there may be a host of reasons why he is not being called.

THE PRESIDENT: Just to understand your first point,

Mr Brealey, all you are saying is one of the bases on which adverse inferences are drawn is where there is a witness who can speak to a specific fact, and he or she is the only witness who can do that, and you are saying, well, of course Mr McEwan could have spoken to these things but so too could Mr Beighton, and you have called Mr Beighton, so --

MR BREALEY: Absolutely correct, sir, and I will come to that on my fifth reason. But AMCo inherited this agreement. It is alleged that Mr Beighton continued with the promise. He sits on the board and therefore we have called him and Mr McEwan is under his supervision. So it is not as if we have done nothing.

The third reason -- so the second was that he left his employment in early 2014. The third reason is the CMA has already been able to cross-examine him twice in two separate interviews under caution, with a very serious caution that these people get when they are interviewed in the CMA's offices, and it is a very much inquisitorial type of affair as everybody knows.

THE PRESIDENT: The caution presumably is you do not have to incriminate yourself?

MR BREALEY: No, it is if you give dishonest information you are liable, I think, to be put in prison.

THE PRESIDENT: Right. Not for now, but I think it would be

helpful just to have the precise terms of that warning.

MR BREALEY: Yes, I am sure we can get the beginning of the transcript because the caution, I think, is read to the witness.

THE PRESIDENT: Yes, that would be helpful.

MR BREALEY: The fourth, as the Tribunal knows, the CMA prepared a witness statement upon which it relies in the Decision, and if there is any aspect of the statement the CMA does not like it could have asked the Tribunal to compel Mr McEwan. We say that should have been done at the PTR at the latest. I note the CMA says rather unfairly that we, AMCo, me, did not want Mr McEwan being called. That is not my recollection of the exchange. I said that we were not adverse, but I certainly did not want the timetable to be upset and there would be prejudice.

But the fifth point is that it is this the Tribunal's practice not to draw adverse inferences, and I tried to persuade the Tribunal to draw adverse inferences in the *Pfizer* case against the CMA, because the CMA had failed to call anyone from the Department of Health on the sole issue. That is the point you were making about whether an agreement had been made. The Tribunal stated that it was unfortunate that the CMA had not called any witnesses, but it would

not draw any adverse inferences because, the Tribunal said, there may be many reasons why a witness is not called. The citation for that in the *Pfizer* Tribunal case is {M/150/32} at paragraph 86. We do not need to turn it up.

So the Tribunal has in the past said no, we are not drawing adverse inferences, even when the CMA refused to call a witness from the Department of Health, and that was the only -- that was really, really important to the claimants, the appellants in that case.

Can I then, with that, move to the involvement of senior management. Can I just -- I will move the -- Mr O'Donoghue -- so is this the statement? Oh, it is a transcript. So the standard is:

"I confirm that I have reviewed this transcript comprising a total of 157 pages and that it is an accurate reflection of statements I made that are true to the best of my knowledge and belief. I understand that I shall be liable to prosecution if I have knowingly or recklessly provided information to the CMA which is false or misleading in any material particular."

So I will be liable to prosecution, but I think we can find out why the person would be subject to prosecution, and I think there may actually be a warning

that is given at the beginning of the --

THE PRESIDENT: One would expect.

MR BREALEY: Can I move to paragraph 12 of this annex {L/8/234}. I make a small, but it is quite an important point, which is the involvement of senior management. We say at paragraph 12:

"The Aesica validation batches were failing stability tests as a result of which AMCo senior personnel get involved as the 10mg hydrocortisone tablet was regarded as one of AMCo's big product launches for 2013/2014."

We say:

"This does not indicate a desire not to launch. Mr Sully explained in cross-examination that it was indicative of the importance given to the 10mg hydrocortisone tablet project -- it being one of the big project launches ..."

The answer is:

"'So in December 2013 a lot of senior AMCo staff, global heads of quality, global head of regulatory, Guy Clark, John Beighton, everyone was going, 'Christ', we have got a real problem here. This is one of our big product launches for 2013/14 and it has completely failed. So there was a huge effort in December and January and then in February it looked like we had found

a way to get over this. There was a change of the analytical methods, so we thought we had resolved it."

But the involvement of senior management is important for two reasons. First, it highlights the importance attached to the launch of the Aesica project, but second, it shows that it would be difficult to get some covert secretive deal past all these senior people.

Linked to that is our next item, which is the board of directors meeting on 29 February which we have at paragraph 14 {L/8/235}. We deal with two issues here. The first is the PPRM recommendation and I will let the Tribunal read, not now but that is at 14 to 19 where we say that that recommendation, which referred to back-up, and more beneficial to be the IP owner versus distribution agreement, launch date of April 2014, the sales strategy, sales risks, we make those points and I am not going to go through that orally.

What I would like to do is go to the board meeting of 29 January 2014 because again it relates to corporate strategy, the senior management.

The relevant document for this is {IR-H/346/1}. This is AMCo at the highest level. There is a chairman and then in attendance we have Mr Sully, Mr Beighton and various other people. So this is at the highest level. Just by way of -- in passing, if we go to page 2,

{IR-H/346/2}, we see that they are talking about other products, hydrocortisone is not just the only product. Then we go on. Sorry, if we just go up a tiny bit, sorry. So I just ask the Tribunal to note the update on the UK wholesaler distribution agreement, because at this time AMCo moved to a Solus agreement with Alliance and a lot of the products -- it was going through Alliance, they had dropped AAH. So if we just look at it, just for context:

"Mr Sully provided an update to the board regarding a disagreement with AAH over the terms of their dual wholesaler distribution agreement with UK sales distribution entities, which had led to the contract with them not being executed. It was noted that AAH had been operating a pricing policy which pharmacists had been complaining about and which had led to the price of Carbimazole increasing month on month since last April 2013 when the agreement with AAH had been signed, such that the price had doubled in the past nine months.

As a result, AMCo had served a final notice on AAH and, separately, discussions had been held with Alliance on a Solus deal in place of their current dual wholesaler agreement that was in place with Alliance. These discussions had been positive and the following

terms had been broadly agreed."

It goes on to show that the board:

"... after due and careful consideration it was resolved that the company was not prepared to let AAH continue to price in this manner and the proposal was approved, along with the execution of a new distribution agreement with Alliance."

I just say it in passing, because putting a lot of the eggs in the Alliance basket, the way it distributed its products. But the main thing I want to refer to is the update on the hydrocortisone which is giving the strategy of the company:

"Mr Beighton confirmed that negotiations with Auden McKenzie to agree formal written contracts for the supply of hydrocortisone ... had proved difficult and that signed contracts had still not been achieved. However, Mr Beighton was hopeful that contracts would soon be signed. It was noted that, as a result of a more positive outlook on the group's own hydrocortisone product that is being developed by Aesica for Amdipharm ... it was hoped that the group would be able to obtain its own fully compliant product in the next 4 months [I emphasise] and thereby move away from sourcing hydrocortisone from Auden under the legacy arrangements that had been inherited from the merger

with Amdipharm. Mr Beighton explained that the issue with the AMIL development was that Auden had obtained orphan drug status for their product in relation to the adrenal insufficiency indication, which AMIL and AMCo were currently investigating. It was currently thought that AMIL's own version would be able to compete with the Auden product, even if it does not have this indication, but investigations continue as this is a GBP 30 million EBITDA market and so there is much at stake."

I emphasise the word "compete", "move away from the legacy agreement":

"... thereby move away from sourcing hydrocortisone from Auden under the legacy agreement that had been inherited from the merger."

This is not a strategy of a company that is going to have ready-made product and then not launch it, leaving it wasting in a warehouse somewhere.

We say at paragraph 22 of our closing, and this is at 238, so if we go back to {L/8/238}:

"On a plain reading of the Board minutes the following facts are apparent and such facts are wholly inconsistent with the CMA's case that AMCo's mindset was not to launch. AMCo's mindset was on introducing into the market AMCo's 'own version' to 'compete' with the Auden product ... once the Aesica product was ready AMCo

would 'move away' from the 'legacy arrangements' ... terminate the Auden supply agreement."

Which in fact it did, we saw that yesterday.

If the Tribunal remembers, Mr Sully was not taken to this document and in re-examination I asked him what was actually decided, so I read it out:

"But can you assist the Tribunal as to what was decided by this company at this meeting?"

And the Tribunal will probably remember his quite strong response:

"Yes, so this was a discussion that took place and the Decision was taken that we would continue to formalise in writing the informal agreements with Auden, bring them to a close in the end of March 2014 and then move to taking supply from Aesica which was our preferred route forwards. We understood at the time at the end of January that Aesica will be able to deliver product in April 2014."

So because this agreement had not really been put to Mr Sully, I said:

"Just to be crystal clear, and this is something that the Tribunal has asked, just to be crystal clear, did the board at this meeting approve an agreement with Auden which allowed AMCo to develop and to manufacture ... but then not to sell it and only have it

as back-up?"

"Absolutely not", was the response. There are other bullet points in this annex but Mr O'Donoghue will pick them up.

Can I go to the fourth issue which is the lack of market demand in 2014, which we say is the obvious reason why AMCo did not launch the product.

For this can we go to our closing at paragraph 46 which is {L/8/22}, please. This issue is: what was AMCo's perception in June 2014 about the demand? At 46, it is quite brief, so I will just go through it:

"As the evidence in Annex 2 shows, AMCo in this period had genuine concerns that even if it could obtain supply of the reduced indication (child's version) ... it would not have a market for it. This lack of demand is supported by:"

And we list eight things:

"First, what in fact materialised as evidenced by the Decision itself: an assured customer based on the major pharmacies and wholesalers in the UK."

One remembers the cross-examination of Mr Bishop by Mr Holmes. We set out the quotes, I will not repeat it.

"Second, the views expressed by the pharmacies and wholesalers:"

That is in annex 4.

"Third, the views of the suppliers of reduced indication ..."

Annex 5.

"Fourth, the evidence of Mr Beighton and Mr Sully: their evidence-in-chief and their answers in cross-examination (Annex 7).

Fifth, the interview transcript of Jane Hill, the ... Commercial Director who had earlier stated that AMCo would be competing with Auden ('there will be two of us')."

We saw yesterday her view is supported by the Boots internal email and the Day Lewis communication, the Project Guardian communication.

Over the page {L/8/24}:

"Sixth, the opinions of all the experts ..."

About how difficult this market was, and then:

"Seventh, AMCo's market research in ... 2015 ..."

And I will come on to some of this in a moment, and then:

"Eighth, the evidence set out in Annex 10 which places in stark contrast the radical change in the market perception in March 2016."

So we have set out a summary of the evidence, and I would just like to go to some of the documents which puts this in context, which support -- and I am not

actually sure what the CMA's case on this is, are they saying there was no perception in 2014 that there would be hardly any sales, or is it -- so we will find out in closing, but it is another innuendo where, when one sits back in the cold light of day, one is not quite sure what is being alleged.

But parking that to one side, could we go first to the decision itself at {IR-A/12/227}. That is paragraph 3.513. So it is at the bottom. I slightly take issue with the way that this is portrayed, but we will read it:

"The crisis in relations between Auden and AMCo therefore prompted AMCo to consider getting 'a really clear plan in place' for launching its Aesica product and taking protective action to 'counter-lobby' stakeholders to explain that its skinny label product was in no way inferior to Auden's full label product. It also made the question of the extent [this is the bit that I emphasise] of the contestable market, already subject to considerable discussion with AMCo ... acute ..."

So the CMA is recognising that whether it was an acute issue as to the nature of the contestable, the extent to which the market was contestable. So even the CMA is saying that there was an acute, the question of

the extent of the contestable market was "acute".

There is no evidence from the CMA that matters somehow improved in April, May, June 2014.

I would now like to go, please, to another document, {IR-H/501/1}. This is an email exchange between Mr Sully and Pinsent Masons, when we get it. It is still faster than paper. (Pause) So page 2 {IR-H/501/2}. This document is important because it shows what Mr Sully's state of mind was, or AMCo's state of mind was, at the relevant time in June 2014. This is the exchange between himself, and I hope she does not mind, I will just call her "Miss P". So:

"Hi Rob, It was very nice to meet with you earlier today.

I thought it would be helpful to formally record my attendance at your offices and on the conference call during the discussion with Auden McKenzie in respect of an own label supply agreement for 10mg hydrocortisone.

Also present on the call were: Rob Sully ... John Beighton ... Amit Patel ... and Charlie Duran ..."

So Charlie Duran, JGR Law, is Auden McKenzie's external solicitor.

But it is the big paragraph that I rely on for Mr Sully's state of knowledge. Could we just expand it a little bit? Brilliant.

"Of key concern for AMCo was Auden's ability to prevent AMCo from launching us own 10mg hydrocortisone and ensuring continuity of supply for AMCo's customers once it entered into the agreement. Prior to the call I discussed with you the extent to which AMCo would be considered a competitor of Auden in relation to the 10mg product (which AMCo has a pipeline source). [This is now the advice:] As a result of the orphan designation for 10mg hydrocortisone, AMCo cannot supply its 10mg hydrocortisone into the market in respect of the main therapeutic use, ie the treatment of adrenal insufficiency. The orphan designation is akin to an IP right and as such, from a competition law perspective in respect of this product and the orphan indication AMCo and Auden would not be considered competitors whilst the orphan designation was in place (however for other products ... [they] would be considered competitors ...) As a result of the orphan designation, AMCo has decided that the best commercial option is to source 10mg supply from Auden whose product is capable of being marketed for adrenal insufficiency."

But I emphasise what Mr Sully's belief would have been at the time, what the discussions would have been at the time. This is why I am taking the Tribunal to this. It would have been, "This is so difficult, it is

almost impossible to market this." Therefore, the solicitor says, you are not competitors. So I am not saying whether it is the right or wrong advice; I am relying on this to show that the discussions at the time were, it is going to be very, very difficult if not impossible to sell this product into the market. I am just relying on this because it supports what Mr Sully said in his evidence about there being basically zero sales.

I also ask the Tribunal to note again paragraph 81 of the Defence. We will just go through it. It is at {A/6/34}. I have mentioned this once, but we will have a look at it:

"Nor does it follow from the CMA's approach and conclusion that the parties' lawyers were involved in a conspiracy to create documents that misrepresented the bargain, or that correspondence and meeting notes were fabricated. These submissions attack a strawman. The CMA does not allege and did not find an elaborate conspiracy."

Now, I just say that because one has to take that document at face value.

Could I go to a further document which supports AMCo's view that there was a lack of market demand in June 2014. This is {H/666/1}. If one goes a bit

further down, and a bit further down, just to put this in context. So this is an internal AMCo email, and it is a PSNC newsletter. The PSNC is the body recognised by the Department of Health as representing the pharmacy sector, so this is the official body that represents the pharmacy sector, and it sends out newsletters.

If one just goes down the -- and again, I think, page 3 {H/666/3}, we see in green this drug Pregabalin does arise, and we will see it a bit later on, but this is about dispensing off-label. So this is in passing, but we do come back to this later.

This is the newsletter:

"At present the generic pregabalin is listed in Part VIIIA of the tariff as a Category C line with reimbursement currently based on Lyrica. Where a generic prescription ... is presented to the pharmacy, if the pharmacy is minded to dispense the generic, they should first satisfy themselves that it is not being provided for the patented indications (peripheral and central neuropathic pain). If it is being provided for those indications, the pharmacy should dispense Lyrica and may wish to advise the prescriber."

So that is just a warning that you should not be dispensing outside the indications.

If one goes up to page 3.

THE PRESIDENT: But here, this is because of the patent --

MR BREALEY: That is what is said.

THE PRESIDENT: -- and to avoid infringing the intellectual property rights of the patent holder.

MR BREALEY: That is what is said, but people take this as a wider point about dispensing off-label. So if we go up to page 3 and keep going. Page 1 {H/666/1}:

"Hi all, In line with the discussions last week in PPRM with regards to an innovator patented indications and skinny SPCs -- please see the comment below about the generic prescription of pregabalin and the patented indications. Actions to be taken by the Pharmacies in UK."

Then we have:

"Thanks ...

I have copied Graeme and John"

And in red:

"... we discussed this ruling at PPRM last week, which could potentially affect use of a Hydrocortisone without indications, because Pharmacies are being instructed not to use products that have skinny labelling ... as a result of the orphan drug designation. They may ignore the guidance, but it's an issue we may need to think about, particularly if supply of AM product dries up now that it's being acquired by

Actavis."

But the point that I draw is that pharmacies at this time, this is why I am going to it, 2 February 2015, pharmacies are still being instructed not to use products that have skinny labelling, and it may well be that Mr Palmer says the Pregabalin is about patents, and again I will come on to this, but there is a concern about dispensing off-label and we have seen that the orphan designation is regarded, maybe wrongly, but has been regarded as akin to an IP right.

THE PRESIDENT: Again, you make the point, I think you just made it but let us be clear, you may be right, you may be wrong about analogising orphan drugs to patent infringements but right or wrong this was something that was in the minds of the persons at the time of these emails, February 2015.

MR BREALEY: That is going to be a very, very important point that I will come on to when I come on to the sixth issue.

THE PRESIDENT: But I have got your submission right, that you are making two points. One is that there is an analogy.

MR BREALEY: Yes.

THE PRESIDENT: But secondly, even if there was not or we find there was not, it was perceived at the time to be

such an analogy.

MR BREALEY: Yes, and the pharmacies are being instructed not to dispense the skinny. So that is six months into the second written agreement but it is consistent with the perception in June 2014.

THE PRESIDENT: Yes.

MR BREALEY: Could I then move from February 2015 to December 2015, and if I can, I can just finish this and then maybe we can have a break.

The next document is {IR-H/806/1}. It is the IR one, yes. It is page 5 we go to first. {IR-H/806/5}. This is an exchange essentially. It starts with Focus and AMCo has acquired Focus. We have seen, I think this before.

"Yes, this is the case in Boots at the moment unfortunately meaning that we are only able to purchase the Auden/Actavis product for use in Boots stores at present."

So that is the market feedback. Then if one goes up to page 4, {IR-H/806/4}, and again, given the time, I will just look at the first paragraph:

"It is interesting and of course gives us very clear market feedback of the issues a product without the full range of indications would have."

This is the bit that I rely on for the simple point,

the consistency point:

"To have such a significant and clear response from the two major retail chains is very useful. This is in line with our own historical assessments of some of the issues with this market."

So again, this is in December 2015, but this is consistent with AMCo's own historical assessment, and all I am trying to do is give some support to the AMCo witnesses who said that in June 2014 they saw a real issue with getting this product into the market.

Then essentially the last email is the famous DE Pharma email. That is at {H/863/1}, {IR-H/863/1}. Again, can we go -- I think we start at the bottom as per normal. This is from the managing director, Mr G., from the short line wholesaler DE Pharma to AMCo:

"Thanks for a very constructive meeting today.

I can confirm that the market dynamics have changed dramatically this month for hydrocortisone ...

Our pharmacy customers have become more accepting of the hydrocortisone 10mg non-Auden line.

Sales have increased 6-fold from only a month ago. In April we anticipate selling somewhere in the region of 3000/1000 units in favour of the non-Auden line."

If one goes up that then gets communicated to John Beighton by Mr Duncan and Mr Sully.

"Hi gentlemen

Please see the below an email from MD at DE Pharmaceuticals. This is a very interesting and significant change in market dynamics. At this morning's meeting DE shared the detail of these changes in the hydrocortisone marketplace. Retail pharmacy seem to now be significantly more accepting of a product without the orphan indication. This is very, very different to all previous market feedback we have had. The prediction from DE is that the market will swing heavily towards slimmer labelled products that are most cost effective ..."

"I think we should now reconsider our approach to the market based on this changing purchase behaviour."

And Mr Beighton says:

"Yes I agree."

We wrap up this email in our annex 10 which is {L/8/274}. It is at paragraph 2. We make four points but for the point I am trying to make at the moment I will only go through the first three.

The first point, it corroborates AMCo's case that previous market feedback was negative because we see the words the previous feedback was "very, very different". So what is happening now is very, very different to the historical assessment.

The second point, second bullet is that there has been a fundamental change in market conditions. There is reference to "market dynamics have changed dramatically" and that pharmacies now seem to be "significantly more accepting". More accepting.

The third point that I draw from this is that this was a very recent change because one remembers on 9/10 December AMCo had reached out to its two main wholesalers Alliance/Boots and "your assumptions are correct ..."

So it was very, very different from previous market feedback, it was a fundamental change in the market and it was a recent change and I pray that in aid to support Mr Beighton's and Mr Sully's evidence that in June 2014 the market was very, very different.

That takes me -- at the end of that issue I have got two more. Maybe we can ...

THE PRESIDENT: Of course. We will rise for ten minutes and resume at 10 to.

(11.38 am)

(A short break)

(11.54 am)

MR BREALEY: Sir, I was going to turn to the fifth issue but can I just read out the warning that is given to interviewees.

THE PRESIDENT: Yes, please.

MR BREALEY: We do not need to go to it, but it is at {IR-H/1144/3}. But for the transcript, this is Mr McEwan's interview, 7 June 2018 and it starts with:

"Mr McEwan, you have been issued with a notice under section 26A of the Competition Act, requiring you to attend this interview and answer questions on matters relevant to the CMA's investigations, and attached to that notice is an Annex setting out the civil financial penalties under section 40A of the Act, and the criminal offences under section 44 of the Act. As such, I have to inform you that you may be fined if you refuse to answer the questions put to you by the CMA today in the course of the interview. However, you may refuse to answer a question if to do so would disclose information that is legally privileged.

In addition, it is a criminal offence, knowingly to provide the CMA with information that is false or misleading, and that offence is punishable by an unlimited fine or two years' imprisonment or both. Do you understand?"

And Mr McEwan says, "Yes, I do."

So that is relevant to whether, in my submission, adverse inferences should be drawn against AMCo and we say it should not.

Can I go to the fifth issue, and a little bit of law for a change. This is market definition, which is not actually unimportant in this case. I will do market definition and then double standards, and hopefully we can finish by lunchtime and then Mr O'Donoghue can take over.

Market definition, if I could go to our closing submissions at {IR-L/8/42} where we deal with market definition at paragraphs 83-91.

If the Tribunal just wants to -- rather than me reading it out. It is very, very quick. But essentially these paragraphs are making three points. The first point is, with respect to the CMA and Professor Valletti, they confuse the relevant competitive constraint. The CMA's regulatory constraint, the drug tariff regulatory constraint is, we say, a market power consideration, not a market definition consideration, and I will come on to that in a moment.

But that regulatory constraint is a market power consideration, dominance, not a market definition consideration. That is the first point we make in these paragraphs.

The second point is that --

THE PRESIDENT: How does one differentiate between the label

that one is applying? You have said that, but why is that right?

MR BREALEY: The straight answer to that is that the constraint dealing with market definition concerns substitution, whereas the constraint dealing with market power is whether you can sustain prices above a certain level. The two are clearly linked, but we will come on to this in a minute. Market definition is concerned with a competitive constraint about substitution. That is your exam question when you are looking at market definition.

When you are looking at market power and how high prices are when you have power, the competitive constraint is relevant there and it is the magnitude of the competitive constraint, and importantly, any external factors, but not concerned with competition as such. For example, a regulatory constraint or buyer power.

So clearly a competitive constraint you will see in the guidelines on market definition and you will see the reference to competitive constraint in the guidelines on market power, but they are performing two different functions. The exam question on market definition is about substitution, as we will see; the exam question, competitive constraint on market power, is about whether

that constraint allows you to price above a certain level.

THE PRESIDENT: Of course, you are right that the test for market definition looks very carefully at substitutability.

MR BREALEY: Yes.

THE PRESIDENT: But the reason it is doing that is because you are trying to identify the ambit of your enquiry in terms of whatever question you are asking next, whether it is a merger question or whether it is an abuse of dominance question or whether it is a collusion question. What you are doing is you are trying to work out the terrain over which your enquiry should run.

MR BREALEY: Yes, and let us just pause there, whether it is a horizontal agreement or a vertical agreement. We are not really into market power there --

THE PRESIDENT: No.

MR BREALEY: -- and it is key, for market definition, to know whether you are actually competitors and so substitution is relevant to that market definition question. Substitution is essentially the exam question when it comes to market definition. Do consumers regard product A and B as substitutes? If they do not they are in separate markets, if they do they are in the same market.

THE PRESIDENT: Yes, and just to complete the thought, we try to respect consumer choice by assessing substitutability not by reference to, as it were, the objective criteria that attached to a given product or products but by reference to price, which then provides the link to something I am sure we are going to be coming on to, value.

MR BREALEY: Price is obviously very relevant, but so is consumer preference, as we will see. If you have an ethical barrier to buying product B -- at some point, we will come on to this, at some point price probably matters, but that is not what economics are all about and market definition is all about.

THE PRESIDENT: Well, I think that is actually quite an important question --

MR BREALEY: It is.

THE PRESIDENT: -- which we may need to grapple with. We had it in, as Ms Demetriou will know, in *BGL* where we, as a Tribunal, were not particularly helped by a SSNIP that was reframed as persistent diminution in quality, and the reason we did not like that was not because it is not a philosophically intelligible test, it is because immediately you get sucked into the Tribunal trumping consumer choice, and that is why price is such an important element --

MR BREALEY: Absolutely.

THE PRESIDENT: -- as opposed to, let us say, ethical restrictions which are inherently subjective and therefore quite dangerous. Price is a very good mind game hypothesising an increase, because it gives free rein to what the market, which after all comprises many individual consumers, not a single global response, it provides a very good mind test as to, or thought experiment as to what would happen.

So if you are assessing substitutability by reference to other features, and of course Ms Ford has a functional substitution because she says price does not really help in this market, well, I think one is moving away from the comfort zone of using price as the determinant.

Now, it may be inevitable that that is what one has to do, but I think it is a SSNIP for a very, very good reason.

MR BREALEY: I totally endorse that, but the two are linked because you may have an embedded preference for something which means no matter what price rise you are going to get, you are not going to switch, and that is what happened here. We will come on to that. But the first point is you have to identify the purpose of the regulatory constraint. In my submission the purpose of

a regulatory constraint when it comes to market definition is to look at substitution. When you are looking at a regulatory constraint for market power it could be -- that is Professor Valletti's, we say.

Can I come on to the second main point, because nearly everyone accepts that the market was bifurcated. The question is whether the bifurcation means there are two distinct segments in one market or the bifurcation was such that there were two markets. So everyone accepts essentially two segments, but are they two segments in one market or are those two segments distinct markets of their own?

That is where, again, the exam question is, we say, the two segments actually formed two distinct markets. I will just highlight the facts that I pray in aid in support of that.

The third point we make in these paragraphs is that if there are two markets it does matter, because we say that the supply agreement with Auden is effectively a vertical one with a small bit of horizontal, if you want, but it is essentially a vertical one and that alters the object analysis. Can you say that the object of this agreement was so clear and obviously to distort competition when, for example, on the CMA's view 50% by volume is de facto incontestable, 70% de facto

incontestable by value and the remaining 20/30% is still restricted.

So there is a kind of a legal conundrum here which does affect how competition law treats an agreement of this -- it is not just a pay-for-delay where someone could enter the market and you have 100% competition. You have a situation here where, even on the CMA's case, 50% by volume, 70% by value was de facto incontestable.

If you are going to give any meaning to that word, if it cannot be contested, strange to say that you are competitors. So from a legal analysis, a legal characterisation, it does matter.

THE PRESIDENT: The trouble is we are all guilty of using the term "market" as if it bears a single meaning --

MR BREALEY: Yes.

THE PRESIDENT: -- and in fact it does not, because markets are in very many different shapes and sizes, and the problem we have here is that we are very far from a vanilla market where one has a group of buyers and a group of sellers who are operating with their own demand and supply curves.

I mean, even the way in which we use the term "consumer" in this case is, I think, giving rise to a very difficult question because one is not actually looking at the person who takes the medicament, the

patient; one is actually looking, when we say consumer, at the pharmacy.

MR BREALEY: Yes.

THE PRESIDENT: The fact that we are not even clear who the consumer is --

MR BREALEY: Correct.

THE PRESIDENT: -- is I think a very significant tell, going back to the oddities that I mentioned a few days ago.

MR BREALEY: Yes.

THE PRESIDENT: The consequence of that is that unless you strip away from your market definition exercise and do something really quite radical in your thought experiment, price as a test for substitutability ceases to be meaningful and you are driven to doing something else.

So you either, I think, in your thinking have to strip away the regulation and ask yourself what would happen in a more conventional market if the price was increased, or you have to re-invent the substitutability test along different lines, which may be functional equivalence or whatever.

MR BREALEY: I understand that, and I am not sure whether I am going to say it helps me or hinders me.

THE PRESIDENT: I really do not know, Mr Brealey.

MR BREALEY: But what I can say is that in *Flynn and*

*Pfizer* one looked at the position from the pharmacy, so if you are supplying a drug, the customer is the pharmacy, and are they price or non-price sensitive, what are they going to -- so it is the dispensing practice of the pharmacy which particularly in *Flynn and Pfizer* was dictating market definition and market power.

THE PRESIDENT: Yes.

MR BREALEY: People have been, in this case, proceeding on that basis. Clearly it is a very, very odd market. We argued that it was a very odd market in *AstraZeneca* in the general court and in the main court, but I am focused, really, in these submissions on what was the pharmacy doing and how does the supplier of the drug to the pharmacy, how is it reacting?

If one looks at it from a supplier/pharmacy point of view, it is easier to see that you are looking at substitution, price, ethical, clinical reasons. I mean, in the *Pfizer* case it was a very narrow market because of the continuity of supply. That had nothing to do with price. It was all to do with continuity of supply, not switching a patient and therefore the pharmacy was careful that the patient should be on the same drug.

So it is the dispensing practice of the pharmacy

which in cases of this type tend to inform what the relevant market is and the market power, but it is not -- it is, I think, Advocate General Jacobs in *Smithkline*, I do not know the reference, but I remember him saying that this is a highly regulated market and it is not a commodity market as such.

THE PRESIDENT: No.

MR BREALEY: There are other things in play.

THE PRESIDENT: I mean, I entirely take your point. What you are saying is there is a difference in attribute between the full label and the skinny label, which in and of itself is an odd one because it is not the case that you cannot lawfully prescribe off-label. We have been very careful in our law not to say that because we want there to be a degree of doctor freedom in exercising their judgment.

MR BREALEY: Yes.

THE PRESIDENT: So you can lawfully do it, but there is nevertheless a distinct -- of course, we heard evidence about how far it matters -- that even though you have, pharmacologically speaking, exactly the same thing in the packet it has different attributes in that the MA lists different effects for which it can be prescribed. Yes, that clearly has an effect.

MR BREALEY: It does, it does. I am going to come on to

that in the last issue, which is the double standards. But it is not unlawful to dispense off-label but it is unlawful to promote a market, the CMA accepts in the Decision. So there is a burden on a supplier not to promote and market its product which is not licensed for an indication. AMCo simply could not go out there, and we will come on to the Alissa flyer in a moment and the back-up, but AMCo could not go out to the market and say: this does not matter. My product, my skinny product is bioequivalent and you can, oh, pharmacy, take it and dispense it to adults.

THE PRESIDENT: But cutting to the chase then, accepting all of this, in a market that is unusual, we will carry on calling it a market though I have to say I have some difficulty even with that label but let us call it a market, what is your test for substitutability? It is not price, or is it?

MR BREALEY: It is. Clearly we rely heavily, heavily on price --

THE PRESIDENT: Right.

MR BREALEY: -- because all the experts are essentially agreed that there were two categories of customer: a price-sensitive and a non-price-sensitive, and one can cite case law upon case law where markets are divided by reference to price-sensitive customers or

non-price-sensitive customers. So no, we clearly rely on price. We have done in our Notice of Appeal. Price is a very important factor, and that is in the Commission's guidelines. Is there a segment of customers? Are they price-sensitive? Are they non-price-sensitive? Business class? Economy class? Markets are divided, by reference to a category of customers, by reference to whether they are price-sensitive or not. We rely heavily on that.

But linked to that, what drives the non-price sensitive customer, it is an ethical, clinical perception that this should not happen. If one remembers the Wells memo, we can go to it, where they looked at how much extra profit they could make if they bought the skinny, but they still did not for clinical reasons.

So yes, price is absolutely, is a very, very important point in defining a market but then you have to work out what are the considerations behind the non-price-sensitive customers? Why are they sacrificing this profit? Why are they non-price-sensitive?

So that is all I am saying when it is quite important in this market, as we had in *Flynn Pharma*, continuity of supply. It ossifies the market. We are not a million miles away from that here.

Again, cutting to the chase, whether we need to go through the -- it is in there. On the question of substitution, I probably do not need to go to it because the Tribunal is familiar with it, but if one looks at paragraph 85 of our closing we rely on recital 13 and 14 of the guidelines, and indeed propositions 1-3 of the joint statement which clearly show that demand substitution defines the market {L/8/43}.

But cutting to the chase on the facts, there are two overarching facts, we say that prove that they are two markets, two critical facts. The first fact is that there are clearly two distinct groups of purchasers. They went in two ways, one price-sensitive, the other one having a greater ethical value, the other not caring. That is the first steer towards a separate market, these two distinct customers, one price-sensitive, the other not price-sensitive. One, the first one, having greater ethical clinical values than the other. That is the first fact.

The second fact, which in my submission absolutely nails it, is the fact that there are two distinct categories of suppliers. What happened was that Auden left the price-sensitive market. That is Professor Valletti's paragraph 74. Stayed away from the skinny. Auden not competing now in that segment of the

market. By contrast, Professor Valletti's 67, the skinnies stayed on the price-sensitive market and did not compete in the non-contestable segment.

So the clear facts in this case are you had two distinct customer groups, and the suppliers are focusing on those two distinct customer groups. Auden is only on the non-price-sensitive; the skinny suppliers are only on the price sensitive.

THE PRESIDENT: Leaving aside pharmaceutical cases, have there ever been market definition tests that have focused on an intermediate consumer, ie, someone who is in the supply chain and passing on the product to someone else? Generally speaking, one applies the SSNIP test to the ultimate consumer, am I right?

MR BREALEY: Mmm.

THE PRESIDENT: That is because it is -- the -- yes.

MR BREALEY: I do not know if you heard.

THE PRESIDENT: It may be context-sensitive in terms of mergers, collusion, dominant position.

MR BREALEY: SSNIP is applied not just to the ultimate consumer, the end-user, it is applied in a variety of situations, as Mr O'Donoghue has just told me, in a wholesale merger-type case. Because wholesale is often regarded as a different market to retail.

Really, the SSNIP test, one has to stand back.

I mean, it has this great label, but all it is doing is asking the question: will this consumer, with a 10% price increase, switch to another product? If it does --

THE PRESIDENT: Sure, but the only reason we are looking at it at the pharmacy level is because in this market the choices of the patient, the ultimate consumer are rendered essentially irrelevant because of the prescription price which sets a uniform price for drugs that are prescribed. So it does not matter whether the per packet price is £10, £30, £400. You still pay your £8.

MR BREALEY: But it matters to the pharmacy.

THE PRESIDENT: I agree, but is that why we are not looking at the ultimate consumer but at the pharmacy? Because in the regulatory market that we are looking at, a very important consideration regarding demand is removed.

MR BREALEY: The answer to that is yes. My experience of dealing with these pharmaceutical cases is that the parties ignore people like me who go to a pharmacy and get their Ventolin inhaler, I am not price-sensitive, I just want it.

The market is really defined by reference to the pharmacy level, as I just said --

THE PRESIDENT: Yes.

MR BREALEY: -- and the European Commission, the CMA all say that this is a quirky market where the ultimate consumer is fairly price-insensitive. Sadly, given where I am now in my life I do not necessarily pay for prescriptions. I used to. I was quite horrified when they said I did not have to pay for it. But you are not looking at the patient level.

THE PRESIDENT: No, I think we are agreed on that.

MR BREALEY: Yes.

THE PRESIDENT: But what I am pressing you on is, what we are doing is we are allowing the oddities of this particular market to shape, more or less without questioning, the nature of the enquiry that we are undertaking. So, we are all saying, you have to look at the pharmacy because actually that is the only area where price matters.

MR BREALEY: Yes, that is the standard way of looking at market definition and market power. I agree. I totally agree, yes.

THE PRESIDENT: I entirely agree, but that is where we are going back to the fundamental question of: does the process by which we define the thing that we call a market depend upon the nature of the market before us? Of course, where you have buyers and sellers and more or less a non-existent supply chain, you simply have got

suppliers, sellers and buyers, price is obviously key to working out how the buyers are going to react to an increase in sellers' price. Nice and easy.

What we have here is something completely different, and yet we are still saying price really matters. Unfortunately, we cannot actually go to the people to whom price really matters because the patient is insulated from price changes, so we are moving one up to the pharmacy because that is the best we can do.

MR BREALEY: Because in this country most people do not pay for their medicine, or they pay a percentage, a small -- they are not actually paying the price of the medicine, the Department of Health is.

THE PRESIDENT: Indeed.

MR BREALEY: That is why you detect from these decisions that the CMA regard the Department of Health as the ultimate consumer, the customer, because it is paying for it.

I do not think I need any pushing back on this because I wholly agree with what you are saying, sir. There is a completely odd market where the patient is not price-sensitive because it gets the drug come what may. There are oddities because of things like continuity of supply which will inform as to the nature of the market. Here, dispensing off-label, we say, is

a critical aspect of how this market is to be perceived.

Essentially the suppliers are having to sell and supply their product, and their market is through the wholesalers but ultimately to the pharmacy, because if the pharmacy does not pick up their product then they do not supply it.

I think you ask yourself the question: where is everything going on here? You are trying to sell to the wholesalers, you are trying to sell to the pharmacists. So that is where the competitive interaction is going, and yes, the patient is relevant because again, the continuity of supply may dictate how you compete.

THE PRESIDENT: Yes, but the one thing that is, on this thesis, irrelevant is the willingness to pay and the value that the patient attaches to the product that he or she actually uses.

MR BREALEY: Not quite. Yes, patient willingness to pay. That does not feature very much, but in the *Flynn and Pfizer* case, for example, that is why I keep on coming back to continuity of supply, it was bioequivalent, everything was the same and yet the only thing that mattered -- and it was an epilepsy drug, the only thing that mattered was the brand. The guidance was patients are going to get very stressed out just by having the same product but a different brand, *Pfizer*

versus NRIM, and all of a sudden, the market got defined by reference to the *Pfizer* product and the NRIM product, because the patient would be stressed out if there is a risk of a fit, if they saw, well, that is not my brand. So the patient is not irrelevant.

THE PRESIDENT: No, what I was saying is that certain attributes of the responses of the patient are relevant. I think you are agreeing at least in this context we are putting a pretty clear line through the price-sensitivity of the patient.

MR BREALEY: Yes, we are. I think that is fair. It is an odd thing but that is the way that the pharmaceutical market works, particularly in this country with the NHS and the drug tariff.

THE PRESIDENT: Yes. In an odd way what we are doing is taking a square peg and we are ramming it into a round hole and bashing away, because what we are doing is we are taking the traditional test and we are distorting it, and the reason we are distorting it is because it is the best we can do. That is really what it boils down to.

MR BREALEY: Again, I do not know if this helps me or hinders me, it is the best we can do but I can see the sense in how the CMA approaches this and the regulators approach it, which is that there is competition between

suppliers. The pharmacies are the people who are agreeing to supply this, and then you do get the oddities with the drug tariff and the patient's preferences which all feed into the mix. That is why I think you have to take all the things into consideration and that is why, when I come to the very last issue, and I am almost done on market definition, I think you have the point, that the non-price issues are relevant to how the market works.

That is pretty obvious really, because you are talking about people's health and perceptions and people have to be very careful about dispensing off-label. It may not matter for one product but it may matter for other products, because patients do get stressed out if they -- I am not giving evidence but I can well see that someone who is given a product that is for children takes it home and says, well, that cannot be for me, I am an adult, and you go straight back. There are all kinds of things going on here.

So, just on the market definition and then I will go on to the last issue. So on the competitive constraint I do pray in aid, as we say at paragraph 85, recital 13 of the EU guidelines, the court in *EasyJet* and then the joint statement, and the first three propositions of the joint statement when it is talking about the object

of market definition, all about substitution. It is all about the fear of substitution that is creating the competitive constraint. Standard.

We have referred to the CMA's guidelines on market power at paragraph 86. I do not need to take them up. You see them, they are at {M/39/1}. But here you are looking at the strength of any competitive constraint and, relevant to this, whether there are any extraneous factors which are preventing the person from raising prices above a certain level. For example, regulation.

We say that Professor Valletti's indirect regulatory constraint has nothing whatsoever to do with substitution. It has everything to do with how it impacts on the person's ability to price at an excessive price. So that is why we say there is a confusion here, and the market power, regulatory constraint should not be used as a market definition tool to unfairly widen the market where you clearly, on the facts, have two distinct customer groups and the suppliers are also in two groups, skinnies competing with each other on the skinny side, and Auden reserves the non-sensitive pricing.

If you look at how the CMA define the market in *Pfizer* and *Flynn* on a very narrow market basis, it is actually quite difficult to see how they come up with

one market in this case.

I will leave market definition, I just want to make one point, and I hope I have got the right citation but it is at paragraph 155 of our Notice of Appeal at {A/2/73}. I put this in very late on. I hope it is the right one. I do not have the Notice of Appeal with me. Yes.

I just want to make this point because I do not want it to be lost, but this concerns the third point that I was making about the legal characterisation of the market. We say at 155:

"It is hopeless to contend that an agreement to forego entry into an 'incontestable' part of the market is an object infringement."

It is counterintuitive.

"The purpose cannot be to reduce competition because competition cannot take place. The Decision spends a considerable amount of time arguing for a single market comprising both the adult and child's version, but this is beside the point. The fact remains that on the CMA's own analysis at least 50% by volume and over 60% by value of that single market is incontestable."

Then at 157 {A/2/74}, and this is the point that I just want to stress, "In the Decision" -- because basically, what then happens is the CMA says it does not

matter because this agreement still distorts the skinny segment. So okay, yes, you can give up the full label, we know you cannot go after that, but you should still enter the market, oh, AMCo for the 30% by value of the skinny market.

We say:

"In the Decision, at footnote 1166 ... the CMA says that 'for the avoidance of doubt' the 10mg Agreement would still have as its object the distortion of competition because, regardless of market definition, AMCo could still compete for the market that was not 'de facto incontestable': namely the 30+% by value or at the at most 50% by volume."

We make the point that it is quite inappropriate to relegate what actually is quite an important point to footnote 1166, because if there are two markets and you cannot compete for the full, it does impact on the object infringement. Is the agreement so clearly and obviously to distort competition if you are only going to be limited to that small part, that 30% by value?

We make that point, and I will come on to -- and this is now relevant to the very last point I want to make, which is dispensing off-label and the double standards point.

We deal with this issue in annex 9 of our closing,

which is at {L/8/259}. I know a lot of this is familiar, but there are a few things that you may not have picked up. It speaks for itself, but in the box you can see that we have set out the restrictions on marketing unlicensed drugs and then we set out the nature of skinny suppliers advertising campaigns and then we look at dispensing off-label.

I know that the Tribunal -- so the first point is the restrictions on marketing unlicensed drugs. This would still apply to that 30% that we have just been talking about. 70% by value you cannot compete on. So now we are told, well, you have to compete on that 30%. It is an object infringement, clear and obvious distortion of competition, if you do not go after that.

The first point we make is, well, there are restrictions on marketing unlicensed drugs and the conclusion on that is at paragraph 8 of the closing, which is at {L/8/261}, and Dr Newton was not really challenged on any of this. We say:

"It is clear therefore that when deciding what AMCo should have done in June 2014 (should it have entered the market with the child's version as the CMA implicitly alleges?) it is important to recognise that AMCo was legally constrained from promoting its 10mg hydrocortisone child's version for use in adults. And,

applying the ethics of the ABPI Code, a skinny supplier like AMCo should not be highlighting to a pharmacist that the medicine is bioequivalent to the Actavis medicine."

So applying the code, it should not be highlighting to a pharmacist that the medicine is bioequivalent to the Actavis medicine. That essentially, I believe, is common ground. It was the evidence of Dr Newton but you cannot go out there saying to the pharmacy: this is bioequivalent, do not worry about it.

Now, on this we then deal with the nature of the skinny suppliers' marketing campaigns. The Tribunal will know about the Alissa flyer, but I would like just the Tribunal to appreciate what Alissa was doing in the context of marketing its own product to the pharmacies and to the wholesalers.

To do that can we go to {H/1151/1}. That is {IR-H/1151/1}. This is a response to the CMA's notice on behalf of Mawdsley-Brooks, which is a small wholesaler. So they have been asked the questions and they have given the CMA some information.

If one goes to page 9 {IR-H/1151/9}. I will not spend time making submissions on it, we saw the cross-examination. In my submission that flyer -- that is a flyer, that is not the packaging, that flyer gives

the impression that this product can be dispensed for adults. One sees "Therapeutic indications", and there is no distinction between the children, adolescents, emergency treatment, and to home in on the word "dose" under therapeutic indications, in my submission that is -- a fair reading of that, Alissa is giving the impression that if I need this and I go into the pharmacy I am not getting a child's version here, I am getting something that can be dispensed in adults.

THE PRESIDENT: To call a spade a spade, this is a breach of the marketing restriction?

MR BREALEY: In my submission it is two things. It is unlawful because it is a breach of the regulations, but in any event it is a breach of the code because it is giving a message which is incorrect.

But I want to go on because I want to see what Mr Davies of Alissa did when he was discussing this flyer with the pharmacies.

To do that, I think if we go to page 12 {IR-H/1151/12}. This is relevant to my main point about the ethical standards which some people may have, some people may not. So if one goes down, please. This is from Rob Davies at Alissa to the relevant person at Mawdsleys.

"Good Morning, We have just launched Hydrocortisone

10mg tablets.

Ready to receive and despatch your order if it's of interest to you!

We will ring fence a quantity each month for you if you like, currently we will supply at £68.00 ...

"[Focus is selling the full up to £73-£74] We will only sell 10,000 packs a month into the market ..."

That, first of all, does not look to be for children's use, that is wider than the 5% children's use:

"As you would expect ..."

Etc., and then he says:

"We are one indication short on the licence and as a precaution I suggest you list as: Hydrocortisone 10mg tablets (Alissa)."

So he is drawing the attention to they are one indication short, which is the adult.

Miss P, if one goes up the page:

"Just going into an [executive meeting] -- what indication is missing?"

She says.

Then one goes up. You see there, "... because of the orphan drug" -- this is a reply:

"... we can only have the 'adrenal insufficiency' indication in children and adolescents!"

It goes on:

"I am told my behaviour qualifies me as adolescent! [smiley]

I discussed this yesterday with [the pharmacy] when I asked him about generic pregabalin [which is what we saw] he said he uses it on all [scripts]. So a somewhat similar situation."

THE PRESIDENT: The Pregabalin is the one that had the patent constraint.

MR BREALEY: Yes, which is why I said we would come back to it, because the pharmacies were quite concerned about it. Was it simply a patent issue or was it a wider issue about dispensing a product which does not have the right indication? But the fact that he is saying:

"I am told my behaviour qualifies me as an adolescent", because obviously his product is only licensed for children and adolescents, in my submission he is communicating, as he does in the yellow, it is:

"... considered to be equivalent to the reference product ... based on the data submitted."

He is saying to the wholesaler/to the chemist, this is bioequivalent, you can use it, but my behaviour is:

"[They tell me] my behaviour qualifies me as 'adolescent'!"

I take from that that he realises that there is an

ethical issue here, and he is not acting -- it is a bit of, "Do not worry about it. It is a bit of a joke but it is all right."

That is the nature of the communication. Now, whether you criticise it or not, at the end of the day in my submission it does not matter. I do submit, and I continue with the submission that that 30% that we are told about that was contestable actually would not have been 30% had Alissa complied with the guidelines. But let us leave that to one side, and if we go back to our closing at page 263 {L/8/263}, and "Dispensing off-label", and then we set out what Dr Newton's evidence was.

Then at paragraph 17 {L/8/264} we set out the evidence of certain pharmacies which almost mirror her evidence on dispensing off-label. It should only be done in the best interests of the patient, if there is no other product around, etc, etc. So the evidence of certain pharmacies clearly support what she said.

But for me, in my submission the punchline is at paragraph 20 of our closing, which is the CMA's view {L/8/266}. This is why I say there is a certain element of double standards here. We say, "In this context" -- so after having, as you said sir, the perceptions, the ethical perceptions, the clinical perceptions:

"In this context, it is important to appreciate the CMA's view on this issue. The CMA expressly states that it was reasonable for Boots and the other major pharmacy chains and national wholesalers (the assured customer base) to refuse to purchase the child's version in any significant quantities. There were ethical issues about dispensing a child's version for use in adults. But equally the CMA considered that it was reasonable for the independent pharmacies to dispense the child's version to adults."

We set out there the relevant passage of the Decision where the CMA says:

"As set out in section 3 ... above, the CMA considers that full label tablets are a differentiated product for which some customers had no choice but to purchase. Those customers were not able to switch to skinny label tablets, and so for those customers there were no alternatives. That sustained Auden/Actavis's market power because it was the only supplier of 10mg full label tablets. Further, the facts that the same regulatory regime applies to all customers or that dispensing is at the 'discretion' of pharmacies does not undermine this position:"

Then I have highlighted in bold why I think this is relevant:

"It is evident that pharmacies reached differing positions on whether to dispense full or skinny label tablets, but both are reasonable positions to take ..."

This is an important statement. It is saying both are reasonable positions to take. Pharmacies can dispense off-label or not, but at 21 {L/8/267} we say this is an important statement because when it comes to the CMA criticising AMCo and saying to Mr Beighton, well, why did you not go after the 30%? We appreciate that 70% by value was not contestable, but you could have gone after the 30%, different standards are applicable because the implicit criticism is that it was unreasonable for AMCo to go after that 30%.

In my submission the CMA cannot have it both ways. They cannot say, well, it is reasonable for the pharmacists to dispense off-label but also to be careful about doing it and then say to the supplier, well, it is unreasonable if you do not go after the 30%.

THE PRESIDENT: In other words, what you are saying is you need to have a degree of consistency in terms of how you analyse the supply chain, if you like.

MR BREALEY: Correct. That is why at paragraph 22 we set out the evidence of Mr Beighton, who says, look, I took the view in 2014 that I did not want to stimulate demand because I thought it was a reputational issue and

I thought it was an ethical issue.

Why is that stance so unreasonable? I cannot compete for the incontestable part, so he is told, he is specifically cross-examined and asked the question, well, you should have gone after the 30%, to which he says, well, do I really want to be the company, the gold-plated company that is going to have a reputational issue, an ethical issue? The whole of this exchange in cross-examination is about whether it would be an ethical, the right, appropriate thing to do, acting contrary to the guidance, to in some way promote dispensing off-label.

It is put to him, well, in 2016 when the market changed you did, to which he says, well, first of all, the market had changed, and I was not stimulating demand and the second thing is well, actually it is reasonable either way according to you, oh, CMA. So you have to be consistent in saying that it is a reasonable stance for AMCo to adopt not to stimulate demand but then, if demand has been stimulated, to actually launch what it did.

So that is why I say in the light of that passage in the Decision there is an element of applying double standards to AMCo and its view on dispensing off-label.

PROFESSOR HOLMES: Might one reconcile those two positions,

or is it relevant that the prohibition, as I understand it, is on marketing a skinny product for adult indication. So a supplier, clearly, to get to market needs to market its product. Whereas the pharmacy, there is no prohibition on actually prescribing or giving the skinny label for adult usage where there is an open script. Is that one way in which the two positions might be reconciled?

MR BREALEY: Erm.

PROFESSOR HOLMES: I am just testing the inconsistency and unreasonableness of the position.

MR BREALEY: That simply strengthens my point about whether that 30% is contestable, because the first thing I do is adopt what you have just said, sir, is you cannot market it. As a supplier you cannot market it. So now you have -- marketing is a lifeblood of any supplier trying to sell a product. You cannot market it as bioequivalent. So that is the first thing you cannot do.

Now you are talking about the ethics of promoting, of dispensing off-label. So let us assume that you can market. Let us assume you can market but it is now a question of whether it is an ethical thing to do. What the CMA says, well, it is quite reasonable for a pharmacist not to dispense off-label or it is

reasonable to dispense off-label. I do not mind. Both -- and so all I am saying is you have the marketing restriction.

PROFESSOR HOLMES: Yes, my apologies, I think I have those the wrong way round. I think I should withdraw that question.

MR BREALEY: Okay. The answer is still the same. In my respectful submission it is a strong point, and it is not an unimportant point.

I notice the time. Unless there are any further questions ... (Pause)

Ms Murphy is married to a doctor, and she has handwriting like a doctor. So it is a reference to the *Pfizer* case about market definition, and the reference is {M/150/45}. We do not need to take it up. The Tribunal says at paragraph 132:

"What matters, for this competition analysis, is what pharmacists ... did."

So that kind of supports that this is an odd market, but that is how the Tribunal, at least, in *Phenytoin* was looking at it.

THE PRESIDENT: Yes. We have no further questions for you, Mr Brealey. Does that mean you are handing the baton over to Mr O'Donoghue?

MR BREALEY: Yes.

MR O'DONOGHUE: I was not proposing to limber up for 90 seconds.

THE PRESIDENT: No, I think there is a limit to what even you can do in 90 seconds, Mr O'Donoghue. We will start at 2 o'clock. Thank you very much, 2 o'clock.

(1.00 pm)

(Luncheon Adjournment)

(2.00 pm)

Closing submissions by MR O'DONOGHUE

THE PRESIDENT: Mr O'Donoghue, before you start, and before we forget, we have produced a -- well, it is polite to call it a note, it is a loosely assembled series of thoughts on excessive pricing which will give those who are addressing excessive pricing something to tilt at in terms of just how wrong it is. So if we could circulate that now. It is not something that you will need to address, but --

MR O'DONOGHUE: I will be cogitating on that.

THE PRESIDENT: You can all cogitate over the weekend, and I think it will just assist us in understanding how far we have it wrong if you were to push back. So it is in that spirit that we have produced it. (Handed) Mr O'Donoghue, over to you.

MR O'DONOGHUE: Sir, thank you. In terms of the roadmap this afternoon I am reminded of what Sir Sydney

Kentridge once said. He was intervening before a judge in relation to prolixity from his opponent, and the judge says, Mr Kentridge, we should give him some latitude. He says, my Lord, it is the longitude I am worried about.

So, sir, in terms of my roadmap in this afternoon I want to spend most of my time on the agreement issue. I have very little to say on market definition thanks to Mr Brealey's sterling efforts. I have a relatively limited amount to say on object, and equally a somewhat limited amount to say on penalty so we should be well on track on the timetable. I think if anything we are slightly ahead.

So, sir, starting with the agreement. On the existence of the alleged 10mg agreement I want to focus on two points in particular. First, the negotiation implementation of the two written agreements, and second, the Aesica development project. What I want to do in particular, sir, is give the Tribunal a very clear sense of the key contemporaneous documentation on each of these points, because first of all the way in which the CMA's cross-examination was conducted, the Tribunal has actually seen very few, if any, of these documents. Of course, a good card player never shows his or her bad cards. Second, of course the sheer volume of paper in

this case is enormous and there is a risk of many needles not being found in the haystack, so I hope that is helpful.

In terms of my overarching point on the written agreements, it is manifestly important to focus on what was actually agreed, and our case is a very simple. The first written agreement and second written agreement reflect faithfully what was agreed which, as I will show you, was initially the CMA's own position during the administrative phase.

I will show the Tribunal the key contemporaneous documents showing that the written agreements accurately reflect what had been agreed and that those written agreements were observed in practice, and we say that once account is taken of the contemporaneous materials that I am about to show you, the suggestion the CMA has made that there was a sham or any broad or any unwritten common understanding is as unworthy as it is misguided.

THE PRESIDENT: Mr O'Donoghue, that will be very helpful because we are conscious that we have not as seen as much as we should have done of the facts, and the facts matter. But just to ensure we are on the same page legally, Ms Ford and I debated the test for shams and written agreements. If you have any disagreement with that then of course we would like to hear it, but if you

are, broadly speaking, happy with the way we described the court's approach to shams then obviously focus on the facts rather than the law, because --

MR O'DONOGHUE: Sir, the short answer is yes, I am content. In a sense, sir, we say this is quite straightforward. I mean, the test for a sham is: what was the common intention? Is what was it written or was it something else? In a very real sense, there is a congruence between that and actually the law on evidence and the law on agreement, because one could look at this in one of three ways. One could look at the sham case law, which is what was actually agreed; one could look at it as a matter of evidence. What are the inherent likelihoods, if parties have reduced a bargain to writing, is it likely that that written agreement reflects the actual agreement or is there some other agreement? Again, that is a matter of evidence and inherently likelihoods.

Likewise, even as a matter of competition law one is trying to define or understand the joint or common intention. So we say there is a congruence, one is trying to ascertain what is the common intention. But we say plainly where there are written contracts, and as I will demonstrate, these are genuine contracts faithfully negotiated and implemented, then we say there

is only one answer. It is the written agreements.

Sir, if the Tribunal will forgive me I will start with the second written agreement, slightly out of sync, since the vast majority of evidence the CMA relies upon actually comes from this period.

We say the rationale for the second written agreement is very clearly explained in a couple of contemporaneous documents. If we can first go to {IR-H/487/3}. If we can scroll down to hydrocortisone, or starting with Carbimazole then hydrocortisone:

"We are having further problems with our own product which we have developed with Aesica. It is now due in July. We are conscious that it will not have the key 'adrenal insufficiency' indication which Auden's product does have ... Auden have suggested that they would supply us with their OD status hydrocortisone for a lower COGS than we will get from Aesica, which we are considering. [Mr Beighton and Mr Sully] are discussing the practicalities of this and getting it checked by Pinsent Masons from an anti-trust perspective. Pinsents will review the contract if we decide to go ahead with this."

Now, just to complete the picture, {IR-H/547/1}, please. So this is obviously post the signing of the agreement, 9 July:

"We have recently signed a supply agreement with Auden McKenzie under which they will supply us with hydrocortisone tablets in the UK. I attach a copy of the contract ... Auden will supply at least 12,000 packs per month ... the rationale, as you are all aware, is that their product does not fall foul of the Orphan Drug status issue, whereas the new product that we are developing the Aesica does (so we have signed this agreement to ensure continuity of supply to our customers while we work out what we are going to do about this OD issue)."

Now, we say the reference to "as you are all aware" is important. Everyone within AMCo knew about the lack of an available market at that stage, and AMCo was therefore, adopting a "wait and see" approach of trying to keep its toe in the market while figuring out its alternative options, and Mr Brealey has shown you a range of documentation making good that "wait and see" approach.

One final document if I may, {IR-H/552/1}. Scroll down, please. It is Mr Sully to Mr Beighton and others:

"It is a real shame that this Orphan Drug [designation] issue has meant that we have had to hold off on launching this (though hopefully we can find a way to sort out the OD issue)."

So we say the context and rationale for the second written agreement very clearly arose out of, first, a lack of certainty as to if and when Aesica would produce a product in commercially saleable quantities, and second, working out if something could be done about the orphan designation issue, for example seeing if the market attitude would change over time or perhaps looking at alternative options.

The Tribunal may have picked up in the last days that, for example, there was discussion during this period of buying the 20mg hydrocortisone full label product from Waymade, and there was a discussion over the course of June and November 2014 of buying Plenadren. So AMCo at this stage had a number of irons in the fire and it was investigating its options, waiting and seeing and trying to see what would pan out and when.

Now, that is by way of context and rationale for the second written agreement. What I now want to do with some care and precision, is go through the negotiations of the contract quite slowly.

If we can start, please, at {IR-H/500/1}. So, this is Mr Sully to Pinsents. We have actually seen this, I think, or we have seen part of this chain. So the first duck that Mr Sully wants to get in a row is to

give Pinsents a heads-up that this second written agreement is being considered, and what he is seeking, as we see there, is effectively an initial or preliminary view from Pinsents. If we can scroll down, please. You see, "In advance of our telecon" -- so this is 5 June:

"In advance of our telecon with Auden tomorrow, I was planning to send them an email with the attached draft ..."

and so on. So he is sending a draft contract to Pinsents for a preliminary review from a competition law perspective. As you see, he alludes there to a call the very next day, with Auden.

Now, there is an attendance note which Mr Brealey touched upon. It is at {IR-H/501/1}, please, and it starts at page 2 {IR-H/501/2}. Mr Brealey looked at this in terms of what was on Mr Sully's mind during this period. I am actually looking at it for quite a different purpose, which is: what does this tell us in terms of recording the negotiations which took place on this day?

If I can invite the Tribunal first of all to read the entire email including down the page.

THE PRESIDENT: Yes, if we could minimise it, get the whole page on. Thank you. (Pause) Is there more on the next

page?

MR O'DONOGHUE: Just the bullet at the top, sir, and the last line.

THE PRESIDENT: Yes.

MR O'DONOGHUE: So, as the Tribunal will see, this was a two-stage process. There was an internal meeting between Pinsents and AMCo first of all, then followed by, it looks like, a conference call looping in Auden and its external lawyers, JGR Law.

So a few points, if I may. First of all, this is a formal attendance note of both the internal meeting and the bilateral discussion, so it is a formal record of what was discussed made by a conscientious solicitor, and if we go back to the previous page, please {IR-H/501/1}, you will see there was Mr Sully of AMCo, Mr Beighton, Amit Patel, Auden and Charlie Duran of JGR Law who was Auden's external counsel. You will see the purpose of the call was to discuss entry into the agreement and a number of the key commercial terms. Then the next paragraph, very important {IR-H/501/2}:

"Of key concern for AMCo was Auden's ability to prevent AMCo from launching its own ... hydrocortisone and ensuring continuity of supply ... once it entered into the agreement."

I ask you to note the "the key concern", and then

further down the page it says:

"As a result of the orphan designation ... AMCo has decided the best commercial is to source 10mg ... from Auden ..."

and so on. Then, critically:

"The following terms were agreed in principle:

The template ... would be the previous agreement ... subject to the following changes:

- 2-year duration.

- ... [it] would provide Auden with at least three months' notice of its intention to do so."

So as you will see, sir, there was an exclusive purchasing obligation coupled with the ability, the carving-out of own development and own supply possibilities with a three-month notice period. Minimum volume of 12,000 packs, and then at the bottom of the page {IR-H/501/3}:

"It was agreed that Rob Sully would circulate the amended agreement that Rob and Charlie Duran [who was the external lawyer for Auden] would finalise the terms."

The last sentence is important:

"Please do let me know if there is anything which I have missed or is not as you recollect."

So she was asking for this to be a faithful record

of what was discussed.

So we would suggest it is obvious in the 6 June attendance note that what took place, at least in the second half, was a negotiation between all of the principals under supervision from internal and external legal counsel, and all of that is formally recorded in an attendance note for the sake of good order.

Now, we saw, and I emphasise that the ability for AMCo to enter with its own product was a key concern, and as we will see, this in particular was the subject of hard-fought further negotiations and hand to hand combat between Auden's and AMCo's lawyers.

We mention in footnote 162 of our closings there were seven drafts of the second written agreement exchanged between the parties over a period of about two weeks, and I just want to look briefly at the evolution of clause 2.2 in particular of the second written agreement. We say it is clear from that evolution that AMCo was very insistent on having maximum freedom under the agreement to launch its own product.

If we can start, please, at {IR-H/505/6}. So this is a mark-up of the draft contract being kicked around between Mr Sully and Auden's external lawyer from JGR Law. So this is a draft dated 13 June 2014, and it shows the changes made by Auden and you can see under

2.2, if we scroll down, please, that Auden's external lawyer is trying to broaden, from Auden's perspective, the scope of clause 2.2 by inserting a restriction which would have prevented AMCo from acquiring a competing hydrocortisone product from a third party. The second major change proposed for my purpose, if you go back a page to page 5, under the definition of "Product" {IR-H/505/5}, you see a cross-reference to 2.2. 2.2 cross-refers to that, the definition of product, or the term "product" is repeated there.

The amendment is said to include any medicinal product containing hydrocortisone as the active ingredient or one or month similar active substances, and the latter was in turn defined to mean the same principal molecular structural features which acts via the same mechanism. So this was Auden's request for amendments to the contract.

Mr Sully then replies to this further round of negotiation, if we go to {IR-H/511/5}, please. For some reason this does not have track changes. It has comment bubbles. So, as you will see under "product" he has narrowed the definition of product to refer solely to Auden's 10mg hydrocortisone tablets, and then you see a comment bubble:

"We are unclear why this wider definition is

necessary when the agreement is that AMCo will not sell a product which competes with the Auden product. This definition goes wider and would prevent a number of other products, such as injections ... This wording is also needed to make sense of the agreement in relation to deliveries of the Product and also points like 8.3 regarding AE's of the Product."

So he is pushing back firmly on a suggestion that the definition of product would be broadened in the manner that Auden intended.

If we then go to the next page and clause 2.2 {IR-H/511/6}, again he is pushing back firmly. As you see, he deleted the proposed restriction on AMCo acquiring competing products, and we see in the comment:

"We have been advised by Pinsents ..." and so on.

So there is a process of negotiation of backwards and forwards going on, where Mr Sully in particular is fighting AMCo's concern on its ability to enter the market firmly and with conviction.

Now, if we then go to {IR-H/509/2}, please. Perhaps we could put pages 1 and 2 of that document on one screen. So, here Mr Sully is reporting internally on where the negotiations have got to on clause 2.2 in particular, and he is explaining, you see over the page, the material terms of the agreement. So this is to

a number of senior people within AMCo, and if we look on the right-hand side where it says "basically", so he is explaining clause 2.2:

"It basically means that we cannot sell any other products during the 2-year term of this Agreement which compete with Auden's hydrocortisone ... unless we first give Auden three months' notice (and Auden can terminate ... if we say we are [not] going to do so."

Then if you look on the left-hand side and to the top of the page you will see that no objections to the clause are expressed in the internal email thread.

So he is reporting back to his principals on where they have got to in the negotiations and explaining in clear terms the scope of the clause from his perspective, and no one internally has recorded any objections or other dissent in relation to that.

Now, moving forward to 18 and 19 June Mr Sully exchanged a number of further emails both internally and externally with Auden's lawyers, again, around this particular clause. If we can go, for example, to {IR-H/517/1} and it is about halfway down to Mr Beighton. He says "they", "they" being Auden:

"... are trying to be very cute around the non-compete and, I suspect, trying to tie up our ability to compete, to acquire other competing products or to

give 3 months' notice and sell our Aesica version (albeit with the OD issues). I really don't like this, nor trust them. So I am going to propose that instead of their overly complicated (and therefore risky to us) wording, we go with a simple clear English summary of what the non-compete should say ..."

That is where you see the text that he is proposing, and again, two very simple parts, an exclusive purchasing obligation, one, and an express carve-out of own entry and own supply and own manufacture possibilities for AMCo, two, subject to a three-month written notice period.

He says:

"I think that this is much simpler and will avoid all kinds of confusion, and in particular will avoid us getting caught up in some dispute if we proceed to buy Plenadren ..."

Sir, that was the point I mentioned a bit earlier, which at this stage AMCo had a number of other irons in the fire to see if it could get around the orphan designation issue, and you see a reference to Plenadren here. One of the many reasons Mr Sully did not want to tie the company's hands was he wanted to make sure that these alternative possibilities of getting around the OD issue, or potentially so, were preserved to the maximum

extent possible and he was highly sensitised to the suggestion that Auden would in any way seek to limit multiple entry routes. He says at the end:

"We know we have this OD issue which we cannot currently get around, but Auden should not seek to extend their rights any further than that."

So, again, we see Mr Sully pushing back hard in the interests of the company and a tough negotiation backwards and forwards with Auden, with on the AMCo side no quarter being given or taken.

Then if we go to {IR-H/517/1}, please. Top of this page, please. Mr Beighton:

"I'm fine with it Rob."

So clause 2.2 in the form set out here has been expressly drawn to Mr Beighton's attention by Mr Sully, so he is looping back via his CEO for approval on the contractual proposal that he is putting forward, and he has obtained the necessary sign-off from Mr Beighton.

Now, then just over an hour later, if we go to {IR-H/518/1}, please. We see Mr Sully emailing the external lawyer for Auden, Mr Charles G, you see the name there, and copying Mr Amit Patel of Auden, attaching a further version of the agreement. His cover email introduced the new drafting which we saw in the email one hour before this to Mr Beighton. You will see

then the second paragraph:

"The only remaining material issue is the non-compete. I'm afraid we don't like the complicated and confusing 'active substance' definitions that you have proposed. They are open to all kinds of interpretation ... likely to lead to argument ..."

and so on, and the next paragraph:

"We propose that the non-compete in 2.1 is therefore changed to a simple clear English summary of the agreed position, which is that AMCo shall not sell other hydrocortisone tablets without giving 3 months' notice (which would allow Auden to terminate on 3 months' notice). This would look like this:"

Then he pastes in the clause.

If we then go to the next tab, it is {IR-H/519/1}, please. If we can go down to the middle of the page, please. So this is Auden's external lawyer saying, the same day:

"Your amendment is broadly acceptable with a few tweaks visible in the DV."

Which is the Deltaview, which he attaches.

Then finally, just to complete the picture, {IR-H/495/1}, please. So Mr Sully has secured the clause that he wants in clause 2.2. He has maximised AMCo's freedom to enter in a way and a time of its

choosing, subject to the three months' notice, but for sake of good order he again goes back to Pinsents in the middle, and she says:

"Good to go ..."

So that is the negotiation of the second written agreement.

Now, just to complete the post-second written agreement implementation before I make some submissions on the back of this, and I can be brief here, we say the picture is actually quite straightforward and clear. Given the detailed negotiation we have seen, supervised very closely by internal and external lawyers from AMCo and Auden, it is unsurprising that the agreement was in fact implemented by AMCo and there was no other agreement.

Now, one immediate action of implementation which Mr Sully took which is important is at {IR-H/547/1}, please. You see the underlined text:

"The most important point is that this agreement, like the OLS with Teva for our supply of Levothyroxine, requires a Chinese wall to be put in place: now that it is signed, there should be no further dealings between the Commercial team (including JB [Mr Beighton]) and Auden -- instead the operation and working of the agreement should be run by a combination of [and you see

the people mentioned] and me ... This will avoid any competition law issues."

So again, you see acute sensitivity to compliance with competition law both as to form and as to practical substance. He is putting in place structural measures within AMCo to ensure that there is no cross-contamination between commercial and the product development side.

THE PRESIDENT: Mr O'Donoghue, just, I see in the underlined bit a reference to no further dealings including with Mr Beighton. We saw cross-examination of the communications that were undocumented between Mr Beighton and Mr Patel. Do we have any understanding as to when in the time frame those occurred? In other words, did they taper off or can we assume that they were conducted at a sort of constant rate throughout the time, or do we just not know?

MR O'DONOGHUE: Sir, I will have to come back to you on that, it is not something I have at my fingertips.

THE PRESIDENT: No, I quite understand, it may be that the answer is "do not know", because of course if the other documents are there --

MR O'DONOGHUE: We will check, sir.

MS DEMETRIOU: Sir, if I can help, by giving indications, of course at the beginning of 2014 the negotiations had

collapsed and they revived at around April 2014, so we see -- what I took Mr Beighton to in cross-examination is a record of various texts and calls and meetings during April, May and June of 2014.

THE PRESIDENT: I am very grateful. Thank you, Ms Demetriou.

MR O'DONOGHUE: Sir, we will double-check, but in any event, the simple point I am making here is that by the time of conclusion of the second written agreement we say the obligations were crystal clear, entirely above board, properly negotiated, properly supervised and, as we shall see, faithfully implemented within AMCo.

Now, the CMA makes great play in its written closings and other documentation of the fact that following the second written agreement there are internal AMCo emails showing that AMCo would not be launching at that stage the Aesica product, which the CMA says is strong evidence of its alleged promise.

But we say this takes the CMA nowhere. It is clear that the documents they rely on were in a direct response to a correct interpretation of the second written agreement, which again the CMA does not challenge as being an object restriction in itself, and I want to show you a number of the documents to make good that point.

First of all, if we can go to {IR-H/568.1/6}, please. If we can scroll down, please. You see, "Where Mr Sully advised ...". If I can ask the Tribunal to read that. (Pause)

THE PRESIDENT: Could you move the document up so we can see the whole paragraph? (Pause) Thank you. Then maybe two pages side by side. (Pause) Just because it forms part of a single continuous paragraph, Mr O'Donoghue, the nature of the blanking out, is that -- for what reason?

MR O'DONOGHUE: Privilege, I am told. It is not a Cinven document. It may be something Mr Brealey is better able to assist with. I understand it is privilege. I mean, so you can see it is headed "Competition law", so that may make sense.

THE PRESIDENT: Yes, it is just that reading that paragraph looking at the last three lines the "Further", one would rather expect a related anterior point being made in the blanked-out portion.

MR O'DONOGHUE: Yes.

THE PRESIDENT: Well, if it is privileged then so be it.

MR O'DONOGHUE: Yes. Sir, as we know Pinsents were intimately involved in reference to the advice they gave.

THE PRESIDENT: Yes.

MR O'DONOGHUE: Sir, from my perspective, what I say we get from this is a pretty faithful recitation of the terms of the second written agreement, and of course this is how it has been reported to the board and it is therefore, of some significance because of that. They were told about the written contract and not about something else.

Second, if we can go to {IR-H/591/3}, please. If we can scroll down about halfway down. So, they say:

"However for contractual reasons, we cannot sell this product in the UK."

Again, this is plainly a reference to the contract, the second written agreement, and of course it is entirely true because under the contract AMCo was required to give three months' notice of an intention to sell, which the CMA does not say itself amounts to an object restriction.

Two more references if I may. {IR-H/551/2}, please. You see the top of the page:

"We can't legally due to the exclusive agreement we have."

So again, plainly a reference to the second written agreement and not some unwritten agreement.

Then finally, {IR-H/582/1}. The bottom of the page, please. You see the middle bullet:

"... no intention to release [the Aesica product] to the market due to contractual reasons."

So these are all clearly references to the second written agreement. They expressly refer to a contract.

Now, bizarrely, at paragraph 147 of their closings the CMA relies on many of the same documents to support a case of an unwritten agreement. But we say they do not help the CMA one iota, because they are plainly referring to the written contract which, again, at the risk of repetition, the CMA does not object to.

In many ways we say the clearest proof the second written agreement was clearly implemented by AMCo was that it did not run its full course. Instead, once AMCo realised in early 2016 that customers' attitude to the skinny label product had changed, the documents that Mr Brealey showed you, it did enter the market. That was precisely what Mr Sully had fought for in clause 2.2. The second written agreement allowed AMCo to see if the orphan designation issues would change in the market and then to pounce when they did.

There was no agreement not to enter; instead AMCo preserved its right to enter and entered unilaterally at a time and for reasons of its own choosing. So in many ways we say this is the proof of the pudding: they were adopting a "wait and see" approach, and when the time

was ripe they jumped, and customers' attitude had changed and they entered with a skinny label product. As Mr Brealey showed you, that was due to a dramatic change in the market that was significantly different from 2014.

I just want to pick up two final points on the contract before I make a number of more detailed submissions as to where this takes us. First, if we can go back to the written agreement. It is at {IR-H/528/7}, please. It is clause 4.6, if we can scroll down. So there we have a clause which deals with parallel trade within the European Economic Area, and it makes express reference to the permissibility of passive sales. This is yet another indication of an agreement that was drafted in strict compliance with competition law. You will see an express acknowledgment that passive sales should be permitted, or at least not restricted, which in my submission indicates a mentality and reality of competition law compliance and not the opposite.

The second, sir, in relation to a question you raised about the issue of trade dress or livery. That, of course, also is addressed in the contract and there is quite an elaborate system under both agreements in relation to how that was intended to work.

If we can go back to page 6, please, the previous page {IR-H/528/6}. The first clause is 3.2. It says, "If and to the extent that ..." and so on.

So Auden would have to apply to vary its marketing authorisation, add AMCo as an own-label distributor in AMCo trade dress, and the clause only bites and if to to the extent that Auden and AMCo, and I quote "reach agreement to submit application". So, in a sense there it is an agreement to agree.

Then 3.2, you see that the costs of the application were to be borne by AMCo, and then 3.5, if the application is successful then the parties have to work together to switch from the Auden trade dress to the AMCo trade dress and so on.

So there is a somewhat elaborate contractual mechanism in relation to a change in livery and get-up, and just to complete the picture on that, it is {IR-H/483/1}, please, and it is the last sentence. This is Mr Beighton to Mr Patel:

"We obviously would prefer our own livery though we would be happy to work towards this over the coming months."

So at least at this stage the clause has obviously mattered to Mr Beighton in some sense even though as far as we know it was not actually activated. Of course, we

do not really know why that was. It was not something the Decision really focuses on. But it is possible that AMCo having only a skinny label marketing authorisation for promoting a full label product on its own brand created some scope of regulatory issues. Again, I am speculating to some extent. But we do know from what Mr Brealey showed you in relation to Mr Beighton's cross-examination that he was pretty fastidious about anything which seemed to him ethically or reputationally questionable for the company. This may help explain why, despite having some enthusiasm for activating the contractual clauses on own livery that it seems that did not in fact happen.

THE PRESIDENT: Because all other things being equal, particularly if you are seeking to enter the market in the future under your own brand, it would make sense to try to establish a beach head in the market under your own label in any event, but I think what you are saying is whilst that may be obvious all other things being equal, there are factors which have not been explored in the Decision and before us which might make that a little less than obvious course.

MR O'DONOGHUE: Sir, yes. Again, I am speculating to some extent. I do not want to give evidence.

Now, sir, of course you are absolutely right that,

all else equal, you prefer to have your own get-up than somebody else's, but of course this was an unusual set-up in the sense that AMCo effectively had one primary customer, which was Alliance, and of course Alliance knew perfectly well that AMCo had this full label supply, and because of that unique bilateral relationship in a sense both AMCo and Alliance would have been able to promote to some extent, I accept it is not entirely fungible with having your own brand and get-up, but they would have been able to promote to some extent that there is a new kid on the block that at least has a foot in the market, even if the livery is not ideally what it would wish to have.

So, my point, sir, is that it was not invisible and we say to the market that this was AMCo, notwithstanding the livery issue, that would have been known to Alliance because of its direct relationship with AMCo and likewise, we say, to Alliance's pharmacy customers.

THE PRESIDENT: There is no material evidencing working towards the goal over the coming months, just to quote from the last sentence of Mr Beighton's email here on the page?

MR O'DONOGHUE: Sir, we have not yet been able to find anything but we are still looking. I suspect the answer is no, but I do not want to be too categoric.

THE PRESIDENT: I am very grateful. Obviously if there is then a note on that would be appreciated.

MR O'DONOGHUE: Yes, we will do that.

Now, sir, in terms where all this takes us on the second written contract, we say that five key points emerge. First, we say it is obvious that the second written agreement was a genuine commercial agreement negotiated in good faith between senior officers within AMCo and Auden, under strict supervision from in-house and external lawyers including specialist competition law advice from a leading City practice.

That is plain, we say, from the back-and-forth, use of multiple drafts, acts of substantial negotiation, records of these negotiations, the wide dissemination of the rationale for, and outcome of, those written agreements widely within AMCo including at board level, and the implementation of practical safeguards under the contracts such as Chinese walls to comply with competition law. We say it is, on any reasonable view, a genuine contract being negotiated, concluded and actually implemented.

Second, the CMA's case that the written agreements were a sham is, we say, not only not made out but would be an unworthy claim in light of the overwhelming body of contemporaneous evidence to the contrary. Now, the

CMA says in closings at paragraph 107, and I quote:

"The CMA's case is not that there was a lawful written agreement, an unlawful side agreement, nor does the CMA have to show that the written supply agreement was a sham."

So that is what they say now.

So we see that they are now trying to disavow the suggestion of the need to show a sham.

We say there are two problems with that reverse gear. First of all, it is not what the Decision says. If we can quickly look at that.

THE PRESIDENT: Yes, let us do that.

MR O'DONOGHUE: It is {IR-A/12/37}, please. Scroll down, 2.27(c), please:

"The CMA no longer provisionally found that the supply agreements between Auden/Actavis and ... Waymade and AMCo themselves amounted to restrictions of competition by object, applying the Fentanyl framework. The CMA provisionally found that the evidence set out in the SSO amounted to a clear, traditional market exclusion agreement between potential competitors: Auden/Actavis agreed to make substantial payments to Waymade and AMCo and in exchange, Waymade and AMCo agreed not to enter the market with their own hydrocortisone tablets. In doing so, the CMA

characterised the supply agreements between the parties as a sham, meaning that their true purpose was for Auden/Actavis to pay Waymade and AMCo, rather than simply to give them product to sell as in a genuine bona fide distribution deal."

The second reference, sir, we do not need to turn it up, it is 6.884, it is {IR-A/12/807}.

So that is how it is put in the Decision. They found in the Decision it was a sham and they should not be permitted, we say, to row back from that.

Second, and in any event and in some ways more importantly, a sham must be the logical consequence of their case. They are trying to back away from it, but it must be the logical consequence. In my submission there are only two options. Either the written agreement is the faithful expression of the parties' intention or it is not. There is not a halfway house open to the CMA.

Now, of course you could say, well, some provisions of the written agreement are a sham but not all, so their case on a sham may well just be their clause 2.2 of the second agreement.

THE PRESIDENT: Well, that is usually the case, is it not, Mr O'Donoghue? I mean, usually it is to do with avoiding tax. That is most sham agreements. You

transfer a product and you disguise the nature of the transaction so that you pay less to the taxman. There are, in terms of characterisation, differences between the real agreement the actual agreement, but it is pretty rare for the written sham to be completely disengaged from the actual transaction. I mean, normally you have some provisions which are --

MR O'DONOGHUE: Yes, those are boilerplate, sir.

THE PRESIDENT: Exactly so, and in the examples I am thinking of, the transfer of the product is usually common to both the unwritten real agreement and the written fake agreement. So in short, I am at the moment at least agreeing with you that you do not have necessarily two completely distinct agreements which do not talk to each other.

MR O'DONOGHUE: Yes.

THE PRESIDENT: Actually, they do talk to each other, the point is the unwritten gloss is doing something to the written agreement in order to achieve what the parties truly want.

MR O'DONOGHUE: Yes. It is the real agreement, in other words.

THE PRESIDENT: Yes, indeed.

MR O'DONOGHUE: But that is the crux of it, because what the CMA needs to nail its colours to the mast on, and has

studiously avoided is what are they saying about clause 2.2? Two parts: exclusive purchasing obligation, express carve-out of right to enter subject to three months' notice.

This is tied into the point we have made from the very outset of this case that we maintain in written closings. The CMA has never particularised its case on what exactly is the nature of the promise and how that is distinguishable, if at all, from the written contracts.

What is the difference between the written contracts we have seen, particularly clause 2.2, and the alleged unwritten true agreement? We still have not had an answer to that rather basic question, and in my submission it is a pretty fundamental problem with the CMA's case.

The third point is that quite apart from the contemporaneous documentation the fact is, the simple fact is that the CMA never put to any Advanz witness that they were part of a sham agreement, and in particular, that clause 2.2 of the second written agreement was a sham or a fabrication and does not reflect the true agreement.

We have seen in the documents I have shown you already the high level of prominence of Mr Sully and

Mr Beighton in particular, and yet it was not suggested to either of them that they were a shammer or that they were at least aware of a sham being conducted by one or more other people from within AMCo, including one or other of them.

The high watermark of the CMA's case in cross-examination was to suggest to Mr Sully that AMCo knew the score. We say that manifestly will not do. A sham agreement is a very, very serious allegation that should not be pussy footed around or put in elliptical terms. To do so is unfair to the witnesses concerned in relation to what would, if true, be career-ending allegations.

Certainly, by the time of the written agreement the CMA gets no comfort from Mr McEwan, because as Mr Brealey told you, he had left by April 2014 so that point has to be put fairly and squarely to one or both of Mr Beighton or Mr Sully, and it was not.

Fourth, what is particularly problematic, we say, for the CMA is that the core aspect of its alleged infringement, that AMCo agreed not to enter with its own product, was the one thing above all that AMCo fought hard to secure in the negotiations and conclusion of the second written agreement. You will recall the email from Mr Sully saying: this was a key concern.

So at this point, at the stage of the second written contract, more than any other AMCo is fighting hard to secure its right to enter. It was probably the single biggest issue in the contractual negotiations, albeit of course price and volume were equally important.

Now, AMCo was, as we saw, successful in the sense that Auden's external lawyer, no doubt on instructions from Auden, accepted in all material respects the right to enter that AMCo insisted upon. So Auden agreed that AMCo had a complete right to enter with its own product subject to the notice provision.

That was the mental or joint consensus actually reached; AMCo would buy exclusively from Auden and could supply its own product at any time by giving notice.

We say it is impossible to contort the clear contractual understanding of the centrality of AMCo's right to enter with an agreement not to enter. The implications of the CMA's case, if it was right, would be extremely serious indeed.

It would mean that Mr Sully fought tooth and nail for securing a right to enter, when in truth that was a complete charade. On the CMA's case, it was the very last thing they wanted to do.

It would mean either that Mr Sully led Auden's external lawyer up the garden path when he insisted on

the right to enter being a line in the sand, or that Auden's external lawyer was somehow in on the charade.

It would mean that when Mr Sully communicated within AMCo why he was fighting hard to push back on Auden's wording and received internal support from Mr Beighton, that too was all made up.

As we saw, the second written agreement was explained in very clear terms internally to all the key decision-makers within AMCo on a basis that was completely faithful to its written terms and no other terms.

It would mean that when Mr Sully sought Pinsent's approval for the second written agreement before signing it, Pinsents was in effect being used as cover to approve a written agreement that was not the true agreement at all. Again, the alleged agreement is that the parties had agreed that AMCo would not enter.

Now, none of these extremely serious allegations was ever put to Mr Sully or Mr Beighton. We say there would have been no proper basis to put them, that in the absence of that being put the CMA's case runs into serious difficulties in relation to a sham.

Now, to take as a thought experiment, you remember the formal attendance note of 6 June 2014 from Pinsents. Pinsents went along to AMCo's offices, they met with

Mr Beighton and Mr Sully. They had an initial meeting on AMCo's position, the negotiations and what they wanted and so on. They then got on the phone to Auden and its outside lawyers and agreed the commercial terms in principle, and all of that, as we saw, was documented in the attendance note.

Now, if the CMA's case is right, who is lying here? Are Pinsents involved? Are Auden's external lawyers involved? Are we to believe that Mr Beighton and Mr Sully, Mr Patel arranged all of this as a means to cover their tracks? If it is none of these possibilities, then why does no one say, when they are negotiating AMCo's right to enter independently, hang on a second, this is all being done on the basis that you are not entering? It is a fundamental difficulty that the CMA does not grapple with.

Fifth, if as we say, the written agreements are genuine, they do what they say on the tin, it follows that it does not help the CMA in any way to point to contemporaneous evidence following the second written agreement being implemented as proof of the infringement, since again the CMA accepts that the written agreements are not infringements by object.

Now, this is particularly the case, we say, where the CMA cites evidence from Mr Beighton, emails from

Mr Belk and others pointing to the fact that following the second written agreement AMCo would at that stage be legally unable to sell the Aesica stock. But that was simply the automatic consequence of the three month notice period in the second written agreement which again, is not objected to, and we have seen in those emails there is express reference time and time again to the written contract, the exclusive agreement being the very reason why AMCo was doing what it was doing.

That is on any view the implementation of the written contract and is not proof in any shape or form of the existence of an alleged unwritten or otherwise different actual agreement.

We say that this clear evidence of faithful implementation of the contractual arrangements following the second written agreement is not just a neutral point, it is a point strongly in AMCo's favour. Far from being a sham, the second written agreement was faithfully implemented. That is the opposite of a sham. It shows genuine contracts that were made to be followed and were followed.

Now, in fact, somewhat ironically, the CMA's position in the original statement of objections in this case was that the written agreements were the faithful expression of the parties' contractual intentions. If

we can go to {IR-H/996.1/15}, please. It is 4.104:

"The CMA provisionally conclude that the First Hydrocortisone Agreement the Second Hydrocortisone Agreement constituted the faithful expression of the parties' intention to conduct themselves in the market in the manner described below."

And so on.

So on this basis, fine, the CMA changes its tune but we do not see how the CMA can say at this stage that it is implausible that the written agreements were not the faithful expression of the parties' intention. That was the CMA's own reaction of what is effectively a draft decision, having seen the agreements and at that stage quite a lot of the evidence.

In any case, it was never put to any of the witnesses before the Tribunal from Advanz that the second written agreement was anything other than genuine.

Sir, that is the second written agreement. If I can now move on, I think more briskly to the first written agreement.

Can I start just to set the scene with the Pinsents' competition audit which was conducted through much of 2013 up to January 2014.

We say this is important contextual evidence of the

corporate mentality within AMCo and its senior management during this period. As is common ground, from mid-2013 onwards AMCo via Mr Sully in particular commissioned Pinsent Masons to do a review of a number of issues concerning the business that it had acquired from Waymade and Mercury. This wasn't just about hydrocortisone on supply agreements with Auden but also concerned other supply arrangements, for example, the agreement AMCo had in relation to the supply of Carbimazole with Auden.

The eventual report which is at {IR-H/554/1} is about 40 pages and covers a wide range of issues, most of which are not concerned with hydrocortisone. So it was a root and branch competition audit of the newly acquired businesses.

I will come on to some of the details within the audit itself but it is noteworthy at this stage that Mr Sully's first instinct was to make sure any informal arrangements were formalised and second, to ensure that the arrangements AMCo had basically inherited from the acquired businesses were squeaky clean from a competition law perspective.

If we can go to Day 1 of the transcript, please. It is page 89, line 5. {Day1/89:5}. It says:

"I want Pinsents to be absolutely sure that I am not

missing something."

So this was the instinctive reaction of AMCo's most senior lawyer. We say it is hardly the reaction of a firm or an individual intent on adopting and maintaining clandestine arrangements.

In particular, AMCo was not seeking to limit in any way what Pinsents would look at. Mr Sully wanted nothing off the table. He wanted to make sure he was not missing anything and he was obviously keen to obtain, and we say, follow their advice. It was an open-book approach.

We then go to the report on page 20, {IR-H/554/20}. It is the bit in the middle highlighted. If I can ask the Tribunal to read from "We understand" to the end of (b), please.

THE PRESIDENT: Sure. (Pause). Thank you.

MR O'DONOGHUE: Sir, three points on the back of this. First of all, as we can see, set out there expressly Pinsents were obviously briefed by AMCo management and of course, Mr Sully, and Mr Brealey showed you before the lunch break an email from Mr Sully into which Mr McEwan gave evidence for Pinsents and critically there is no mention of any agreement not to enter. Indeed, as you can see, the full intention is to enter if they can secure a product.

Now, again, if the CMA is correct in relation to sham agreement, Pinsents was being wilfully and deliberately misinformed by some combination of Mr Sully or Mr McEwan or AMCo more generally because on the CMA's case the critical information, this unwritten promise not to enter was not disclosed to Pinsents.

Second, we would say that the content of this audit report insofar as it records contemporaneously what AMCo's position was at the time is strongly supportive of the evidence you heard from Mr Sully and Mr Beighton and indeed Mr Middleton and Ms Lifton. Pinsents are recording AMCo contemporaneously saying Aesica do not yet have a product, AMCo are somewhat unsure about Aesica's ability to deliver but if Aesica can get a product AMCo would then consider going it alone. AMCo did not want to be the in the worst of all worlds with nothing from Aesica and no supply agreement from Auden and AMCo was genuinely concerned that even if Aesica could succeed in making a product, the orphan designation issue might still prevent AMCo from competing with Auden.

The final point I would make in relation to this extract from the audit and the audit itself is that given that senior management within AMCo were aware of the competition law audit and had given Mr Sully full

authority to obtain and follow Pinsents' advice, there was every possibility of course that Pinsents might advise that the arrangement with Auden needed to be ended or materially amended in some fashion.

Now, AMCo of course could not predict what Pinsents would say, we say that the mere act of seeking this audit, the open-book policy is itself significant since it shows that AMCo was putting all cards on the table. It was effectively agreeing to be bound by the outcome of the audit, whatever it was and, indeed, there is no doubt about that. You may recall that Pinsents expressed a low-risk concern in relation to possible resale price maintenance. It would be important to avoid any suggestion of alignment in price between AMCo and Auden and that was something that AMCo was keen to avoid.

So insofar as low risk recommendations were made, they were followed faithfully by Mr Sully and by AMCo.

So again, the fact of seeking this audit is a significant act because they did not know what the upshot would be and they were effectively bound to follow that advice whatever it was.

The simple practical point, and the common sense point, is if this was a firm at this stage who had some clandestine unwritten agreement not to enter, divulging

to Pinsents these arrangements was on one view the last thing you would to do because there was every risk that Pinsents might say, well, we are concerned about this, we want this to end. So the act of seeking a full audit compliance we say is itself significant.

I am going to move on to the agreement itself. I wonder is that a convenient ...

THE PRESIDENT: Indeed, it is. We will resume at 20 past 3, Mr O'Donoghue. Thank you very much.

(3.11 pm)

(A short break)

(3.24 pm)

MR BREALEY: I am not cutting short Mr O'Donoghue, I could not do that. Could we just go back to that document at {IR-H/568.1/6}. It was the redacted bit.

THE PRESIDENT: Yes.

MR BREALEY: The next page. Sorry, if we go back. So going to the bottom of page 6, you see there, just so we have the whole thing:

"Mr Sully advised that it was extremely irritating that, due to the Orphan Drug status of the Auden product, the hydrocortisone product developed by the Company did not (and could not) include the key 'adrenal insufficiency' indication on its licence and SPC. As a result, it was inferior to the Auden product and so

a supply agreement had been made by Amdipharm ... in order to stay in the market while it considered its options."

Then I do not know why, I do not know whether it was the CMA or AMCo had the next sentence redacted, but I will read it and then I will upload it. So the sentence proceeds, after "options":

"Mr Sully explained that given the sensitive nature of such an agreement external legal advice from Pinsent Masons had been obtained in relation to the supply agreement."

So he is just informing the board of directors that he -- the company had obtained external legal advice as regards the supply agreement, and that is what it says.

THE PRESIDENT: Thank you very much, Mr Brealey.

MR O'DONOGHUE: Sir, can we first look at the first written agreement itself. It is at {IR-H/172/1}, please. If we can go to clause 3.2, which is on page {IR-H/172/6}. So again, two parts exclusive purchasing obligation, the first sentence, and then second, expressly carving out own supply, own manufacture and so on from that obligation.

Now, it was AMCo who insisted on this provision. We do not need to turn it up, but the clause appears in one of the very first drafts of the agreement. It is at

{IR-H/253/6}. The second point, if we can go to {IR-H/335/1}, please. It is Mr McEwan to Mr Patel:

"... I now attach a revised set of contracts which reflect the agreements which have been in place during the past 12 months."

So the first written agreement was not re-inventing any wheel, it was said to reflect the historic supply arrangements which had been in place for the previous 12 months.

Now, we say clause 3.2 coupled with what we see there is significant since the first written agreement, at least in isolation, is not objected to. If it is the case that the arrangements for the previous 12 months were the same then it is hard to see how the arrangements before the first written agreement were objectionable.

Now, sir, I obviously heard what you said about the oddities of the first written agreement. I think it is fair to say, in part because it is based on a template, that it would not get a double-starred first in a contract law exam, and so there are untidy aspects to this. Now, Ms Ford dealt with a number of those points in her submissions, and I think the fact that it was a legacy from a template in many ways caused as many problems as it solved. But critically, no one is

suggesting that clause 3.2 providing for a right to enter was not a genuine contractual provision that was important to AMCo, and we submit was different to what had proceeded it. In particular, it was not put to any of the Advanz witnesses that this particular clause was a fabrication or sham, for example.

The third point in relation to the first written agreement, so in temporal terms we are February 2014, albeit it was expressed to be retroactive, but during this period in early 2014 it is fair to say that relations with Auden were not in good shape. Indeed, it is probably the one point of common ground with the CMA since its own case in the Decision, it is at 3.501(a) for your refence, sir, was that by this stage the relationship between Auden and AMCo was experiencing a period of breakdown.

Now, just to see how this is reflected within AMCo at the time, if we can wind back to the end of 2013. It is {IR-H/268/11}, please. I think "Mr Beighton confirmed ...". So this is an AMCo board briefing on 3 December 2013 giving an update on the two products you see there. So:

"Mr Beighton confirmed that negotiations with Auden ... had proved difficult and that signed contracts had not yet been achieved ... Mr Beighton was hopeful

that contracts would soon be signed."

He says:

"... as a result of a more positive outlook on [Aesica] it was hoped that the Group would be able to obtain its own fully compliant product in the next 4 months and thereby move away from sourcing hydrocortisone from Auden under the legacy arrangements that had been inherited from the merger from Amdipharm."

So the board is being told at this stage, we have a difficult relationship with Auden, we have cautious optimism in relation to Aesica. If that cautious optimism proves well founded we want to move away from Auden and do our own thing with Aesica in the next four months or so.

The same thing is repeated in January 2014. We do not need to turn it up, it is {IR-H/346/3}, and of course there can be no serious suggestion that the board was being misled at this stage as to AMCo's true intentions. This was coming from Mr Beighton, straight from the horse's mouth.

Now, just to copper-fasten this, there is an important email from Mr Beighton in January 2014 at {IR-H/299/2}, please. It is in the middle:

"I really wish that we could find a way to put our own product on the market even without the indication."

So Mr Beighton is gagging to enter with his own product. Now, Mr Brealey showed you a number of documents from around this period. For example, if we can go to {IR-H/331/2}, please. It is about halfway down. Mr Clark is noting his frustration, this is 21 January his frustration with Aesica. So they were keen that things would progress well with Aesica, and things with Aesica were never straightforward so there is some frustration. Then {IR-H/332/1}, please. Next tab. You see about halfway down, this is Mr Sully, 24 January, he is recording the intention to document the arrangements with Auden and bring them to a close, of course, following in particular the Pinsent Masons's advice that all this should be fully recorded.

Now, there are three further important points around this period. Around the time the first written agreement was being negotiated AMCo had made significant progress on the so-called MIBE development, which was a full label product. On 15 January 2014 MIBE had finalised the dossier and applied for a marketing authorisation, so in the period immediately preceding the first written agreement in particular it was very important to AMCo that its hands would not be tied to Auden's product, which is why, we say, one sees clause 3.2 written in the way it is, carving out own

entry possibilities.

Now, of course AMCo obviously did not tell Auden the irons it had in the fire. Now, it is, of course, the case that MIBE, like a lot of these developments, it waxed and waned, and some difficulties arose quickly after with MIBE, and in fact the product was not finalised until 2016. But the basic point holds good, which at this stage AMCo was pursuing a number of options to get away from Auden and to do its own thing.

The second point is that things with Aesica, at least at this stage, were looking up. If we go to {IR-H/341/1}, please. There you have a purchase order dated 27 January 2014 for Aesica, and we have seen in the board minutes some cautious optimism being expressed in relation to Aesica.

Now, as we will see, hopes with Aesica were eventually and quite quickly dashed, but there was certainly, a strong desire on the part of AMCo at this stage to try and ensure that Aesica would be a success and would be a success as quickly as possible, and indeed, it is common ground that for this early period in 2014, with the CMA, that the Aesica route was a priority at this stage.

Again, the reason I mention all of this, of course, is that it explains why clause 3.2 appears in the first

written agreement in the form that it does. At this stage AMCo was intent on maximising its possibilities for independent entry and was cautious about being tied to Auden any longer than it needed to be.

The third point, which again goes in the same direction, and I think I mentioned this briefly before the short break, AMCo at this stage was exploring purchasing Waymade's 20mg full label product as a possible way to get around the orphan designation issue. If we go to {IR-H/375/1}, please. There is an email in the middle of the page from Mr Beighton, he spoke to Vijay of Waymade:

"... I think he would be happy to sell it with certain terms ... not currently marketed."

And so on. "We need to be confident we can make it", and so on.

In fact, a formal offer was made by AMCo in May 2014. We do not need to turn it up. It is {IR-H/458/2}. So an offer was actually made. Of course, this also dovetails with the second written agreement, because again it coincides with the period in which AMCo had a number of irons in the fire, and again it wanted to preserve maximum flexibility to do its own thing and not be tied to Auden any longer than it needed to be.

Now, the obvious commercial point to make about all of this, Waymade acquiring Plenadren, MIBE, Aesica and so on, all of these development efforts took time, effort and substantial amounts of money. We are talking hundreds of thousands of pounds. If we just go to one striking example, it is at {IR-C2/3/34}. At the bottom of the page, please. You see the under "Packaging" -- so this is in January 2014. So at that stage AMCo was even funding capital equipment for use by Aesica within its manufacturing operations.

The point is a commercial one. It is very hard to see why AMCo would rationally go to all of this expense if, as the CMA says, it was in truth being paid to stay in bed and do nothing. It does not make a lot of sense, we suggest.

So the reason for this sort of circuitous introduction is that we would suggest that seen in context, it would be inconsistent to suggest that when AMCo was insisting in clause 3.2 of the first written agreement on any exclusive purchasing obligation being subject to an express carve-out of its own entry possibilities, that AMCo was in substance agreeing not to enter. In other words, that the true agreement, on the CMA's case, actually means the opposite of what clause 3.2 says. Again, given the amounts of money AMCo

was spending, the number of different irons in the fire, it makes absolutely no sense to say at this moment in particular, AMCo would be agreeing not to enter.

Everything it was saying and doing, putting its money where its mouth is, was full steam ahead insofar as possible with own entry possibilities.

Now, AMCo of course did not know this at the time, but we also see on the Auden side of the equation they understood full well that AMCo was fully intent on entering as soon as it reasonably could.

If we go to {IR-H/535/5}, please. So this is 12 February 2014, which is not long before the first written agreement was signed. If we see under point 5, this is Auden saying:

"The other MA [sold by Amdipharm) who will launch their product in Q2/3, 2014."

So the counterparty to this alleged promise not to enter at this stage, they understood full well that AMCo would be entering. So we say this is incongruous and inconsistent in the extreme.

Finally, of course, again as with the second written agreement, the first written agreement was approved by Pinsents and those are hardly the actions of an undertaking intent on some clandestine arrangement. Prior approval was sought, final approval was sought,

everything was intended to be above board.

So again, sir, I make the simple submission, seen in context there is every reason to think and no reason not to think that the first written agreement, in addition to the second written agreement, particularly in relation to clause 3.2, did not do exactly what it said on the tin.

Sir, I am moving to my final topic in relation to ground 1 and that may be it for today, but we will see how we go. That is the Aesica development project.

THE PRESIDENT: Yes.

MR O'DONOGHUE: Sir, as you will have no doubt sadly apprehended from the volume of written material, there is a lot that could be said about the twists and turns of Aesica and I cannot possibly hope in the time available to me to do that justice in some ways. So what I want to do instead is two things: one, to react to the witness evidence we heard from Mr Middleton and Ms Lifton, in particular to respond to what the CMA says about these witnesses, which we find frankly staggering.

Second, to go through in rather quickfire fashion what I say are the key contemporaneous documents in relation to Aesica.

Now, sir, one could of course do this in one of two ways. One could do it in a thematic way according to

the various issues that arose with Aesica. That is one way. We have done that in our written closings to a good extent, and annex 1 of Mr Brealey's goes to town on all of this and many other things.

But what I want to do is something slightly different which is to look at a number of the contemporaneous documents. What I am trying to achieve here is, it is really the point that the plural of anecdote is data, which is to give the Tribunal some fabric, or a clear sense of the contemporaneous documents of the attitude on both sides of the Aesica/AMCo relationship, in particular the frustrations and problems which we say were clear for all to see. So it is to really put that in technicolour, but of course the detail on a thematic basis will have to be approached in maybe a more forensic way as is set out in the written documents.

THE PRESIDENT: Yes.

MR O'DONOGHUE: So, starting with the witness evidence. The Tribunal, of course, heard from two people who were able to speak directly to the Aesica project, and of course we had evidence from both sides from AMCo, Mr Middleton, and Ms Lifton on the Aesica side.

Now, as I said, the CMA's synopsis of this witness evidence in its closings is somewhat surprising. If we

go to the CMA's closings at {IR-L/7/26}, please, and it is paragraph 54. So the CMA says that Ms Lifton's evidence was very hazy. We say this is a surprising reading of the evidence.

MS DEMETRIOU: It says "recollection of events".

MR O'DONOGHUE: Yes, "recollection of events", fine. Now, if we can go to what she actually said, it is at {Day4/131:1}. It starts on line 4 {Day4/131:4}. This is the President's questions, and if I can ask the Tribunal to read from there on to page 133, line 2, please {Day4/133:2}. (Pause)

THE PRESIDENT: Yes, thank you.

MR O'DONOGHUE: So we say it is crystal clear what the bottom line is here. So, she says the project was an absolute nightmare. She says it is "scarred in here forever", pointing to her brain. "Not an easy project to manage at all." "Aesica was a very overstretched company ... They took on too much work." A very striking piece of evidence. She was a regulatory affairs person. She was co-opted, apparently with no experience, into project management. It seemed to have been a situation of chaos and expediency within the company at the time. She did her day job on regulation side by side with project management.

There were problems with plant and capital

equipment. There was a pecking order on the customer side, she says. Big pharma came first, AMCo was not big pharma, so they were not top of the queue, and there was internal competition for scarce and in many ways defective resources, she says. Always fighting various people for the same pieces of equipment, same packaging lines and, sir, you asked her, well, did you have an Eeyore-ish view of this company? She said, no, if you asked anybody who worked there at the time they would, if they told you something different, they would be doing that for the company and not for themselves.

So we do not accept that it is correct to dismiss her evidence as being very hazy. The bottom line could not have been clearer.

We do say what possible evidence, or reason rather, did Ms Lifton have to put herself and the company in this light? It was in many ways manifestly evidence against her and Aesica's interests. We say she was plainly an honest witness trying to do her best to help the Tribunal.

Then in relation to Mr Middleton, if we go back to the CMA's closings at {IR-L/7/25}, please. This time it is paragraph 53, if we can scroll up, please. So you will see, sir, under (a) -- so they make three points, (a), his evidence lacks credibility. Then over the

page, (b), he was not there in 2014. Then -- sorry, (c), He wasn't there in 2014, and (b) he was not privy to strategic decision-making. We say this is both an unfair characterisation of his evidence and actually beside the point.

Again, on credibility the bottom line with Mr Middleton was crystal clear. You asked him, sir, point blank, did you have any reason to think anything was out of the ordinary and he said no. He was very candid, we say, and very fair and balanced because he accepted, albeit with hindsight, that some individual things might well have been done quicker but overall, he was clear that he did not think anything odd was going on.

Of course, he in particular was able to speak with some authority to this entire issue because he managed a portfolio of more than 1,000 product lines.

He also made a very important point, in my submission, that the CMA has completely ignored which is that in 2013 and 2014 AMCo was in the process of integrating two very substantial previously independent businesses, the Amdipharm companies on the one hand and the Mercury companies on the other. I think in cumulative terms we are talking about £500 million of revenue, so a very large duo of going concern

businesses.

Of course, the short-term effect of integration is to create some inefficiency and as reporting lines and people change in the hope of generating long-term synergies and efficiencies.

This critical context was completely ignored by the CMA when it comes to assessing the efforts on the AMCo side.

The second point the CMA makes, that he was not there in 2014, we say that really goes nowhere. The decision's key finding, if we can go to {IR-A/12/217}, please, and it is at 3.472. So the CMA says:

"... AMCo engaged only sporadically with Aesica in the 14 months prior to the January 2014 crisis in relations with Auden."

But this is precisely the period for which Mr Middleton gave evidence. So that really takes them nowhere.

It is also bizarre for the CMA to suggest that his lack of involvement in 2014 makes all the difference because their own case, certainly for early 2014, is that for this period Aesica was a priority for AMCo. So we do not understand, looked at either end of the telescope, how this point helps them in any way.

Finally, it also does not help the CMA either to say

that Mr Middleton was not directly privy to the strategic decision-making in relation to Aesica.

First, if there was some strategic decision to go slow on Aesica he would have been on the receiving end of that. If somebody was putting a stone to the wheel or tugging on the handbrake he would have been directly exposed to that. But his evidence was clear that nothing out of the ordinary occurred on the Aesica project compared to the many thousands of other projects he worked on.

Of course, Ms Lifton's very candid evidence that certainly a significant proportion of the blame lay at Aesica's door supports Mr Middleton in this connection.

Second, the reason this strategic decision-making does not help the CMA in any way is it certainly was not put to Mr Beighton or to Mr Sully that they, or indeed anyone else within AMCo, was engaged in efforts to bring about a go-slow in relation to Aesica. So we say this is not an allegation that can fairly be made in closing in respect of Mr Middleton, or indeed any other Advanz witness.

MS DEMETRIOU: Sir, can I just make that clear that never has been the CMA's case, and it is certainly not our case in closing, and Mr O'Donoghue will search high and low in the Decision for any finding of a conspiracy of

a go-slow. So I am just flagging it now so that I can hopefully short-circuit these submissions which are irrelevant to the CMA's case.

MR O'DONOGHUE: Sir, then we are in violent agreement.

But the consequence of Ms Lifton's and Mr Middleton's evidence, we say, is significant. There is no doubt the CMA's criticism of AMCo's approach to the Aesica development was a material part of the case on the existence of the alleged agreement not to enter. The Decision says, we saw this:

"The fact AMCo sporadically continued the development of its own 10mg tablets with the Aesica during the lifetime of the 10mg Agreement therefore does not undermine the CMA's [case] regarding the existence of the 10mg agreement and its terms."

Let us quickly look at that, it is {IR-A/12/799}, please. It is 6.861 at the bottom, that is the quotation I read out. But we submit that it must follow that if AMCo did with at least reasonable diligence engage on the Aesica project then that does undermine the CMA's findings. The CMA's main point here is that the developmental engagement was sporadic, and it was effectively de-prioritised by AMCo management. Now, if, as we submit, it is crystal clear that was not the case there is no good reason why a firm would spend large

amounts of time, effort and money on a project like Aesica if it did not intend for that project to succeed within a reasonable timeframe and to make use of the product that emerged.

The go-slow on the part of Aesica, it is an important part of the Decision but it must follow that if their case is not well founded then it becomes a strong contra-indication of the CMA's case that AMCo agreed not to enter.

AMCo was trying diligently, through multiple avenues in fact, to enter albeit it encountered significant and genuine issues on the Aesica project in particular.

So that, sir, is on the evidence you heard.

Now, if I can quickly rattle through some of the contemporaneous documentation, just to give the Tribunal a very clear flavour of what we say was clearly going on here. I cannot go through every twist and turn, so for your note the thematic approach I mentioned in our closings is at paragraphs 39-50, and of course annex 1 of Mr Brealey's written closings. If we can just turn up {IR-L/3.1/21}, please, and it is paragraph 41. There, you will see, we go through thematically each of the issues over time and we explain the context and where we say this takes matters, and I was not proposing to rehash that.

But just to go through in quickfire chronological order some of the key documents, and I will do this fairly rapidly. I am going to start in 2012 at the outset of the alleged infringement. It is {IR-H/144/3} it is the bit in bold:

"... manufacture and to schedule this [this is 10mg] in as soon as possible".

The next one, {IR-H/150/12}, please. This is from Deloittes. Under "Hydrocortisone" you see new product launch planned to be launched in the UK in 2013, taking market share:

"Management plan to launch their product to take a share of this market."

{IR-H/169.1/1}, please. You see at the top, manufacture a 10mg batch as quickly as possible, so 20 December 2012. Early 2013, {IR-C2/3/7}, please, at the bottom. It is an internal AMCo email chasing Aesica:

"Any news on a meeting on these?

Things are starting to become a little fraught at this end, we need to place orders."

5 February 2013, {IR-B2/5/3}. It is paragraph 13. You see a meeting with Aesica on 5 February, "we discussed stability issues", and so on.

Then {IR-H/177/1}. In the middle it says, "Initial

feedback ... not great."

Then {IR-H/177/1}, the top of the page, Mr Brealey showed you this, "Appreciate your efforts to expedite."

{IR-H/186/2}, please. 25 February 2013, top of the page, Ms Lifton:

"... apologies for the delay in contacting you ..."

{IR-C2/5/9}. Top of the page:

"I'll have the PO sent to you ASAP."

{IR-H/199/3}, please, the bottom of the page, Ms Lifton:

"Please accept my sincere apologies. I will get on the case!!!!"

Then, just for the reference, later the same day -- well, let us look at this. It is {IR-H/199/3}, please. At the bottom of the page -- sorry, top of the page:

"Am not sure what has happened, but it looks like the Hydrocortisone P/O has gone astray ..."

So it looks as though it might have been lost on the Aesica side.

Then {IR-H/223/1}, please. You see Aesica informing AMCo that the blister packs had failed stability tests and therefore, they should rely on the glass bottles of 30 tablets, and if you note the request about halfway down:

"Please may I have your urgent approval ..."

Then {IR-C2/3/18}, please. If the Tribunal can quickly look at that.

THE PRESIDENT: Yes. (Pause)

MR O'DONOGHUE: Sir, the basic point is Aesica had come to realise that it could not make 30 by 10mg in bottles since they had forgotten that the MA in a bottle presentation -- that wasn't permissible under the terms of the MA.

Then at {IR-H/245/1}, please. We see at the top of the page AMCo's internal reaction to that problem, and I do ask the Tribunal to note that this is Mr McEwan.

{IR-C2/5/156}, please. At the top of the page we see it says:

"Could you confirm if the bulk tabs have been produced? I thought you had the starting materials but someone mentioned this had already been converted to tablets. It will help emphasise the urgency."

So that takes us up to 2013. Now, I was not proposing to go through the first half of 2014 because, as I said, it is common ground for this period at least that the Aesica project was a priority. But I would note one striking fact which I think I alluded to already. There was a problem with the purchase of capital equipment on the Aesica side, and in February 2014 AMCo from its own pocket funded the

procurement of capital equipment by Aesica, and we say it is a very rare thing that a purchaser needs to dip into its own pocket to fund equipment that its manufacturer ought to have in any event, and we say that it is antithetical to a strategy of delay.

I have a handful of final references before I wrap up on Aesica. This is for the second half of 2014 and into the end of the Cinven period in 2015.

Now, the CMA makes great play of the fact that a batch was delivered to AMCo in mid-August 2014, but it fails to mention that that batch from the word go was never in fact saleable.

If we can go to {IR-H/591/2}, please. It is at the bottom of the page, "Dear Rahul". It says --

"... will not get released to any other market without proper deviation in place ... I still require some more ..."

So from the word go there was a problem with the batch as delivered.

Now, the CMA has been critical, in closings and otherwise in relation to the Advanz witnesses, that they did not mention the quarantining of these three batches in mid-August and the suspension of the Aesica project. We say seen in context that criticism is unfair, because in truth in 2014 AMCo never had a commercially saleable

Aesica product. The batches, as we see, delivered in mid-August 2014 were dead on arrival.

AMCo did work hard with Aesica to fix those issues and of course, issued subsequent purchase orders, so we say that in substance the Aesica project did continue and certainly, from the perspective of someone like Mr Beighton, we say that would have been his perception. So we say this criticism about this momentary suspension or ephemeral saleability in mid-August 2014 is completely overblown and does not really go anywhere.

Three final references, if I may, for this period. {IR-H/598/4}. This is 5 September 2014. At the top:

"... potential to lead to a Recall for a product we manufacture for AMCo. We have opened an internal investigation."

The issue was the packaging that was used was not compliant with AMCo's marketing authorisation owing to the thickness of the foil, and that led to batches being placed immediately on hold.

A couple of final references. {IR-H/642/5}, please. This is 6 November 2014. Here we see AMCo asking Aesica to provide the required documents to support its application to the MHRA for a variation of the MA to support the different foil thickness that Aesica had packed the batches in, and there was a further chasing

in {IR-H/642/4} of Aesica in relation to that issue.

Then a final reference in 2014, {IR-H/631/1}, please. You will see in the second paragraph, the long paragraph AMCo requesting Aesica's urgent support in obtaining a variation to the MA.

Now, I could go on, but I will not because it is tedious and tough on the operator, but the Tribunal, I hope, gets at least a flavour of the picture, and we say that at all material stages at the very least reasonable diligence was being employed on the AMCo side, and as Ms Lifton made crystal clear, they were pushing and pushing, and unfortunately for an extended period not getting very far.

Now, there are two final particularly striking things on Aesica that I do want to mention. If we can go to {IR-H/725/1}, please. So this is 26 May 2015. So you see Mr Karl Belk, COO of AMCo, writing to the managing director of Aesica and, for want of a better phrase, reading him the Riot Act. If I can ask the Tribunal to read that, you see concern that Aesica had been unresponsive in key matters, multiple key leadership changes in Aesica, the main project manager, Kelly Lifton, was struggling to manage AMCo's projects as this was not her core role, which of course was her evidence, and that the development project was

frustrated by Aesica's equipment capacity constraints, which again was her evidence, and a crisis meeting was eventually scheduled for 15 July 2015.

So things had become so serious over time this was escalated right to the top, and I would submit that the gist of the evidence given by Ms Lifton is very faithfully reflected in what is set out here, and you do not see push-back from Aesica on any of this.

There is an expression that the straw will show which way the wind is blowing, and in December 2017 AMCo actually ran out of stock on the Aesica product because of production and compliance issues with Aesica, and as a result AMCo actually stopped selling the Aesica product in December 2017, only 20 months after it had actually commenced sales, and was forced to switch to a different CMO.

We say those facts speak for themselves.

So, sir, that is all I wanted to say on ground 1. On market definition I can be extremely brief in light of Mr Brealey's efforts. Sir --

PROFESSOR MASON: Just before you do, could I ask one question on Aesica before you move on then, and forgive me if we have seen it and I have simply forgotten or overlooked. Is there any evidence of AMCo looking for an alternative supplier to Aesica other than Auden?

MR O'DONOGHUE: Sir, in the end, yes, that is indeed what happened.

PROFESSOR MASON: Indeed, but during the period that you have just been referring to?

MR O'DONOGHUE: Sir, as I think I alluded to there were a series of parallel projects with the MIBE and Focus, where other sources of product would be -- skinny label product would be acquired from third parties. So in terms of the shopping list of projects there was the acquisition of Plenadren, the acquisition of Waymade's 20mg MA, buying the Auden business at one stage in early 2014, the MIBE development, the Focus development and there was also an injectable hydrocortisone product with a company called VUAB. So there were six parallel projects in addition to Aesica, so that is why I kept saying AMCo had many, many irons in the fire. Now, of course some of these, MIBE actually came to fruition in 2016, some of these were discussed but did not eventuate. But AMCo, we say on any view, was trying its damnedest to ensure that it had something to come to the market at some stage, and we say that Aesica and these other efforts were pursued with at least reasonable diligence.

PROFESSOR MASON: Thank you, that was a helpful summary.

MR O'DONOGHUE: Sir, of course hindsight is gilt-edged and

one can almost certainly do things quicker. It is slightly facetious, but I remember at one stage in this trial we suggested that the hearing might be conducted in two or three weeks. It turns out to have been five weeks, and at least speaking for myself I have found that somewhat compressed.

So one does not know, but we say looked at in the round AMCo certainly pursued multiple avenues with at least reasonable diligence.

THE PRESIDENT: Sure, but the question, I think, was more -- you have described it as the "Aesica avenue", but it did not have to be Aesica and I think what you are saying is that it could have been another manufacturer.

MR O'DONOGHUE: Yes.

THE PRESIDENT: But the difficulties that you have been taking us through did not trigger a shift away from Aesica to another manufacturer, even though in hindsight perhaps that might have been a good idea.

MR O'DONOGHUE: Sir, yes and no. Of course, the projects I have mentioned were essentially being pursued in parallel, these were not sequential.

THE PRESIDENT: Yes.

MR O'DONOGHUE: So I mean, as with any development one does not know who is going to hit the jackpot and when.

THE PRESIDENT: No. What I am saying is that of course the

acquisition of Plenadren, for example, is an alternative to leveraging your 10mg MA skinny label by way of a manufacturer, but the manufacturer does not have to be Aesica.

MR O'DONOGHUE: Yes.

THE PRESIDENT: So all I am saying is keeping the Plenadren and the other irons in the fire one can achieve the successful outcome of the 10mg skinny development with someone other than Aesica.

MR O'DONOGHUE: Yes.

THE PRESIDENT: But that did not happen until later on when the supply ran out.

MR O'DONOGHUE: At the same old level, yes, that is right.

THE PRESIDENT: My point was simply that did not happen but you would say, well hindsight is a wonderful thing and maybe they should have taken a different course, but nothing is to be inferred from that beyond hindsight is a wonderful thing.

MR O'DONOGHUE: No, no such question was posed in cross-examination, which we say is striking.

Sir, on market definition we have put together a note on, sir, your oddities --

THE PRESIDENT: I am grateful.

MR O'DONOGHUE: -- the questions you have asked, if I can hand that up, please. (Handed)

Sir, we have gone through the seven questions, I hesitate to call them oddities because we say in many ways they are not as odd as one might think. This is not, of course, agreed but we are putting it forward in good faith in the hope that it might help more than it hinders.

THE PRESIDENT: I am very grateful.

MR O'DONOGHUE: Now, sir, just to pick up on one point, Mr Brealey has covered this, we say extremely effectively, and there is a risk of me mangling or undoing the good work he has done. But if I can just focus in on question 1, please, which is picking up, sir, on your point: well, what do we get from the fact that the ultimate consumer does not, apart from a prescription charge, pay for the underlying medicine.

We obviously agree with that, as you see in paragraph 3, and we also make the point in the last sentence that the prescribing doctor does not directly, through the practice, pay for the medicines to the patient either. So both the prescriber and the prescribed may not be terribly price sensitive.

But we say paragraph 4 is the critical point, because in a sense what one has -- so the supply chain, we say, is actually not that complicated. You have manufacturers, in some cases wholesalers, and

pharmacies. So you have two or three layers, and at each stage there is a price, there would be a price to the wholesaler and there may be competition in relation to that, and there will be a price from the wholesaler to the pharmacy, so you can call it PTW and PTP.

At both of those levels there is competition, discounts, rebates and so on, and in principle both of those prices at both of those levels can be the subject of competition. Now, of course there is a symbiosis because if the wholesaler does not leave enough margin for the pharmacy and the manufacturer does not leave enough margin for the pharmacy and the wholesaler, the sale may not be achieved. But in principle at those two layers of the market there are prices in a conventional sense and therefore, we say, SSNIP tests and other tests which can be done in the ordinary way to perform the usual pricing analysis and substitution analysis at those levels. We say in that sense it is relatively orthodox.

The wrinkle, of course, sir, is the drug tariff. They have, effectively, the underwriter of the national health system saying, I will set a maximum level of reimbursement for the entire value chain that I am willing to pay, and of course on a practical level because it is a ceiling, that has an indirect impact on

the supply chain because unless there is margin for the pharmacy and the wholesaler the maximum ceiling will be exceeded and the system on one level collapses.

But we say that does not really detract from price competition in the sense, or necessarily so, because it is a ceiling and of course there can be very intense competition to price below the level of the ceiling. Indeed, we see this very clearly in this case because there is a huge disparity between skinny label prices and full label prices below the drug tariff. The skinny label prices are substantially below the drug tariff price and the full label prices are much, much closer to that ceiling.

So you see in a universe where in this market there are six, seven, eight skinny label suppliers at different point in times, that intense price competition between them can have a very substantial depressing effect well below the drug tariff in the ordinary way.

That is why we say although the drug tariff is a factor it is really more of a question of underwriting and setting a maximum ceiling and it does not materially detract from the existence of price competition at the wholesale level and at the pharmacy retail level.

In a sense, sir, that is where probably the only

issue where Ms Ford and I fall out. True it is that the ultimate patient does not pay for the prescription but we say that is nothing to the point when it comes to analysing at a pharmacy level, at a retail level.

In effect the pharmacies step -- they are the intermediate consumer and they effectively step in the shoes in terms of a proxy for what could be a form of intermediate consumer demand.

Of course, in a sense, the wholesalers, although they are also intermediaries, they are a form of intermediate consumer as well because they buy from the manufacturers.

So one could look at this as involving two layers of intermediate consumers, wholesalers and pharmacies, albeit there is an ultimate consumer and an underwriter, the Government for want of a better word, sitting within that structure.

THE PRESIDENT: That is if I may say so a very helpful way of analysing it but I think the reason Q1 is framed as an oddity is because of the inter-relationship between the layers of a supply chain and the fact that the ultimate consumer and what the ultimate consumer is prepared to pay for a given good informs the prices that are charged by the intermediate levels, however many there are.

Let us take the widget which has, let us say, 10 components and you have got competition between component manufacturers as well as widget manufacturers.

Now, the price of widgets will be competed down by what consumers are prepared to pay. You will have that competition pushed down the line so as to affect the, as you call them, intermediate layers.

Now, that is, I am putting to you, a critical element in the markets definition test which is after all concerned with, as we have all discussed, substitutability. So you have said, yes, there is competition as between producers of skinny label goods.

MR O'DONOGHUE: Yes.

THE PRESIDENT: Yes, of course they are, but they are the same good. What we are really trying to work out is the extent to which the other products in the market constitute competition.

MR O'DONOGHUE: Yes.

THE PRESIDENT: There the price that is received by a pharmacist rather breaks down. Perhaps what one ought to be asking is what would a properly informed patient, in other words, knowing what the doctor is thinking, the prescribing doctor, what would a properly informed patient do if faced with a series of identically priced products, let us say at the prescription price, if one

of those was then increased by a SSNIP?

MR O'DONOGHUE: Yes.

THE PRESIDENT: So let us take, for example, full label and skinny label 10mg hydrocortisone, both of which are, as it were, selling at the prescription price of, let us say, £8 a packet and you then apply a SSNIP to the full label 10mg product. If the patient knowing that they are pharmacologically the same but not properly prescribed for this particular indication because, let us say, the patient is an adult rather than an adolescent, will an increase of let us say 50p to the £8 make a difference?

That is precisely the sort of question that is not being answered at the moment and I am not sure that it can be answered in the intermediate stages because you are not factoring in the sensitivity of the ultimate consumer. Really what I am putting to you is that the ultimate consumer is what makes this all work because if you are talking about price and sensitivity to price and substitutability in the light of a price increase, at the end of the day it is the person who is footing the bill which is the person we do not have here because as we all agree, the consumer is not paying or is not paying the market price. That is the problem that we are all wrestling with.

MR O'DONOGHUE: In a sense, no, we say in this context the ultimate patient is a bit of a straw in the wind because they are not paying in any event beyond the prescription charge. They do not give a monkeys.

THE PRESIDENT: They are paying -- I mean, two things. First of all, they are paying --

MR O'DONOGHUE: As taxpayers.

THE PRESIDENT: -- a sum which is not necessarily equivalent to the market price. What is more, they are paying a price that does not differentiate between the various medicines. So I mean, it is well known that you should not have aspirin on prescription because you can actually buy it cheaper off the shelf than via a prescription. So there is one oddity. But most drugs will be higher priced than the prescription price, but there is no differentiation between prescription price according to expense.

MR O'DONOGHUE: Yes. Sir, my fundamental submission is that the pharmacy level is a strong proxy for a consumer in this context, maybe not a perfect one but a strong one, and in a sense, one sees this very clearly with skinny label product. Because we have had six, seven, eight suppliers the actual price, at least recently, has fallen below the cost of goods as determined by the CMA. So there you have a very striking example of where

competition between multiple skinny suppliers has been able to depress the retail pharmacy price to a level which seems to be below cost.

The point I would make on Monday is because of a single supply situation, and of course the regulatory and ethical issues, that phenomenon has not occurred in relation to full which is why we say the SSNIP in relation to full is passed with flying colours.

We do say in a more or less conventional sense one can get enough of a handle on price for the SSNIP and the analysis to be meaningful, we say, actually quite strong, and that the fact that the ultimate consumer in the end will not be price sensitive does not materially detract from that.

Of course, there are other facets to this. Now, one of course, is that the pharmacy profit may be clawed back from time to time. So that is a further constraint. There are also policy guidance. Prescribers for example are given guidance that if a generic is available it should be, all else equal, dispensed in preference.

So there are policy -- there are hard and soft measures that effectively engender forms of price competition or at least low-priced product preferences within the system. So one has to look at this in my

submission in an integrated manner.

We say that ultimately the market at a retail level is able to assimilate in a very real and effective sense a form of price competition on which essentially traditional market definition tools can be employed, albeit conscious of these features or oddities, but I will come back to that on Monday.

THE PRESIDENT: I am more than happy to use the word "feature" rather than "oddity".

MR O'DONOGHUE: Certainly we can highlight that.

THE PRESIDENT: But feature it shall be from hereon in.

Mr O'Donoghue, we will read your very helpful note in time for when we resume. It struck me in the last point you just made we asked this morning for a granular understanding of how the drug tariff operated. I think included in that, though it may not strictly be drug tariff, is an understanding of how the overall profit clawback would operate in respect of a pharmacy.

MR O'DONOGHUE: Yes, sir, it will.

THE PRESIDENT: As I understand it, there is a regime that I completely, my fault, do not completely understand at the moment but there is, as it were, a per pharmacy control so that no matter what you get by way of the operation of the drug tariff there is an overall cap on how much profit you can make, and I think it would be

helpful to understand how that works as well.

MR O'DONOGHUE: Yes. The basic mechanism is that if the pharmacy through procurement is consistently able to get well below the drug tariff some of that extra margin may over time be clawed back but it is not sort of a complete net off.

THE PRESIDENT: No.

MR O'DONOGHUE: This is episodic. It applies across all products and there is a sort of rough and readiness to it and of course these views are periodic, and they are not set in legislation, so I would not want to suggest that it is a perfect netting off mechanism or anything like it.

THE PRESIDENT: No, I am sure you are right that it is a more broadbrush umbrella designed to ensure that you are not making windfall profits out of the operation of the system. So one would expect it not to be dovetailed precisely to the drug tariff.

The reason I am asking is because it struck me as you were making your submissions that that might explain the difference in approach between pharmacies in that if you have got the large operators being more subject to this, as it were, umbrella control, and the smaller pharmacies being less so, then that might explain their different attitudes to something like full label and

skinny label.

MR O'DONOGHUE: Yes, sir, I see that.

The other thing, sir, which I think we can check is whether in fact there was a clawback operated in the period we are concerned with because it is quite periodic, as I understand it. It may be much less frequent than one would have thought, but we will investigate that.

THE PRESIDENT: Very grateful, Mr O'Donoghue. As ever these are questions made from ignorance rather than strength and it may be they take us nowhere but it is better to know the answer than wonder that it might make a difference.

PROFESSOR HOLMES: Can I just on the question of rounding up our understanding there. You made a reference to the guidance in relation to which product the pharmacy should prescribe. I think we may have seen that but I am particularly interested in the aspect of providing where they can the cheapest or most cost-effective available. If somebody could remind us where that is.

MR O'DONOGHUE: We will dig that out. To be clear, I am not suggesting that in this case with these products guidance in fact applied but there is policy guidance in many respects that where possible prescribers should dispense, for example, parallel import or generic where

1 they --
2 PROFESSOR HOLMES: Yes, I think it would be good to have
3 a clearer understanding than at least I have at the
4 moment.
5 MR O'DONOGHUE: Sir, I am doing well on timing. I have not
6 much to say on market definition. I am in the
7 Tribunal's hands. I am wondering would it make sense to
8 start at 10.15. I want to give Mr Palmer at least his
9 allocation. There is always a problem coming at the end
10 that you get squeezed. That happened in
11 cross-examination. I want to avoid it if possible.
12 I am in your hands.
13 THE PRESIDENT: No, we quite understand. Should we say
14 10 o'clock on Monday.
15 MR O'DONOGHUE: I am grateful.
16 THE PRESIDENT: Mr Palmer, we absolutely do not want anybody
17 squeezed, least of all you. You are not perturbed by
18 the position we are at in terms of timing.
19 MR PALMER: We seem to be -- of course provided
20 Mr O'Donoghue is finished by the mid-morning break that
21 will allow me my time. If he finishes earlier all the
22 better.
23 THE PRESIDENT: Grateful. Thank you all very much. We will
24 resume then at 10 o'clock on Monday.
25 (4.35 pm)

(the hearing adjourned until Monday, 19 December at 10.00 am)