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, 25 November 2022

(10.30 am)

THE PRESIDENT: Good morning.

MR BREALEY: Morning. The next witness is Mr Middleton, so could I call Mr Middleton, please.

MR WAYNE MIDDLETON (affirmed)

Examination-in-chief by MR BREALEY

MR BREALEY: Mr Middleton, you should have a witness statement in front of you. For the transcript it is {IR-B2/5}. Can you just have a look through that statement to check that it is yours. It should be dated 22 November. That is at page 9. {IR-B2/5/9}. Can you confirm that is your signature on page 9?

A. Dated when, sorry?

Q. 22 November. Is it 22 November, yes? On page 9?

A. Yes.

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

A. They are.

Q. I think you need to speak a little bit --

THE PRESIDENT: I think you had better raise the volume a little bit otherwise the transcript will not reflect your answers. You might want to try and direct the microphone.

MR BREALEY: Mr Middleton, you probably know Ms Demetriou is going to have some questions for you.

Cross-examination by MS DEMETRIOU

MS DEMETRIOU: Morning, Mr Middleton. I just want to start by asking you a few questions, which I think will not be controversial, just to establish from your witness statement what your role was at the time. So you joined Amdipharm in March 2010, did you not?

A. Yes.

Q. You were in the supply chain team. That is right, is it not, when you joined?

A. Yes.

Q. But you are now senior -- or you were until recently senior operations manager at Advanz, is that right?

A. Yes.

Q. You manage the project -- from the AMCo perspective, you manage the Aesica project for 10mg Hydrocortisone tablets between January 2013 and December 2013, so effectively for the whole year in 2013. That is right, is it not?

A. At the beginning, it was Amdipharm but, yes, by the end of the year it was AMCo, yes.

Q. You describe your role in your witness statement as managing the day-to-day and supply chain elements of the project in the technical team. So your role was on the

technical side, we can take it from that?

A. My role at the time was supply chain, so I was supply chain orientated but, yes, I was looking after the technical aspects at that time as well.

Q. Thank you. Would it be fair to say you were quite close -- you were managing the nuts and bolts of the project?

A. Yes, at the start of the year, yes.

Q. You were making sure -- to put it another way -- you were making sure that Aesica were getting on with producing the product that AMCo had asked it to produce?

A. Yes.

Q. In other words, that is the 10mg product of Hydrocortisone that AMCo had been authorised to sell, yes?

A. Yes.

Q. You were liaising with Aesica over any stumbling blocks that occurred along on the way?

A. Yes.

Q. You were not responsible, were you, for questions of business strategy?

A. No.

Q. So you were not responsible for questions such as do we go to the market with the Aesica product? That was for other people.

A. No, my role was primarily to secure the production of saleable product.
Q. Thank you. Now, you were Aesica's client or rather AMCo was Aesica's client?
A. Yes.
Q. So you instructed Aesica to do things, yes, so you might instruct them to manufacture a batch of tablets, for example?
A. Yes.
Q. Or you might instruct them to carry out certain testing like stability testing?
A. Yes.
Q. You did that sometimes informally at first, but then you would always follow up with some kind of formal documentation like a purchase order, yes?
A. Yes, that's correct.
Q. Now, you say at paragraph 8 of your witness statement and sometimes I am not going to go to your witness statement, but if you want to look at it, please do just say and we can look at it and I will give you time to look at it, but you say at paragraph 8 of your witness statement that you managed the project with Aesica to develop 10mg Hydrocortisone and you say from the existing 20mg marketing authorisation. But you knew, did you not, when you became involved that they also had

a marketing authorisation for the 10mg product? That is right, is it not?

A. At the time, yes, we had just been granted the MA for the 10mg.

Q. It had been obtained by Waymade, had it not, in 2012?

A. Yes.

Q. You would have come up to speed -- when you took over the supply chain elements of the project, you would have had to have come up to speed with what was going on?

A. I had to try and familiarise myself in very quick terms, yes.

Q. You knew, did you not, that Aesica had produced development batches and validation batches of the product in June 2009 and July 2010?

A. I was aware there had been several batches made previously, yes.

Q. The 10mg MA authorised Waymade and then AMCo to market the 10mg product and you say at paragraph 12 of your statement -- do you want to have a look at that? That is at {B2/5/3}. So you say that the MA contained certain specifications that needed to be complied with and these included the assay limits, which had been tightened by the MHRA, yes?

A. Yes.

Q. Again, that is a matter that you would have -- that is

an important matter, is it not, so you would have familiarised yourself with that when you took over managing the project?

A. Yes, that is a critical matter, because we had been given an approval for a product that we hadn't actually produced yet, because it had changed essentially.

Q. Let us have a look at the marketing authorisation itself, which is at {H/123.1/1}. It is a short document. It is 11 or 12 pages. That should come up on your screen. This first page is the letter which attaches it. You do you see that? You can see the date at the top, 27 September 2012, and then this letter it says "The formal documents are enclosed". Do you see that the third paragraph down?

A. Yes.

Q. Then if we then go to page 12 of the bundle -- of this document {H/132.1/12}, so do you see under "shelf-life" -- you can see the reference to shelf-life, which is the reference you are talking about at paragraph 12 of your statement, yes, so you talk about that paragraph 12 and you say that the bottles -- the 24 months shelf-life and the blister pack is 18 months shelf-life. You can see that on the MA itself, yes?

A. Yes.

THE PRESIDENT: Just so I understand this is aspirational

rather than actual?

A. This is what was actually granted by the MHRA. Whereas I believe -- my understanding is that originally we had requested 36-month shelf-life, which makes life a lot easier when producing and supplying to the market.

THE PRESIDENT: So it can stay in stock for longer.

A. Yes.

THE PRESIDENT: Thank you.

MS DEMETRIOU: You would have been given this document, would you not, when you took over the project?

A. I do not recall actually seeing this document, no. This would have been held by the regulatory teams.

Q. But you were managing the project, yes?

A. Yes.

Q. So you wanted to make sure that Aesica were producing the product that you were licensed to market?

A. As I say, I did not take care of that, those aspects. They were dealt with by our regulatory teams and they would have liaised directly with the Manufacturer and I was just informed those were the parameters granted by the MHRA.

Q. So you were told about what was in the marketing authorisation?

A. Yes.

Q. You would have made sure you knew what was in the

marketing authorisation when you took over the project, would you not?

A. I would have trusted my internal departments to provide me with the correct information.

Q. Because if you did not know what you were licensed to produce, it would have been difficult, would it not, to liaise with Aesica and make sure they were doing the right thing?

A. Correct.

Q. If we go to paragraph 6 of your statement you say there that -- so that is at {B2/5/2}. Paragraph 6 says that you were asked to respond in your witness statement to certain paragraphs in the CMA's Decision, yes?

A. Yes.

Q. You have stated there what those paragraphs are. Can you see that? You said 22, 58, 59 and 93.

A. I am sorry. Am I looking at the right?

Q. If you look at paragraph 6. It should be in front of the screen in front of you?

A. Yes.

Q. So, sorry, it is the CMA's Defence?

A. My apologies, yes.

Q. I misspoke. I am very sorry Mr Middleton. So you were asked to respond to certain paragraphs of the CMA's Decision and those paragraphs are listed there, yes?

A. Yes.
Q. Presumably you have read those paragraphs of the CMA's Defence, have you?
A. Yes.
Q. You also say that you have been shown certain paragraphs of the CMA's infringement Decision and you say what those are as well, 6.283 and so on?
A. Yes.
Q. So that is 14 paragraphs in total, I think. Now, it is understandable, given that it is a very long Decision, but can we take it that you have not read the rest of the Decision, you have just focused on those paragraphs?
A. I may have skim read some of the other documents.
THE PRESIDENT: You have seen other bits.
A. Not in fine detail, no.
MS DEMETRIOU: That is totally understandable. But you were given certain documents, were you not, when you provided your statement? You were given certain documents to look at.
A. Yes.
Q. These are the -- let us just go to {C2/5/2}. These are the documents that are listed in the exhibit to your witness statement and if we go over to page, there is one more {C2/5/3}. There is a few more in fact. So that is 29 documents. They were given to you -- who

gave you those documents to look at?

A. I believe they would have been provided to me in the offices in consultation with counsel.

Q. Do you know on what basis those documents were selected or were you just given them?

A. I was just given them.

Q. Now, if we go back to your witness statement, so paragraph 6 again, and at 6(a) of your witness statement you say that the CMA says -- so what you are doing here, I think, is trying to summarise what the CMA says in those paragraphs of the Defence referred to and at (a) you say that the CMA says in the paragraphs -- in those paragraphs of the CMA's Defence that:

"AMCo did not get on with the development of the 10mg tablets fast enough in 2013."

Those words "fast enough" they are not words that are actually in the CMA's Defence, are they? You have just tried to paraphrase what the Defence says; is that fair?

A. I could not quote what was in the CMA's Defence, but, yes, that is what is stated in my statement, yes.

Q. So that is your take on what the CMA's Defence is?

A. Yes.

Q. I am just going to take you to the paragraphs of the CMA Defence that you refer to just so that we can try to

agree what parts of those paragraphs you are covering in your evidence and what parts you are not.

So let us go to {A/6/20} and this is the first of the paragraphs you refer to, so paragraph 22. Do you just want to read paragraph 22 to yourself, first. (Pause).

A. Okay.

Q. So let us just take it in stages. So the CMA says that Waymade/AMCo did not press forward with the manufacture and marketing of its own 10mg tablets after obtaining the MA in September 2012. Now, you were not working on the project, were you, until January 2013?

A. Correct.

Q. But you were aware that neither Waymade nor AMCo manufactured the 10mg tablets for sale before that, yes?

A. Up until January, I had had no involvement with that project.

Q. But you knew that there weren't tablets that had been manufactured for sale up to that point?

A. From January, yes.

Q. Right. Then the -- but presumably if there were -- when you came into the project in January, if tablets had been produced before then for sale, you would have known about it?

A. Yes.

Q. Right. Then the CMA says that AMCo did not launch its own product until May 2016. That is accurate, is it not?
A. From my understanding of the document -- of the actual launch dates, yes.
Q. Then the CMA says that AMCo prioritised the development of its own product when it believed that the deal with Auden and Actavis would come to an end. That is a reference to the fact that the project became an urgent priority for AMCo in January 2014. You were not involved in January 2014, were you?
A. No, I was not.
Q. Then the CMA says that Waymade and AMCo used the threat of independent entry to secure a 97% discount on the supply of product from Auden. You do not address those arrangements, I think it is fair to say, in your witness statement, because you were not involved in negotiating that deal at the time. That is right?
A. No, I wasn't.
Q. Now, let us go to the next paragraph of the Defence you refer to. This is at {A/6/27}. It is at paragraph 58. Why do you not just read that to yourself before we take it in chunks. (Pause).
A. Okay.
Q. Thank you. So the CMA says there that there was little

evidence -- sorry, little activity by AMCo in late 2012 and throughout 2013. Now, that is addressed in your evidence, is it not, at least from late January 2013, so you are addressing that in your evidence, yes?

A. Yes, that's correct.

Q. We will come on to talk about that in a moment. At the moment, I am just trying to sort out what you do address and what you do not.

A. Okay.

Q. But the second part of the sentence:

"It had not decided whether to proceed with the project, and no approval had been sought from the AMCo board."

You are not disputing, are you, that board approval was not sought and obtained until January 2014?

A. I am not sure that I would agree with that, because we were proceeding with the continuation or the efforts to produce product within accordance of the marketing authorisation that had been granted with or without -- but I mean at the time that was with board approval from the internal board that I was reporting to, which was Brian McEwan.

Q. This is a specific question about approval from the board to proceed with the commercialisation of the project, but you are not disputing that that was not

sought, are you, until January 2014?

A. I wasn't responsible for commercialisation.

THE PRESIDENT: I think that was really -- my question was: is there something that you can actually give evidence on? I mean, was AMCo board approval something that you regarded as necessary in order to work on the project?

A. No, it was not. I was instructed by a board member of Waymade at that time to continue with the development of the product through 2013. So it was not anything to do with the launching or the marketing of it.

MS DEMETRIOU: All right, thank you, Mr Middleton. Then we see, going back to 58, AMCo's greater concern was to formalise its deal with Auden, and, again, I think that is something you have already said that you are not giving evidence on, because you were not involved with that.

A. No, that's correct.

Q. Let us go to the next paragraph, which is 59, just below that and this says here that:

"The evidence also shows that, if AMCo had decided to press ahead with independent entry in this period, it would likely have been able to enter within a period of six to eight months."

You do take issue with that in your decision, yes,

and we will come back to that again.

Then let us read the subparagraphs of 59. So you can see that what the CMA is saying in the first subparagraph is that:

"In January 2014, there was concern at AMCo that its deal with Auden would not continue."

Again, that is not something that you are able to help us with, is it?

A. No, unfortunately.

Q. We can see that the board -- if you look down to (c), the board approved a recommendation on the 22 January and I think, again, you can see there that 45,000 packs were ordered. But I think you cannot help us with that either, because your involvement had come to an end, yes?

A. Correct.

Q. Do you know that those packs were in fact delivered to AMCo in August 2014. Is that something you know about?

A. My responsibilities for the supply chain team had pretty much ended in a direct activity. I was responsible for integrating the two departments and working on other projects at the time.

Q. I see, so you are not -- you weren't involved during the 2014 period?

A. No.

Q. Okay. Now, the final paragraph of the Defence that you refer to is paragraph 93, which is at {A/6/37}. I think that maybe it is a typo and that you were intending to refer to paragraph 96, but I am going to show you both and you can see what you think. The reason I think that is because in your Defence you talk about the high watermark of AMCo's activity and that is something which is in paragraph 96 of the Defence rather than 93. But do you want to have a look and tell us what you think. So look at 93 first. (Pause)

It is talking there -- I do not think you are able to help us with what is in 93, because it is talking about the link between the development of the Aesica project and the Auden supply and I think you have already said you do not know about that, so I do think it is 96 that you are intending to refer to.

MR BREALEY: I do not want to interrupt, but I am not sure that is necessarily correct. I mean --

MS DEMETRIOU: Let the witness answer.

MR BREALEY: You are putting a statement to him.

MS DEMETRIOU: I am cross-examining him.

A. Again, I cannot comment about independent entry of anything.

Q. No.

A. I wasn't responsible for the launching of that product.

I was tasked with manufacturing products that were in a saleable state in accordance with the licence.

Q. Then if we scroll down on 96, I do think -- I am trying to help -- I do think this is what you are referring to, because it picks up the high watermark that you make. I am not trying to trap you. I do think it is just a typo, but if you think differently then do say.

Can we scroll down to see the rest of paragraph 96, please. Do you see there a lack of urgency and the high watermark was the manufacture of a single batch and those are exactly the words you pick up at paragraph 6 of your witness statement, 6 (c) of your witness statement. Do you see that?

A. Yes.

Q. So I think that must be what you are referring to. Anyway, it does not matter. I just wanted to point that out to you to see if we could agree that.

The CMA says at 96, I am -- can we go back to the beginning of 96. It is a bit inconvenient it is across two pages, but so the CMA there say that:

"The communications between AMCo and [back again please to the next page] Aesica demonstrate at best a lack of urgency by AMCo, and the high watermark was the manufacture of a single batch of 10mg tablets in October 2013."

You say in your statement that you disagree with the statement that the high watermark was the manufacture of a single batch of tablets, yes?

A. I disagree with the lack of urgency.

Q. You disagree with the lack of -- so you say that -- you disagree with the lack of urgency, but you do not disagree, is this right, that the high watermark was the production of the single batch?

A. Essentially that was as far as we had progressed with the further continuation of manufacturing products, yes. That is correct. We managed to produce one batch of products in the course of nine, ten months.

Q. Okay. Let us go to -- I want to think a bit -- I want to ask you a bit about the assay limits and let us have paragraph 12 of your statement to hand.

THE PRESIDENT: Just to articulate the issue you have with paragraph 96, if we could go back to that. Sorry, we have moved on. It is less the precise facts and is more the implications that are being drawn from it that you are disagreeing with. Is that fair?

A. Yes.

THE PRESIDENT: So you do not like "high watermark" and if we go over the page to the other bit, you do not like "demonstrating at best a lack of urgency".

A. Correct.

THE PRESIDENT: These in a sense are characterisations which I am sure we will be debating later on, but there is a difference in 96 between the facts, and I am sensing you are not disputing that there was the manufacture of a single batch of 10mg tablets in October 2013. You are happy with that, but you do not like the way it is been presented.

A. Correct, yes. I mean, the implication that, as plenty of other evidence within there states, that there was a lot of other activities took place during the course of that year and there were other issues outside of our control that that meant that that batch could not be produced until that point in time.

THE PRESIDENT: I am sure you will be asked about that.

A. Yes, I am sure. Thank you.

MS DEMETRIOU: Mr Middleton, let us go to paragraph 12 of your statement, which is at {B/5/3}. Thank you. We see there that you were aware, as we have established, about the assay limits in February 2013 and you say at paragraph 12 that you understood these had given rise to serious stability assay issues that still required resolution.

Now, just let us just take this in stages. So stability, just for everyone's benefit, because this wasn't at all obvious to me when I first came to this

case, but stability means whether the quality of the drug varies over time, yes?

A. Yes.

Q. You obtain stability data through testing the product. That is right, is it not?

A. Yes, that is right, you test the period -- over the period of time that you want that to put on the box and have that product saleable for, you have to test it over that period of time to demonstrate that it stays within the required parameters.

THE PRESIDENT: Presumably that is in the packing that it would be held in.

A. Yes.

MS DEMETRIOU: The assay limits are -- so as you have just said, when you are testing stability over time, you are testing to see how much the quality of the drug varies over that time period?

A. Yes.

Q. Assay limits are the permitted variation in quality, are they not?

A. Assay -- and, again, I am not a technical expert, but my experience from just working in a pharma environment, the assay limit is the concentration of the active pharmaceutical ingredient and it has to remain within a certain tolerance from the label claim over the

shelf-life of the product.

Q. Thank you very much. What you say here is that the MHRA had reduced the maximum permitted shelf-life to 18 months for blister packs and 24 months for bottles?

A. Yes.

Q. That is connected to the assay limit. The issues are connected together, are not they?

A. I could not say what the MHRA's reasoning was, but I could assume from the outcome of that that they had concerns about the stability of the product, yes.

Q. Now, just to be clear, AMCo's understanding was that the issue -- the issue was with the assay method, was it not, so the method for testing the quality of the product rather than with the product itself?

A. That is my understanding, yes.

Q. By the time you took over in January 2013, neither Waymade nor AMCo had applied for a variation to the assay limits, had it?

A. It had only been granted its MA in September previously.

Q. So I think you are agreeing with me, you hadn't applied --

A. No.

Q. No one had applied for a variation?

A. Not at that time, no.

Q. Let us go to paragraph 13 of your statement {B2/5/3}.

You are talking there about a meeting with Aesica on 5 February 2013 where you discussed the stability issues?

A. Yes.

Q. You talk about investigative work that DSG Biotech had been commissioned to carry out and you say that you shared that with Aesica in February 2013 in order to help them resolve the stability issues. Again, just to be clear, the DSG work related to a new assay method. That is right, is it not? So a new testing method?

A. Correct.

Q. You then say in paragraph 14, {B2/5/4} that the new batch, so this is the one you had not yet ordered, would be manufactured according to the tightened assay specifications. Just to be clear, I do not think you mean that the manufacturing process would be any different, do you? So there weren't going to be any changes to the product itself. What you mean is that the new batch that was manufactured would have to be tested against the tightened assay specifications. That is right, is it not?

A. That's correct, yes.

Q. Now, it is right, is it not, that AMCo did not instruct Aesica to carry out any investigative work in relation to the assay issues in 2013. That is correct, is it

not?

A. I am not -- sorry, could you just repeat that again?

Q. So it is right that AMCo did not instruct Aesica to carry out any investigative work in relation to the assay issues in 2013 during the course of 2013?

A. No, my understanding is the assay work was conducted by DSG.

Q. So you had that investigative work from DSG quite early on, but you did not then ask Aesica to do anything with it during 2013, did you?

A. With their own work or with the DSG work?

Q. To use the output of the DSG investigation into a new assay -- into a new testing method, you did not ask them to do anything with that? You did not ask Aesica to do anything with that until January 2014 when you were not involved, but in the course of 2013 you had not asked Aesica to do anything, any investigative work in relation to the assay limits?

A. I personally had not, but I would assume that when they were provided with the documentation from DSG, that they would have conducted internal works to start implementing that process or that revised method.

Q. They are not going to carry out work unless they are instructed to do that by the client, are they? So if you did not instruct them, do you know if anyone else

did?

A. I did not. I do not know is the answer.

Q. So you cannot help us on that?

A. No.

THE PRESIDENT: Mr Middleton, how would it normally work if you are progressing a medicament? What is the chain of command?

A. Basically, Aesica knew that we were carrying out this external work with DSG and my understanding was that the work from DSG had been done and that those reports and findings would have been passed to Aesica and my assumption would have been that they would have taken those in house and implemented those new methods, but I do not -- I do not have any evidence to see that, yes.

THE PRESIDENT: You cannot provide positive evidence.

A. No.

THE PRESIDENT: So it is very much articulating what you think would have happened drawing upon your experience.

A. Yes.

THE PRESIDENT: I think the point that is being put is, it seems slightly counterintuitive that work would be done without it being told to be done.

A. Yes.

THE PRESIDENT: But what you are saying is there is a kind of impetus which is independent of specific instruction.

A. Yes.
THE PRESIDENT: Why is that? Is that because there is a sort of overall objective that is given to someone like Aesica that means they will get on with things without being told to or ...
A. Essentially, they knew that the work was going on and that they knew there was issue with the product and my assumption would have been once it was provided a solution to that issue that they would have progressed and implemented that solution.
THE PRESIDENT: Thank you.
MS DEMETRIOU: Mr Middleton, normally if you are asking Aesica to carry out some work they would charge for that work, yes, and you would issue a purchase order?
A. In most cases, yes.
Q. That is what happened in January 14 with the assay issues and the DSG work, but I think you cannot help us with that because you were not carrying out the project then, yes?
A. Correct.
Q. If we go to paragraph 25 of your statement, {B2/5/8}, we can see that you say in the last two sentences that it was standard practice only to order sufficient product for testing if a product was not -- so you would only order sufficient product for testing purposes if

a product was not passing assay specifications and you say it was important there was testing to ensure that the assay issues were resolved before you went to a larger scale manufacture order?

A. Yes.

Q. I just told you, but I appreciate you cannot help us with this, that AMCo took steps to resolve the assay limits issue in early 2014. Are you aware -- you probably cannot help us with this either, but are you aware they did this in parallel with ordering three additional batches of product for commercialisation?

A. No, I am sorry, I wasn't party to those discussions.

Q. Let us go to paragraph 15 of your statement, please. {B2/5/4}. You explain there that you had a meeting with Aesica in February 2013 and you say that the feedback was not positive. The first thing you talk about is lead times, yes?

A. Yes.

Q. You say that on 25 February Kelly Lifton had indicated that the earliest date you could get the 10mg tablets was late July or early August, yes?

A. Yes, that is correct.

Q. You say it was not ideal, but you replied to tell her to proceed because you had been told to expedite manufacture and you exhibit your email to Ms Lifton.

Let's go to that. If we go to {C2/5/9}. If we go to the bottom of that page. We can see, first of all, there is an email from Ms Lifton to you and if we go to page 10 {C2/5/10}, you can see that on Hydrocortisone that she is offering a manufacturing date in June, do you see that, a manufacturing slot of mid June 2013?

A. Yes.

Q. With a ship date of late July, early August. Do you see that?

A. I do.

Q. Then let us scroll up to your email on page 9 {C2/5/9}. You say:

"On Hydrocortisone, no problem please proceed on the timing you have below. I will have the PO sent to you ASAP."

Now, you -- so you were not at this stage, you were not pushing Aesica to bring forward the timeline, were you?

A. They had already indicated to us at the meeting in February that there was going to be some lengthy lead times for materials to be procured and I therefore assumed that that was the best lead time they could give us.

Q. Let us look at your email. So do you see that there is a reference to another drug, the lengthy timeline on

Morphgesic?

A. Yes.

Q. Do you see there you are saying:

"Please proceed with the manufacture but please do press for and explore every possibility to improve on the dates indicated."

But you did not do that in relation to Hydrocortisone, did you?

A. No, I did not.

Q. Let us look at the internal response, which informed your response to Ms Lifton. You do not exhibit that, but we will go it to in the bundle. So it is {H/186/2}. That is the email we have just seen, yes, so that is Kelly Lifton's email to you that we have just seen. If we scroll up, you forward it and it looks -- you then say to -- it looks like you are saying it to Mr Patel and Mr McEwan, do you see that? That is who you are sending the email to. It says -- you say -- and that is an Amit Patel that is at AMCo, is it not?

A. Yes. I cannot remember if he was at Waymade or AMCo at the time. I believe so it was Amdipharm.

Q. At Waymade?

A. Yes.

Q. So you say:

"Can you advise if the below meets your needs or if

you need us to pushback and see if there are any improvements that can be made?"

Then the response is:

"This is okay on the hydro.

"However, any improvements on the Morphgesic would be most welcome ..."

Just going back to paragraph 15 of your statement where you say that this was not ideal, would it not be perhaps more accurate to say that you replied to Ms Lifton to tell her to proceed with the Hydrocortisone, because AMCo management was okay with the lead times proposed by Aesica?

A. I cannot recall what my thought process would have been at the time. All I was aware of was that they had already informed us that there was going to be some lengthy lead times to produce it and those were the dates that they had given us. There had been many other discussions on the Morphgesic project which had other issues.

Q. There is nothing in these exchanges, is there, Mr Middleton, to suggest that the AMCo management team were unhappy with the lead times, you accept that?

A. I would not say they were best pleased with the outcomes, but there is nothing to suggest otherwise.

Q. Let us look at paragraph 16 of your statement. So you

say there that -- let us get that up. We have got it. Thank you. So, you raised a purchase order on 21 March, which was then reissued in Mid-April. Let us go to the purchase order. That is at {C2/5/19}. You issued this, did you not?

A. It was raised by a member of my team. I probably would have approved it at the time I believe.

Q. You would have approved it, did you say?

A. Yes.

Q. We see that it is for 10mg Hydrocortisone. Do you see under "PIP Code Details", 10mg tablets in 30mg bottles?

A. Yes.

Q. If we read under "Additional Information", we can see that you are waiting for a quote, yes, to requote? So:

"Price on PO is incorrect, waiting for Jeremy Drummond to requote once we have the new price we will update PO and re-send."

Do you see that?

A. Yes.

Q. But you can also see, can you not, that the delivery just below that is requested for 1 November 2013. That is when you were asking for delivery, yes?

A. That is what it states on the purchase order.

Q. That was your request, was it not? It was your purchase order.

A. Ah, right, okay. There was a reason for that and that was because the carton and label artworks were not currently available for the bottle presentation. After the transfer from Waymade, we had to register the licence, the transfer from Waymade to Amdipharm. I think it would have been Amdipharm, but in the process of doing that that changes the artworks and, obviously, we hadn't started that process. So that process takes between three and six months, which would have pushed back the lead time for packing of the product. That is not necessarily linked to the bulk manufacture of the product.

Q. Just to be clear, Aesica is not responsible for the artwork, are they?

A. They are responsible for approving it from a technical perspective, but generation of it, no.

Q. No, so who does the generation of it?

A. We would have either done it in-house or with external providers.

Q. That could in principle have been carried out in parallel, no?

A. In parallel to what?

Q. In parallel to receiving the product, to ordering the product?

A. It was always ongoing. It was already going on in

parallel to manufacturing the bulk product, yes.

Q. So it was because the artwork was delayed that you ordered this to arrive in November 2013?

A. It would have meant that Aesica would not have been able to pack the product until the artworks were already in place and the component re-ordered.

Q. It is right, is it not, just to complete the picture on timing, that this batch, as you say in your statement, was actually manufactured in October 2013?

A. Yes, that's correct.

Q. So despite various delays that you have described with purchase orders and quotes, the manufacture was on time to meet AMCo's request, was it not?

A. It was on time to meet the November first date, yes.

Q. Which was your request?

A. Yes, based on the availability of artworks, yes.

Q. In your statement, you explain that Aesica provided a quote for packaging in bottles in August 2013. If we go to {H/223/2}, you can see that, "Dear Wayne", from David Ross at Aesica, yes, and it is an email from him with a quote:

"Please find an approval for the manufacture and bottle packing of 1 batch ... attached for your review." Yes?

A. Yes.

Q. If we go up to page 1, please, {H/223/1}. You forwarded that on to Mr McEwan and others on 20 August 2013. So you got it on 13 August. You forwarded it on and you say that the quote has finally been provided and you ask for urgent approval, yes? Do you see that:

"May I have your urgent approval?"

A. Yes.

Q. Let us look at your PS. You say "Brian..."

That is Brian McEwan?

A. Yes.

Q. "I need to know the future strategy for this as Aesica are pushing us to provide a production forecast."

Aesica would have needed a production forecast, would they not, to block out manufacturing capacity, yes?

A. It would have been to earmark capacity in their plants and to ensure availability of the necessary materials.

Q. For commercial supply?

A. Yes.

Q. So at this stage, we can see from this exchange that AMCo had not actually yet decided whether the strategy was to proceed to commercialise it or not. That is right, is it not?

A. The understanding at the time was we were not sure we would have a product to market or not, given the changes

in parameters and the assay issues.

Q. So no decision had been taken and you are asking for a decision, are you not?

A. I am asking for an indication.

Q. Of what the future strategy is?

A. Yes.

Q. That is what you say.

A. Yes.

Q. Now, you asked for an urgent response, but you did not receive an urgent response, did you? Do you remember that?

A. An urgent response on the purchase order approval, yes.

Q. You chased various people. Let us look at {C2/5/49}. You chased people on 25 September, including Mr McEwan. So this is now 25 September:

"Could you please provide your acceptance to the new price proposed by Aesica. They are chasing for confirmation."

So Aesica are chasing, but internally there has been a delay to respond, yes? You accept that?

A. Five days, could have been a weekend. The arrangements at the time are dictated because of the structure of the company. We had to get approvals for new pricing from a board member of the Jersey board and it wasn't always available, so sometimes it would take a few days to get

things approved.

Q. Mr Middleton, it is not five days, is it, because I showed you the quote -- the email from Mr Ross. That was 13 August. You then forward it to Mr McEwan on 20 August asking for an urgent response.

A. My apologies, I missed the dates, yes.

Q. So we are well over a month later. What you are told there is:

"In answer -- "

So if we scroll up, please. Just bear with me. A bit more. If we scroll up a bit more. To page 48 {C2/5/48}. This is the response and you are told -- you get a response the same day as your chaser and you say:

"Thanks, in the circumstances this is a decision for the AL board."

What is the AL board?

A. Amdipharm Limited. Again, there were different structures of the business.

Q. I think it is fair to say, is it not, that this delay and the request for a business case did not suggest any degree of urgency amongst AMCo management to get this product packaged, did it?

A. I could not comment as to what the delay was for, only that we were pressing for it and the production was still ongoing, with or without this approval.

Q. Now, the quote was never approved after that, because it became clear, did it not, that you could not have the product in 30 tablet bottles without varying the MA. That is right is it not?

A. Yes.

Q. Let us look at what you say about that in your statement. If we go to paragraph 19 {B2/5/5}. You say halfway down:

"However, on 26 September Aesica dropped a bombshell on us by announcing, that despite having said a few days earlier that everything was on track, Aesica had suddenly realised that it could not make the 30 times 10mg HT in bottles as we had ordered in March, because the MHRA had not approved it."

Then you go on to say, if we go over the page, that you were flabbergasted by that, yes?

A. Yes.

Q. You were the person though, Mr Middleton, that actually placed this order for the 30 tablet bottles, were you not, back in March, yes?

A. Yes.

Q. You would have known, would you not, that 30mg tablets were not authorised under the MA. That is something you would have found out about when you took over the project?

A. On the information that I had at the time or I was advised to place it in bottles. I had no reason to believe it had not been granted.
Q. You did not think that that was something you should have bottomed out before placing the order, what you had authorisation for?
A. Again, as far as we were concerned, it was a mirror of the 20mg presentation that had 30s bottles.
Q. You did not check?
A. No.
Q. So your evidence -- is this right, your evidence is that you do not have any responsibility for that mistake, it is all Aesica's, is that your evidence? That is what you seem to be saying here. It seems a bit unfair to us.
A. I am sure with hindsight that, yes, some of the blame could have been placed on our own internal departments for missing it, yes.
Q. All right. One of the things you say in paragraph 19, I think as justification for blaming -- putting all the blame on Aesica in your statement is that whilst all the staff on the Waymade and Amdipharm side had changed as a result of the sale of Amdipharm, mostly the same team at Aesica had been working on the project so that is the points you make there?

A. Yes.
Q. You explain that you took over the day-to-day running of the project with Aesica in late January 2013. You took that over from Mr Milham, did you not?
A. Yes.
Q. But it is right is it not, that Mr Milham had been involved in the project before the sale of the Amdipharm business so when it was run by Waymade, yes?
A. Yes.
Q. And also Brian McEwan, yes?
A. I do not know what Brian McEwan's involvement with the project up to that point was, but he would have been around, yes.
Q. But you knew that Brian McEwan and Mr Milham carried on being involved in this project for quite some time after you first took over?
A. They were both involved after I stepped in, yes.
Q. Now, let us go to the internal discussions which followed Aesica noticing the error. If we look at paragraph 20 of your statement. You say that there was considerable concern and consternation at the time. Do you see that in the first sentence?
A. Yes.
Q. You ran checks, you say, and explored -- so you explain that you ran checks and explored your options.

Let us go to one of the chains you exhibit. Let us go to {C2/5/43}. This is an email on 27 September and you are asking -- this is redacted, but you are asking two people from AMCo, whose names have been redacted. You are asking them to confirm whether or not the presentation and registration of the product is for bottles of 30 or 100 tablets, yes?

A. Yes.

Q. Then if we go to page 42, the next email in the chain is the same day {C2/5/42}. You get a quick response, do you not, providing you with the answer? Do you see that?

A. Yes.

Q. We have seen, or perhaps we should go back to it, but it is clear on the face of the marketing authorisation itself. So let us go to {C2/5/40}. Sorry, it is at {H/132.1/12}. Do you see "nature and contents of container", so it is set out there, is it not, the same point? That is what you are authorised to market, yes? So it is the bottle with 100 tablets and not 30 and the blister packs with 30?

A. Yes.

Q. If we go back to the email chain we were just on, which is at {C2/5/42}. There was then some discussion, because somebody at AMCo was refused. This is all in

the course of the same day. If we look at pages 38-39, {C2/5/38-39}; what we see is that if you go down a little bit, you can see an email to you at 2.54 pm and it says:

"Please find regulatory comments in green."

They do not appear in green here, but we can see it is a lighter type on page 40 {C2/5/40}. The regulatory comments are in lighter type, do you see next to the bullet? So:

"Hydrocortisone 10mg Tabs ... packed as 30's not registered.

"10mg Tabs ... packed as 30's in blistered registered.

"10mg tablets Tabs ... packed as 100's in glass bottles ... registered."

Yes? So you got all of that confirmation internally within the space of a few hours, yes?

A. Yes.

Q. You then exhibit another chain with internal discussions on this issue. Let us pick that up at {C2/5/192}. Let us start at the very bottom of {C2/5/191, please. There is an email from Mr Ross, do you see just at the very bottom? I am just showing you the dates and who the email is from. It is from Mr Ross to you, so if we go to the next page {C2/5/192} and that says:

"I have not managed to catch up with you by phone today but just wanted to follow up on the Hydrocortisone point that was raised last month.

"Please could you send an update regarding a decision on the packaging format."

So they are chasing you, Are they not? This is in November 2013. So they are chasing you for an update, a decision, on the packaging format, yes?

A. Yes, that is right.

Q. Then at 191 you forward that to Mr McEwan. Do you see that in the middle of the page? So you are sending that on November 7, to Mr McEwan, and you ask him to confirm the direction that he wants you to take with regard to the product, yes?

A. Yes.

Q. Then let us look at what you say. So you ask him what direction you want him to take and you explain what your understanding is. So we have got approval. You say what you have got approval for. You say:

"We have ordered the product to be packed in 30s bottles. Aesica provided the pricing which has been accepted. Artwork status is complete. Aesica are chasing for a forecast which to my knowledge does not exist as we currently have no plan to market Aesica manufactured material. Aesica have all the starting

materials ready to commence manufacture once all the approval issues are resolved.

"Would very much appreciate you providing your guidance if we are to continue with requested manufacture ..."

Yes?

A. Yes.

Q. So this -- the upshot here, let us take this in stages, is that in November 2013 you do not yet have a decision from your management on packaging, yes?

A. Well, they previously decided on bottles, but we had subsequently found out we could not produce it in bottles so, yes, I was seeking further guidance on which format we went forward on.

Q. You are asking for a decision on that here?

A. Yes.

Q. In fact, what we see from this email is that you do not know whether the AMCo management actually want to proceed with the project, yes?

A. I do not think that is what I am saying.

Q. Let us look at what you are saying. So you say at the bottom -- let us look at Point 4 first:

"Aesica are chasing for a forecast which to my knowledge does not exist as we currently have no plan to market the manufactured material."

So your understanding at that point was there was no plan to market the product?

A. There was no plan at that time to market that batch until such time as we could ensure that, one, it met the parameters set by the new MA approval and, two, that we could ensure that it was stable in the 30s bottles.

Q. All right. So there was no plan at that stage to market the product?

A. To market that particular batch, correct.

Q. Was there any other batch that you thought you could market at that stage?

A. No, because until we could demonstrate that we had a product that was suitable and in accordance with the MA, we did not have a product.

Q. Then what you are doing at the end of the email is you are asking a more general question, are you not:

"Are we to market Aesica product, if so what is the strategy to switch from Auden and what would the marketing strategy be?"

There you are asking a more fundamental question, are you not, Mr Middleton? You are saying are we going to market the Aesica product at all?

A. That is seeking clarification as to whether we would, given the Auden product.

Q. Are you agreeing with my question?

A. Could you repeat the question again?
Q. Of course I can. What you are doing at the end of the email is asking a more general question: are we to market the Aesica product at all?
A. Yes, in the context that we would essentially have two sources of supply and in such cases, from a supply chain perspective, you need to know what portion of the market supply you would fulfil from each of those suppliers, whether it would be half and half or whether you would just seek it from one supplier or another.
Q. I think your understanding -- what you understood there, looking at the email, is that marketing the Aesica product would mean switching from Auden, yes?
"Are we to market -- if so what is the strategy to switch from Auden?"
That is what you are saying, is it not?
A. Would it be a switch 100% or would it be a partial switch.
Q. By this stage of course, the batch has been manufactured, has it not, so that was done in October?
A. Yes, in November, yes.
Q. Mr McEwan asks for some more information. If we go to {C2/5/191}. Sorry, so:
"Wayne.
"Thanks for summarising.

"Before deciding on the way forward we need confirmation of the following..."

He says he sets out what he needs.

The date of that is November 8, yes? Then on 4 December, so that is nearly a month later, you tell Mr McEwan that he has already had that information. Let us look at that. That is at {C2/5/190}. You say:

"I have been contacted again by Aesica. They have produced the bulk (a few weeks ago) and are now requesting payment for it as there is currently no defined timeline for the packing.

"A decision needs to be made as to what pack ... they should proceed with and we need to complete any regulatory/artwork ... that would be required.

"You called me a few weeks back to say you were looking into submitting a variation, please advise status.

"Brian, I believe your questions were answered in the attached mail (dated 27/9) to which you were cc'd."

So, essentially, you are there saying, are you not, that you have been chased by Aesica and it is AMCo that hasn't taken the internal decisions that are required, yes? You accept that?

A. For the packing format, yes, that is right. The decision was not yet reached.

Q. If we see what he says, if we scroll up, so he gives you an answer at this stage, right, so that is December 4. He says that the current batch of bulk tablets should be packed in bottles of 100. An appropriate quantity in bottles of 30 and placed on stability.

Do you recall whether that decision was actually communicated to Aesica or was that the end of your time in charge?

A. I do not recall at this time.

Q. You would accept, would you not, that this decision on the part of Mr McEwan did not demonstrate any particular urgency to move this project forward. He is not pushing for an immediate solution, is he?

A. I would have said it was some urgency as he replied the same day, which was quite rare for Brian.

Q. His reply was the same day, but this was following a protracted period of time in which you were asking for an answer. You provided him answers at the back end of September and you are finally getting a response on 4 December?

A. Again, I cannot answer on behalf of Brian. I can only assume there was some other discussions internally as to what format it should be packed off into.

Q. I suppose, Mr Middleton, what I am asking you is not what was in Brian McEwan's head, but in your witness

statement you are keen to give the impression that this was all pursued with a lot of urgency by AMCo management in 2013 and I have shown you a lot of documents that show otherwise, do they not?

A. I would say I would want to demonstrate that we proceeded with good pace. I cannot attest as to whether there was any other factors in there.

Q. Mr Middleton, I think you and I will have to differ over what good haste meanings. Those are all the questions I have. Thank you very much.

PROFESSOR MASON: If I could just ask one question while we are on this exhibit and if we could return to 191, please, so the following page. Just a small question, Mr Middleton. On point 5 you refer to "once all the approval issues are resolved". Are you referring to internal or external approval issues there? I will just give you a moment to reread. (Pause).

A. Which number was it that you were referring to?

PROFESSOR MASON: It is point 5. It starts with "Aesica have all the [starring] materials" and then at the end of that:

"Once all the approval issues are resolved."

Which approval issues are you referring to there?

A. I believe that would be either the approval for the -- I'm assuming that would have been in reference to the

packing format, the approval for the packing format.

PROFESSOR MASON: Okay, thank you.

THE PRESIDENT: If we rise, Mr Brealey, before re-examination, I think it would be helpful whilst the witness is in the box just to clarify exactly what the CMA's case is going to be in this regard.

When one has competition infringements like this, you have patchy knowledge of the infringement across an organisation. You are not, I think, suggesting that this witness or the manufacturing process that he has been describing was deliberately slowed down by him.

I think what you are saying is that there was an absence of urgency which is indicative of thinking elsewhere in the organisation regarding the failure to enter the market with an independent product. Would that be fair?

MS DEMETRIOU: Sir, that would be fair and accurate, yes.

THE PRESIDENT: So what we have got is an objective question of characterisation of how the process went in terms of speed and that is all you are seeking to elicit from this witness.

MS DEMETRIOU: Sir, I think with respect, it may not be helpful for me to elaborate on precisely what our case is about, but I have asked all the questions I need to put to this witness in order to establish what I need to

challenge of his evidence.

So I am not suggesting, as you have said, sir -- I am not suggesting that he had some extraneous reason personally for deliberately slowing down the project. I would have put that to him if I had been suggesting it.

THE PRESIDENT: Okay, that is helpful. Thank you. Because it does close out certain points that you might be making later on. That is very helpful.

Mr Middleton, can I ask you this: you have quite fairly acknowledged that at certain points you and your team could have done things differently, the catching of the wrong sized bottle being a sort of case in point.

A. Yes.

THE PRESIDENT: It is always the case that with hindsight one can do things quicker, better, faster than one actually did. What is being put or what may be being put is that this process here was sufficiently unusually slow for certain inferences to be drawn and, in general terms, I think it is probably right that you be given the opportunity to comment on that just so that we have your general views on the record. I mean, clearly, this could have been done faster, you have accepted that in at least one point yourself.

A. Yes.

THE PRESIDENT: But looking at the more general flavour of the process, what do you say in response to that rather general question.

A. So in the 15 years that I have been working with pharmaceuticals, I would say that this was a period of time that has gone on was not excessive. Yes, I agree things could have been done faster in some cases, but in many cases not so. There is lots of other decisions that need to be taken, lots of other reviews and investigations need to take place before decisions can actually be -- even start to be considered.

The other thing as well that I think the CMA may be missing here is the context of which the period of time that we were actually going through with the acquisition and the merging of two businesses and the amount of work and other activities that were going on at that time throughout that period. I think it was probably around half of that year that I spent a considerable amount of time travelling to Mumbai as part of the integration of those two businesses.

Also a number of complications introduced by the fact that there were two companies being put together and that at that time Amdipharm was essentially being replaced by the support team of Mercury when we were generating or creating AMCo Pharma and so there would

have been a number of cases where people were having to re-establish their understanding and knowledge of what information they had to hand and also quite a bit of knowledge and learning of what these products were and what they were doing with them at the time.

THE PRESIDENT: If I could ask effectively the same question, but from a different angle. One almost always will have views of how one's superiors in an organisation are doing business. We had a little exchange when you mentioned that Mr McEwan responded on the same day and the implication I got from that was that was unusual rather than usual in that case. People clearly operate at different levels of efficiency and speed.

Would you say that the speed of response in driving this project forward from those whose instructions and direction you needed was unusually slow in this case or was it just the way in which the business normally operated?

A. I would say I had no thoughts that it was anything out of the ordinary. I would not have said it was exceptional. There were -- again, from the comment about it was quick to see in one day, it is not surprising that some responses take some time to be provided. So, no, I would say that it was -- at that

time, I would not have said it was a surprise that some of those responses took as long as they did.

THE PRESIDENT: If I can put it slightly tendentiously, it was in your judgment the usual level of incompetence rather than anything more than that.

A. I wouldn't want to say that. Yes, there was not anything that gave me suspicion that anybody was unduly delaying anything.

THE PRESIDENT: Thank you. Obviously this will be a matter for submission, but it seemed to me helpful to at least have your views on the record.

Ms Demetriou, if you want to ask any further questions arising out of that please do.

Re-examination by MR BREALEY

MR BREALEY: Just one question arising out of that and the integration. How many schemes were you involved with during this time in 2013?

A. At that time I think Amdipharm had in the region of 11 to 1300 SKUs and this was just one new product.

Q. One new product and how many were you --

A. My team directly were involved in managing the supply and manufacture of over 1100 products.

MR BREALEY: Thank you.

THE PRESIDENT: Thank you very much, Mr Middleton. Very grateful for your assistance. You are released from the

witness box. Thank you very much.

A. Thank you, sir.

THE PRESIDENT: Would that be a good moment to rise for the break. In that case we will resume at ten to midday.

(11.42 am)

(A short break)

(11.50 am)

THE PRESIDENT: Mr Brealey.

MR BREALEY: So the last factual witness is Kelly Lifton. So could I call Kelly Lifton, please?

MISS KELLY LIFTON (affirmed)

Examination-in-chief by MR BREALEY.

MR BREALEY: You have got your witness statement in front of you. Could you just flick through it to make sure it is your witness statement. You have got it on the screen and then go to page 11 and check that is your signature {B2/3/11} and it is dated 22 November.

A. Yes, that's correct.

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

A. I can.

Q. Thank you. Ms Demetriou will have some questions for you.

Cross-examination by MS DEMETRIOU.

MS DEMETRIOU: Good morning, Ms Lifton. Did you see some of Mr Middleton's evidence?

A. Yes, I did.

Q. Now, you were senior regulatory affairs officer at Aesica from 2007 to 2017, yes?

A. That's correct.

Q. You are not there anymore, are you, because you left it in 2017?

A. No.

Q. What are you doing at the moment?

A. I just have a very simple part-time office administrator role.

Q. So you left Aesica nearly six years ago and you signed this statement in September 2021. Do you remember when you were approached to give the statement?

A. No, to be honest, I do not.

Q. All right. Never mind. Aesica is a pharmaceutical contract development and manufacturing organisation, sometimes referred to as a CMO, yes?

A. Correct, yes.

Q. Its clients were pharmaceutical companies?

A. Yes.

Q. Aesica helped those companies to develop products, did it not?

A. It did some development work, but it also did a lot of routine already established product manufacture.
Q. So manufacturing work for commercial supply?
A. Yes, yes.
Q. Now, if we go to paragraph 8 of your statement which is at {B2/3/2}. The operator is ahead of me. If we have a look at that then you can see you say there -- you explain what the role of a senior regulatory affairs officer involved. You were, I think, involved -- you were in that role involved across a range of products, were you not?
A. Yes, as the regulatory role, yes.
Q. You mean not on the technical side. So you were on the regulatory side?
A. On the regulatory side, not on the technical side.
Q. On the regulatory side, would have involved something like advice on MHRA requirements or helping prepare submissions for the --
A. It would, yes.
Q. But it would be the pharmaceutical company itself that was the applicant for the marketing authorisation?
A. Correct, yes.
Q. The pharmaceutical company would presumably liaise closely with you when putting in an application?
A. Yes, yes.

Q. The pharmaceutical company would be the holder of the marketing authorisation if it was granted, yes?
A. Yes.
Q. Perhaps an obvious question, but the holder of a marketing authorisation has to comply with its terms, does it not, so it can only supply product that complies with the terms of the authorisation?
A. Yes, that is correct.
Q. So another obvious question, but the marketing authorisation holder will need to be aware of the terms of the authorisation?
A. Yes.
Q. Now, that obligation does not change, does it, if it asks another company, a CMO, to manufacture the product? The marketing authorisation holder still has an obligation to make sure that the product that is manufactured and marketed complies with the authorisation?
A. Yes, that would be correct.
Q. Now, you were senior regulatory affairs officer until you left in January 2017 and, in that capacity, did you assist Aesica to respond to the CMA's request for information during the investigation?
A. Apologies.
Q. Let me say that again. That was quite a quick question.

I am thinking about the CMA's investigation into this case that has led to this appeal and the CMA sent Aesica some requests for information during the investigation. Were you aware that the CMA did that?

A. No, no.

Q. So you were not involved --

A. No, not at all involved at all, no.

Q. Now, you say that towards the end of 2012 you took on the responsibility of managing the project for the development of the 10mg Hydrocortisone product for AMCo?

A. Yes, that is correct.

Q. Again, you were not responsible for the technical side of the project, were you?

A. No, so it was just the coordination.

Q. Coordination?

A. Of the various areas of the project.

Q. Now, you say -- if we look at paragraph 9 of your witness statement, you say that you were -- you recall getting involved in the project in late 2012 as project manager. Does this mean that you became project manager in late 2012?

A. Yes, that is correct, yes.

Q. But you had some involvement in the project before then, did you not?

A. As part of the regulatory role, yes.

Q. I see. You have not really dealt with -- it is not a criticism, but you have not really dealt with that earlier period in your witness statement and you have not exhibited any documents relating to the earlier period. Is that because you cannot remember much about it, because it was a long time ago?

A. Yes.

Q. Now, you stopped being project manager in around August or September 2014, is that right?

A. That is correct, yes.

Q. So your statement is concerned, is it not, with the period during which you were project manager, so we are talking about the period between the end of 2012 and the summer of 2014, so it is about 18 months, yes?

A. That is correct.

Q. Now, let us go to paragraph 36 of your statement, which is at page 10. So you say in the third sentence:

"The Issues experienced [can you see that?] were related to constant changes of project manager at both Aesica and Waymade (and subsequently Amdipharm)."

Do you see that?

A. Mm-hm.

Q. On the Aesica side, you were project manager for a bit more than 18 months and so when you talk about constant changes during that period, you are not talking about

yourself, obviously?
A. No, no.
Q. Do you recall -- were you here when Mr Middleton told us that he was involved throughout 2013 on the AMCo side or do you remember him being involved throughout 2013?
A. I remember him being involved from a materials management supply chain perspective. In terms of my contact, it was Mr Milham until he left and then Mr Frankland after he left and then, subsequently, Ms Parent and Rahul later on.
Q. Do you remember Mr McEwan being involved as well?
A. I had absolutely nothing -- anything to do with Mr McEwan at all. That was above my pay grade.
Q. I just want to ask you a bit about the preparation of your witness statement. So you explain in your statement that because you had left Aesica, you did not have access to any of the documents from your time there. That is right, is it not?
A. That is correct, yes.
Q. So your witness statement is based in part on your own memory?
A. It is, yes.
Q. In part on documents that were provided to you, presumably by the Advanz legal team?
A. Correct, yes.

Q. You exhibit copies of the documents that you were given and let us just have a look at the list. They are at {C2/3/2}. Then if we scroll down to the next page, we can see that there are 23. I think actually there are 22. It does not matter, but they cover the period, you can take it from me, December 2012 to December 2014.

Now, that is not a complete set of the documents you would have had/seen at the time, is it? So during that period, you would have -- you would have seen more documents than that in relation to the relationship with AMCo?

A. I would say that it is a fair representation of the documents that I would have seen or that would have gone between myself and AMCo.

Q. Okay.

A. Yes, yes, definitely.

THE PRESIDENT: When you say fair representation?

A. I think probably not absolutely every document is there, but the important documents connected with this project are definitely there. So my communications with them regarding the issues with the project. That was my role. So, yes, the issues that we had, the things we found subsequently trying to resolve the issues, things like that. That is all definitely represented here.

THE PRESIDENT: I see, so if I can just capture what

I understand you to be saying, you can tell me if I am wrong. Although it is not a complete run of your exchanges with the other party, it is complete in the sense that you cannot see anything material that has been left out.

A. Absolutely, yes, correct.

THE PRESIDENT: You may have forgotten about it but --

A. Yes.

THE PRESIDENT: -- but looking at it now in 2022, you cannot see anything missing that should be there.

A. No, no.

THE PRESIDENT: If you are trying to look at the --

A. That is correct.

THE PRESIDENT: I am very grateful.

MS DEMETRIOU: But you do not know for sure, do you, because you do not have access to all the documents you had then? So there may be some documents missing. You just do not know for sure, is that right? There were maybe some other emails that you are copied or that you sent that are just not on this list?

A. Possibly.

Q. Do you know how these particular documents were chosen or were they just given to you?

A. I do not know. I cannot comment.

Q. So you were just given these documents when you were

preparing your statement, were you?
A. To be honest with you, I do not honestly remember, but I think that I put -- no, honestly, I do not remember. I do not remember. I cannot remember.
Q. Do you remember about the process? So it was about a year ago you provided the statement. So did you look at these documents at that time?
A. I honestly cannot remember. I do not remember.
Q. All right. Let us go to -- first of all, you explain -- if we look at paragraph 3 of your statement, which is at {B2/3/1}, so you say that you understand that the CMA -- do you see that at the bottom of the page -- has determined in its Decision that AMCo entered into an anti-competitive agreement with Auden whereby Auden paid AMCo in return for AMCo agreeing not to the enter the market independently with its own product, yes? Do you see where you have said that?
Are you aware that the CMA found that the agreement started in October 2012?
A. Yes.
Q. That it ended in June 2016. Are you aware of that?
A. No.
Q. You do not mention anything in your evidence about the arrangements for supply of the Auden product to AMCo?
A. I knew nothing about Auden at all.

Q. All right. Now, the MA for the 10mg tablets was granted in September 2012, yes?
A. Correct, yes.
Q. It is right, is it not, that Waymade, or then AMCo, did not ask Aesica to manufacture any of the product in September 2012 once the MA was granted?
A. That is correct.
Q. Or in October or November, yes?
A. Correct.
Q. Now, let us go to paragraph 12 of your statement. You talk there about the MA and you talk about stability data and assay limits. You explain that the MA covered two presentations. That is two forms of packaging, yes?
A. Yes, that is correct.
Q. So 30 tablet blister packs and 100 tablet bottles, yes?
A. Yes.
Q. So there would have been stability data presented to the MHRA for tablets packaged --
A. In those two presentations, yes.
Q. You then say that the MHRA tightened the assay limits, yes?
A. Mm-hm.
Q. The MHRA -- it is right, is it not, that the MHRA would not simply grant an MA within tighter assay limits without discussing it with the applicant first? They

would have raised it with the applicant, would not they?

A. So the MHRA would send through what we call an RFI, so a request for information, or in regulatory terms we call it deficiency questions. So they look at the submission and then they decide from there what they believe that should be. So they would send those questions back to the applicant and then they would -- you are given the opportunity to respond to those questions, challenge them, so, yes, that would be, but it is not a verbal dialogue. It is a written dialogue you have with them.

Q. Okay. So the applicant would be in no doubt about what the MHRA was doing when it was tightening the assay limits. They would know about it, because the MHRA would write to them?

A. Yes, they would have asked for it in their RFI yes.

Q. Do you remember that Waymade's understanding at the time was that the problem in meeting the tighter assay limits was the accuracy of the testing method rather than the product itself. Do you remember that?

A. Yes, so the indication was that there was an issue with the method because of the inconsistency with the test results.

Q. Do you remember that steps were taken by Waymade in July 2012 to commission a company called DSG Biotech

to develop a new assay method?

A. Yes.

Q. We will come on in a minute to look at what DSG -- to see that they did do the work. But just to complete the picture on this, it is right, is it not, that as expected some of the products, some of the batches, the validation batches, did fail against the assay limits using the original stability testing method, did they not?

A. Against the tightened limits, yes.

Q. Using the original testing method?

A. Using the original test method, yes.

Q. Do you remember that once AMCo had asked Aesica to investigate the source of the problem in early 2014 that you quickly confirmed that the problem was the assay testing method and there was not a problem with the product itself. Do you remember that?

A. Yes, that is correct, yes.

Q. Let us look at {IR-H/355/1}. So this is an email -- this is in early 2014 and if you scroll down, please, because it is the email -- I think it is the earlier email of 31 January. Yes, that is it. So it is an email from you and it is to Mr Thornton and others at AMCo. Do you see that?

A. Mm-hm.

Q. You say that Aesica is going to start the analytical work needed -- that is needed that weekend. Then you say on the 2 February, so I think we have to scroll up for 2 February. Yes, I think that is right. That is it. So there we go. You say that you have just called the lab to see how the testing went and have been advised that the lowest result was 100%.

So what you are saying there is that the initial results using the new assay method were very good, yes, that is what you are saying in that email?

A. This is actually referring to validation within Aesica of the new method.

Q. That DSG had produced?

A. No, so this is nothing to do with the DSG method.

Q. So this is a new assay testing method?

A. This method was instigated internally by Amdipharm with their own technical people.

Q. They asked you in early February 2014 to take it forward, did they not?

A. Yes, that is correct, yes.

Q. Then if we go to {H/378/1}. So here is an email from someone at AMCo. So that is Genevieve, is it, Parent? Is that her name?

A. Yes.

Q. Do you remember her?

A. I remember Genevieve, yes.
Q. She sent that email on 21 February, do you see that, 2014? It is an internal email so you would not have been sent it at the time, but I am just showing it to you. She is confirming -- she is saying that this is "a quick update on the Hydrocortisone project ..."

She is confirming internally that the results of the investigation -- if we look at the first bullet, do you see that:

"High assay result investigation of the first batch.

"... We received the results this week and they demonstrate the issue was due to the analytical method."

Then:

"The related variation will be filed next week and it will be the only variation necessary."

So she is saying there, is she not, that the results of the investigation demonstrate that the issue was due to the analytical method, not the product itself, yes?
A. Yes, that is correct.
Q. She is saying that a variation application is going to be put in to the MHRA to cover the new method; is that right?
A. That is correct, yes.
Q. Do you remember that AMCo was able to very easily vary the MA to change the assay testing method?

A. I cannot remember.
Q. Let us just look at -- she is talking about a type 1B variation, so that would normally take, what, a month or two months for approval? Is that something you can help us with or not?
A. It is a long time since I have done that and I honestly cannot remember.
Q. I mean, again, maybe you cannot help us with this, but in fact AMCo was able to use an even simpler variation, a 1A variation, do you remember that?
A. No, I do not remember.
Q. And the variation was submitted on 3 April and approved on 1 May, but perhaps you do not remember that?
A. No.
Q. Let us go to paragraph 15 of your statement at {B2/3/4}. This all relates to the manufacture of the single batch in October 2013. What you are saying is there you say:
"As early as December 2012, Waymade/Amdipharm informed us that 'it was agreed ... to manufacture a 10mg batch as quickly as possible' ..."
Yes?
A. Yes.
Q. Now, I want to look at the email that you are referring to. So let us go to {IR-C2/3/4}, the bottom half of the page. Here is the email you refer to that is dated

20 December 2012 and you can see that that was sent to you by Mr Milham. Do you see that?

A. Yes.

Q. Looking at the email, what they are saying is that they are asking for a batch of 10mg Hydrocortisone to be manufactured as soon as possible, as quickly as possible. You can see your response at the top of the page. You say you have forwarded the request:

"But we will Not be able to formally plan the batch until we have the appropriate formal communication/forecast from the Amdipharm supply chain."

So that would have been a purchase order, would it? Would that be a purchase order?

A. Yes, that would be correct.

Q. Now, then if we go back to paragraph 15, you say -- so still in paragraph 15. Sorry, let us go back to {IR-C2/3/6}. There is an email from Amdipharm and if we go down the page, if you scroll down, please. We see there that Mr Middleton's -- I think we need to go down to page 6. I am so sorry. It is a wrong reference. So there is another email, {IR-C2/3/6}. If you go up a bit. Do you see that is from Mr Milham on 31 January and we see that Mr Middleton is in copy, so by this stage he was involved, yes?

A. Yes.

Q. Let us read -- let us have a look at what is said. So you say:

"It will be either Wayne Middleton or [someone Else] from supply chain next Tuesday. The agenda is effectively... "

Then you set out an agenda for Hydrocortisone and something and then you have Morphgesic, which is another drug?

A. Sorry, this is Malcolm's agenda not mine.

Q. That is quite right. That is Malcolm's agenda. So that is the agenda you are being sent. If we go back to have a look at it, so Hydrocortisone -- so take you through stability results, show you the DSG assay work, intend to order 1 batch in bottles.

Just turning back to paragraph 15 of your statement, is that where you say:

"The same email chain shows that Amdipharm had shared with me a well-defined agenda for the meeting."

Is that the agenda you are talking about?

A. That is correct, yes.

Q. So what is happening here then, going back to that email, relates to the new assay work, the new assay method, yes? Amdipharm wants to manufacture a single batch of product to make sure that the new assay method, so the stability results using the new assay method, are

okay before it commits to manufacturing any more product. That was what was going on at that stage?

A. Yes, so this is the DSG assay method, not the method that was introduced in 2014. So this is the DSG assay method that they had worked on and they wanted to make one batch, make sure that everything was okay with that batch before they proceeded with anything else.

Q. Exactly, so they were not commercialising at this point. They wanted to carry out further stability tests?

A. Erm ...

Q. Mr Middleton explains that.

A. Yes.

Q. Then if we go to paragraph 18 of your statement, so {B2/3/5} you say that AMCo ordered this batch in March 2013 to commercialise 10mg Hydrocortisone, but do you agree with Mr Middleton that the plan at this stage was not to commercialise it, but it wanted to test it?

A. I cannot comment on whether they wanted to commercialise it or test it. We were just asked to manufacture it and that is what we did.

Q. So when you say in your statement:

"I am aware that in March 2013, Amdipharm took steps to commercialise it."

Are you saying you were not aware that they took

steps to commercialise it?

A. No, so, sorry. So as far as Aesica was concerned, the product that we were manufacturing was for commercial purposes.

Q. Normally, when -- so when they did actually in 2014 tell you, when AMCo told you that they wanted to commercialise it, commercial supply, it ordered three new batches, did it not?

A. Yes.

Q. If it had wanted to -- if it had wanted to sell the product, it would have ordered more than one batch, would it not?

A. No. My recollection is that, because of the issues there were around the stability at the time, they wanted to manufacture one batch, prove that everything was okay and then from there, we would move on to manufacturing the next batches for commercialisation.

Q. All right. I think that we can agree on that. So this batch was not to be sold. It was to be tested and then commercialisation would follow if the testing was successful?

A. Of this batch?

Q. Yes.

A. So this batch would be manufactured, tested, if everything was okay, this would have been

commercialised.

Q. So you were told at the time that this is going to be commercialised, were you, because we know that there was not board approval within AMCo until later. So do you recall --

A. As far as Aesica were aware, any batches that we manufactured, post the original validation batches, were for commercialisation.

Q. All right. Thank you. Now, let us go to {C2/3/8}. This is a document you exhibit and it is an internal chain from Amdipharm following the meeting. Actually, sorry, can we go to the IR version, because it is easier to see so that Ms Lifton can see who the names are. {IR-C2/3/8}. The message is sent by -- can you see there is a message from Mr Middleton on 13 February?

A. Is it possible to make it bigger? Thank you.

Q. It is an internal email, as I have said, and it reports that -- it says:

"Further to our meeting at Aesica last week..."

That is the meeting that you referred to:

"We requested commencement of production for 1 batch of Hydrocortisone and 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!"

So they had not raised purchasing orders yet, because they were waiting to hear from you on the earliest production date, yes? That is what that is saying?

A. Yes.

Q. So from Aesica -- let me just think about how this would have been from Aesica's perspective -- there was not yet an order to go ahead with the manufacture of this batch at this stage, because AMCo wanted more information first. That is right, is it not?

A. That is correct, yes.

Q. But there was no reason why they could not have in fact just put an order in immediately, was there? There was nothing to stop them doing that that you know of?

A. Not that I know of, no.

Q. All right. Now, let us go back to paragraph 16 of your witness statement. What you say there is:

"Amdipharm was eager to receive the product as soon as possible, it had requested that we commence production and was enquiring as to the earliest

production date. The initial feedback we gave was that the lead time for procuring the relevant raw materials would be up to 149 days, this was before production could even start."

So is that based on the email we have just been looking at, the 149 days?

A. Yes, that is correct.

Q. By "relevant" you meant presumably the raw materials for Hydrocortisone, yes?

A. Yes.

Q. Now, if we go back to your response in the same document we were looking at a minute ago, so {IR-C2/3/10} and if we go to page 10. So this is an email from you on 25 February and you see there -- so you see there that you are responding and you say:

"Please accept my apologies for the delay in contacting you following the meeting."

And then you say:

"The conclusion of this work tied in with plant availability once all materials are available is as follows.

"Hydrocortisone, there are two raw materials that we need to buy that have long supplier lead times of 44 days and 60 days."

Yes?

A. Yes.
Q. And so that means you say:
"A manufacturing slot of mid June 2013, with a projected ship date of late July/early August 2013 for the first batch of Hydrocortisone tablets."
It is right, is it not, that AMCo did not push back on that and ask whether it could be done more quickly, did they?
A. Not that I can remember.
Q. Now, we can see that that paragraph below is redacted. Has it always been redacted, blanked out, in the version that you have had when preparing your statement?
A. Yes.
Q. I think it is worth looking at the unredacted version, because it is relevant. So let us go to {H/186/2}. This is the unredacted version. Can we zoom in, please. Thank you. If we look under the heading of "Morphgesic Tablets":
"There is one raw material we need to buy which has a very long supplier lead time of 149 days."
I think the 149 days that you are referring to at paragraph 16 of your statement refers to that other product, does it not?
A. That would seem to be.
Q. Not Hydrocortisone, right. But you would not have seen

that, because you did not have this unredacted version, yes? Okay.

Just to summarise where we are on timing, so AMCo said it wanted to manufacture one batch of tablets as quickly as possible before the end of -- they told you that before the end of December 2012. The purpose of that was to test the new assay method, yes? They were going to test the new assay method on that new batch?

A. That wasn't the purpose of the batch. The purpose of the batch was to make a first commercial batch, but --

Q. Sorry.

A. But they did not want to progress with more than one commercial batch until they knew this one was okay using the new method. Does that --

Q. I think you said before -- I think you clarified as far as you were aware that was -- it was to produce a new commercial batch?

A. Yes.

Q. Now, they did not place the order at that stage. You had a meeting first. We have seen that, yes?

A. Yes.

Q. After the meeting, they still did not place the order because they were waiting for information on lead times, yes?

A. Yes.

Q. Then you provided that information on 25 February 2013 and we have seen that for Hydrocortisone you said that you could manufacture in mid June with a ship date of late July or early August, yes?
A. Yes, that is correct.
Q. You say if we look back at {IR-C2/3/10}, you say there that:
"The above production slots have been allocated but in order for us to formally start the ball rolling and procure the necessary materials, please could you send the appropriate P/Os via the normal planning/materials management routes."
Yes?
A. Yes.
Q. They could have responded with a PO immediately or within a day or two if they had wanted to, but they did not, did they?
A. I do not know when the PO was provided.
Q. Let us go to the PO. So that is at {C2/3/12}. So we see that that is printed on 16 April 2013. Do you see that at the top of the page?
A. Yes.
Q. It is asking -- you can see that AMCo are asking -- you can see what they are asking for. They are asking for Hydrocortisone tablets in quantities of 30, so blister

packs and bottles. Do you see that? So if you go -- do you see so 10mg Hydrocortisone in 30s?

A. 30, yes.

Q. That was a direction, was not it, this order was the direction from AMCo to Aesica to get on and produce this, yes?

A. Yes, that would seem to be correct, yes.

Q. As you then explain in your witness statement, it was an order which could not be fulfilled because the MA did not allow for 30 tablet bottles. That is right, is it not?

A. Yes, that is correct.

Q. So where it says here on this order, "tabs 10mg, 30, Hydrocortisone bottle", that was an error on AMCo's part, was it not? It should not have put in an order for that, because it was not authorised to market it?

A. Yes, it was an error on their part.

Q. So if we go to paragraph 21 of your statement, {B2/3/6}. You say that you -- Aesica wrote to AMCo, do you have that?

A. Yes, yes.

Q. That Aesica wrote to AMCo to "flag an issue" and it was this issue and then you explained to AMCo at the time:

"Where we have all gotten confused is that we have forgotten, in the long gap between filing, approval and

commercialisation, that the 30 tablet bottle was removed from the dossier ..."

You explain what you mean by long gap.

We have just established that the error originated with AMCo's purchase order and this was an email -- so this email that you are quoting here was an email you sent to Mr Middleton, was it not? Do you remember that? The email you are quoting at paragraph 21?

A. I remember sending an email.

Q. When you say here "we have all gotten confused", do you mean by that people at both Aesica and AMCo?

A. I do, yes.

Q. You do not mean just people at Aesica, do you? You are not offering to take the whole blame for this, are you?

A. No, I mean both parties, yes.

Q. You are actually being tactful, is that right, to your client to say it is all of our faults rather than why did you put in the wrong order?

A. No, no, I would not say that. I would disagree with that. I am not being tactful. As a manufacturer, you also have access to that marketing authorisation. We had a full copy of that marketing authorisation on site and we, as well, should have been aware that it was not appropriate to take a purchase order for 30 tablet bottles. So there is blame on both parties.

Q. All right. Thank you. Thank you, Ms Lifton.

Let us go to paragraph 20 of your statement at {B2/3/5}. What you are referring to there is a face-to-face meeting with AMCo in May 2013 and we can go to a note of that meeting at {H/204/1}. You also exhibit this. So it is a document you have seen, but it is more heavily redacted so I am going to this one because it is easier to look at. It is prepared by somebody at AMCo. We can see that at the top. Would you have seen this note at the time, do you remember?

A. I do not remember.

Q. But when you are explaining what happened at the meeting at paragraph 20, you are really basing it on this document, are you?

A. Yes, I would have been at the meeting, although it says "Loftil", I was at the meeting.

Q. In fact it does say that, exactly.

A. That is me.

Q. Okay. We can see the purpose of the meeting. That is set out at the top of the page and it says to request quotation for Hydrocortisone. It says actually 10 and 25mgs, that must be 20mgs, must it not? That must just be an error.

A. Yes, that is somebody's error, I am guessing.

Q. The attendees that we looked at a second ago, where your

name was misspelled, that only lists people from Aesica, does it not, but do you recall who attended from AMCo? Would Mr Middleton --

A. No, I do not remember that meeting. It was a long, long time ago.

Q. So your witness statement really is based on this document?

A. On that one.

Q. Let us go to page 3 {H/204/3}. Before the discussion of -- so let us just scroll up, I think. That is the top of the page. So there is "Update on Products" and that is at the bottom and it says that you provided an -- so you can see reference to various products and on (b) it says:

"Morphgesic is ready to go all validation batches complete. Aesica not sure if we are to run the Hydrocortisone 10mg product -- can we confirm?"

Now, that suggests, does it not, that you were uncertain at that time about whether AMCo in fact wanted to go ahead with the manufacture, yes? That is what that must mean, is it not?

A. No, I would not -- without -- can we go back to when this meeting was?

Q. Of course, yes.

A. Sorry, apologies.

Q. So you can see that the meeting was 10 May 2013.
A. Okay. I honestly cannot comment on why they are saying whether we are not sure to progress. It could have been a number of reasons for it, so --
Q. This is a meeting with AMCo, yes? So they were there as well. It is drawing a distinction, is it not, between Morphgesic and Hydrocortisone? So it is saying Morphgesic is ready to go and on Hydrocortisone it is saying:

"Aesica is not sure if we are to run the product -- can we confirm?"

That must mean can we confirm with AMCo, must it not?

A. No, this is an AMCo set of minutes, so this -- the way I am reading that, is --
Q. Is can AMCo confirm?
A. Yes, so when he is saying "can we confirm?", it is saying: can we, AMCo, confirm to Aesica?
Q. I think you must be right. So can AMCo provide the confirmation?
A. Yes.
Q. Then if we see -- you can then see under "General Points":

"Aesica will issue a quote for Hydrocortisone".

Yes?

A. Yes.
Q. So going back to paragraph -- let us go to paragraph 23 of your statement. Where you say at the very end of that:

"It was clear to me that the 10mg ... project was an important one for AMCo and that the AMCo team were serious and were pushing us to resolve the issues and to start commercial supply".

The meeting notes suggests, does it not, that at least in May 2013 you were not clear that AMCo was pushing the project forward. Do you agree with that?
A. No, my recollection of this -- so my recollection of this is that, as a project manager, they wanted this product and we tried to do our utmost to deliver that product. With regard to the previous comment, I think -- like I say, I do not know what the context of that is. It could be around the packaging issue. It could be waiting for decisions. It is not clear from the context -- I cannot comment on what the context of that is. As far as I am concerned, as the project manager, they wanted the product and they were pushing us to make it as quickly as we could make it.
Q. You cannot remember the meeting?
A. I do not remember that meeting. It was a long time ago, a very long time ago.

Q. Would it be fair as a general matter to say that you cannot independently remember the events, because they were a very long time ago, which is understandable?
A. There are things that are very, very clear in my head with regard to this project. It was -- it was not an easy project and I know that as Aesica we had multiple issues with the project and that throughout that time AMCo, Amdipharm, Waymade, whoever we dealt with, wanted the product and they were pushing us to make product for commercial sale and that is my recollection of the project.
Q. All right. Now let us look at -- let us just look at paragraph 22, since we are on this page if we go up. This is a statement I think you have corrected. You provided an updated statement. When you corrected it, you made clear that it was the -- it was not the October 2013 batch that failed stability tests. It was the earlier batches that failed stability tests, yes?
A. That is correct, yes.
Q. Then you say that you had to halt production, because there were problems with the tightened assay limits and so your evidence seems to be that AMCo wanted to push on with the production of additional batches, but Aesica was unable to do so because of problems with the assay

limits. Is that fair? Is that what you are saying there?

A. No, my recollection of this is that we manufactured that batch in October and the last -- so stability data is a number of time points across a shelf-life of the product and the last set of stability data from the original validation batches was tested in, I believe, September of 2013, so the results would have been provided to the client probably a month or so after that, and my recollection is that it flagged the assay results were not meeting the tightened limit and I think, from what I can remember, we'd manufactured that batch and it was like, well, let us not do anything with it at the moment until we know what the problem is with the assay and whether we can resolve that.

Q. Right. Let us go to {H/272/5}, please. This is an email from you to Mr Middleton. Do you see that? Let us look at the date, so it is 27 September 2013. It is an email -- you are asking how to proceed as far as the packaging is concerned. If you just skip down -- this is the same email "where we have all gotten confused". Do you see that? We have forgotten in the long gap.

It is after that the problem has arisen:

"So, I guess the next step is now whether to proceed with the 100 tablet bottles or 30 tablet blisters? We

have all necessary artwork approved for the blister pack, but nothing at the moment for the bottle pack. We are checking if the leaflet size ...

"Either way, I guess the proposal from David will need to be amended.

"Please advise how you wish to proceed ... Also, please will can you confirm if you still require the 30 tablet bottle stability study to be set up?"

Do you remember -- do you recall that in fact -- so this is dated September. Do you remember when you got a response to this, when you got an instruction about how to proceed?

A. No, I do not.

Q. So we will see shortly that the instruction eventually came in January, so this was in September and, eventually, AMCo responded in January 2014 to package in 30 blister packs. So there was a delay of more than 3 months on the AMCo side in the end to respond to this question of yours.

Now, going back to paragraph 23 -- but you do not remember that? You do not remember that timing issue?

A. I -- now that you have said that they gave us the PO to proceed with or had made the decision, the reason for that was because of this stability issue so --

Q. I am not following that, because you have produced -- so

there is -- what you are asking here -- you are not saying anything about the stability issue. You are saying?

A. No, this is before that 36-month time test point would have -- data would have been available. So this was September, I believe, yes.

Q. That is right. What you are saying is the next step is we need to know how we are going to proceed with packaging, "so please advise how you wish to proceed"?

A. Yes, so if I can go through the timeline. So the batch that we are talking about here, we manufactured in October 2013.

Amdipharm, AMCo had given us a purchase order to manufacture tablets in 30 tablet bottles. We then subsequently realised that they could not be manufactured in 30 tablet bottles, because that wasn't part of the marketing authorisation. So this email is talking about that and we are asking at that point: what do you want to do, because we cannot do it in 30 tablet bottles so do you want to go with the 30 tablet blisters or 100 tablet bottles?

Subsequent to that the batch would have been -- the 36 months stability data would then have become available and it would have become apparent that there were issues with that. So that stability data would

have been for the 30 tablet blisters and the 100 tablet bottles.

So because of the -- as I have said before, because of the inconsistency of the data, it was very up and down, it indicates that there is an issue with the assay. So the 10mg batch that we have manufactured in October was placed on hold, pending resolving the assay issue, which we did with AMCo technical group and once we knew or once they had resolved the fact that the assay was okay and we knew we could transfer that into Aesica, that is when in the January, they then said, which presentation they wanted us to move forward with for that batch.

At the same time, we were asking if you still at some point want to proceed with that 30 tablet bottle pack, you would need to submit a variation to the MHRA, they would need supporting stability data, so do you still want us to use some of that batch, place it on stability to generate that data to support your variation.

Q. Let us look at {H/272/4}. This is an email from David Ross at Aesica -- do you see that -- to Wayne Middleton?

A. Yes.

Q. It is in November. So he is saying:

"I have not managed to catch you by phone today but I just wanted to follow up on the Hydrocortisone point that was raised last month.

"Please could you send an update regarding a decision on the packaging format for the tablets that have recently been manufactured at Aesica?

"Also please could you indicate if AMCo will require a stability study to be set up for the 30 tablet bottle format using so some of the available bulk material.

"I can update the previous proposal accordingly once the next steps are clarified."

It is not shown, because it is blanked out, but you are in copy to this email. So you can see in November Mr Ross is saying, well, we haven't had an answer on either of these things. Do you see that? That is a chaser email. So you raised it in September and Mr Ross is raising it in November, precisely the same point.

If we look up the internal chain at AMCo, so if we scroll up, please. You can see -- if we scroll up a little bit more, please. You can see that what Mr Middleton does with that, so he responds quite quickly, so he sends an email on 7 November to Mr McEwan:

"Please can you advise -- "

This is internal so you would not have seen this:

"Please can you advise what direction you wish for us to take with regards to this product?"

He sets out his understanding and he says -- this is number 4:

"Aesica are chasing for a forecast which to my knowledge does not exist as we currently have no plan to market the material."

That is not something he told you, is it?

A. No.

Q. And then 5:

"Aesica have all the starting materials ready to commence manufacture once all the approval issues are resolved."

Then 6 over the page:

"Would very much appreciate you providing your guidance on if we are to continue with requested manufacture, if so do you approve the stability studies to be put in place?

"Are we to market Aesica product, if so what is the strategy to switch from Auden and what would the marketing strategy be?"

So that is what he is asking internally, but you did not know about any of that, did you?

A. No.

Q. If we scroll up, we see the email response from Brian McEwan:

"Thanks for summarising. Before deciding on the way forward we need confirmation of the following ..."

Mr Middleton then later says -- then later tells him that is information you have already had. Let us go up a bit.

We see there on December 4:

"Dear All.

"I have been contacted again by Aesica. They have produced the bulk (a few weeks ago) and are now requesting payment for it as there is currently no defined timeline for the packing (see attached)?"

That is because no decision had been taken by AMCo, was it not, Ms Lifton, because he is saying next:

"A decision needs to be made as to what pack they should proceed with and we need to complete any artwork ... approvals that would be required to release said pack."

So just pausing there. I think what you have just said, your recollection is not quite right, is it? So what has happened is in September you have pressed for a decision on the packaging and then what we can see is that Mr Middleton takes it forward within AMCo and what he is saying internally is: I need a decision and this

is all taking a terribly long time. So nobody is saying that the packaging issue is irrelevant. They all accept it needs to be answered, but they are just not answering it, are they, Ms Lifton? Did you know about any of that?

A. No. This is nothing to do with me. I worked for Aesica, so ...

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

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

Q. So where they say -- where Mr Middleton has said here:

"Aesica are chasing for an answer".

You do not remember that?

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

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

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

Q. But you do not know, do you, because you do not know --

A. No, I do not know, but I can understand why, knowing how long these things can take to do and the things, the data you need to support things, why it would take some time to make a decision.

Q. Ms Lifton, Can I just ask you this: are you being paid by Advanz to give evidence in this?

A. Absolutely not.
Q. All right. Your last -- let us have a look at this so your last sentence of paragraph 23, {B2/3/6}. You say:
"It was clear to me that the 10mg Hydrocortisone project was an important one for AMCo and that the AMCo team were serious and were pushing us to resolve the issues and to start commercial supply."
Now, you have identified three issues in your statement. The first one is lead times, but AMCo did not push you for shorter lead times, did they? They did not ask for an earlier production slot for the October batch. In fact, they ordered it for November. That is right, is it not?
A. They did not push back on the times that we gave them.
Q. No.
A. But knowing how Aesica was at that time, there probably would have been very little point in them pushing back anyway.
PROFESSOR HOLMES: May I ask for a clarification on something. It may be my misunderstanding. We have been discussing the delay or significance of it or otherwise between your -- the witness's statement or email on the 27 September and the response in January, but we have also noted that -- and your evidence is that the batch -- you manufactured a batch in October 2013. That

batch, just to be clear, was after -- you received that batch after the 27 September. Was that receipt of that batch a factor in that delay?

A. Sorry, I lost ...

PROFESSOR HOLMES: You asked for various information and asking how to proceed in relation to the bottles and the packaging and so forth on 27 September and we have been discussing the internal chasing within AMCo in November/December and so forth. But the failing of the batch was in October, in other words, after that letter, so the failing of the batch in October cannot have been in your mind when you were chasing on 27 September. How did the failure of that batch, how did that play into things after 27 September?

A. So -- I am not sure I am understanding.

MS DEMETRIOU: Sir, can I try and clarify?

PROFESSOR HOLMES: Please do.

MS DEMETRIOU: I think you and I probably agree, don't we, Ms Lifton, that the question about packaging that you raised in September and was finally answered in January, that was about that October batch, wasn't it?

PROFESSOR HOLMES: October comes after September.

MS DEMETRIOU: But they are pre-planning. They wanted to know how to package it when it is produced.

PROFESSOR HOLMES: So he did not know the outcome of that

batch at the time.

A. That is total standard practice. You manufacture a batch. You plan to manufacture a bulk batch and package that batch, yes. You do not manufacture a batch, wait for it to be tested and then plan the packaging of it. That isn't how pharmaceutical manufacture works. It is a continuous process.

So when they ordered that, the tablet bottles, we would have gone straight into manufacturing the bulk batch after we'd got the materials from the delayed lead time.

PROFESSOR HOLMES: In the meantime you discovered these problems.

A. In the meantime we discovered the issue so we have now started manufacturing that bulk batch and we are saying like we need to know how you want to package that. That bulk batch can be stored, so a bulk batch has a shelf-life, so it has -- in this case it was 12 months so you can store that in big tubs or containers for 12 months before it has to go into the pack. So it is not an issue from that point of --

PROFESSOR HOLMES: From that point it was always already set in train and that was going on in the background.

A. Absolutely, yes.

PROFESSOR HOLMES: Understood, thank you.

MS DEMETRIOU: Then just relatedly, Ms Lifton, and just to clarify one point that just emerged from that, I think you and I both agree, because you amended your statement to say so, but the October batch did not fail any assay testing, did it? You were testing -- the stability issues were known about.

A. It was the stability batches.

Q. That had been produced in 2010?

A. Yes. So the provision of that 36-month test data I think re-focused people's attention on the fact that it was -- the validation batches were failing stability and, therefore, you have just manufactured a nice new fresh batch and you would think, why would I start packing that or do anything with it if down the line it is going to fail stability because in that -- the validation batches, it is fine, they never went to market. But if you put a product on market that then failed stability, you have got a recall and no pharmaceutical company wants a recall.

So that was why I say it was put on hold but basically the bulk batch was manufactured, it was parked until we resolved the assay issue and then once the assay issue was resolved and we knew, moving forward, that there weren't going to be stability issues for that batch, then we needed a decision on how we are going to

pack it.

PROFESSOR HOLMES: Thank you.

MS DEMETRIOU: Just on the stability issues, you had known about those for some time, right, because you test every, I think it was monthly, was it not, and you would send the results in?

A. It starts monthly and moves into yearly, as it goes along.

Q. So those issues had been known about for some time, right, so it was in January 2014 that you use new assay testing to resolve the stability issues?

A. That is correct, yes.

Q. Just going back to -- if I can just ask one more question and then I can finish -- I am just looking at the time -- finish this section and then I do not have much more but I am not going to finish before lunch.

So going back to that last sentence of paragraph 23 and what you say and the issues that you have identified. We have dealt with lead times. I think we have dealt with the packaging issue, so you flagged it to them and there was a delay in them responding.

Then there was the assay issue which AMCo had known about that throughout 2013, as we have just agreed.

It was the assay issue that was the reason for the manufacture of this batch, was it not? They wanted to

carry out more stability testing?

A. No.

Q. That is Mr Middleton's evidence. You disagree with him, do you? He says it was the assay issue that led them to order this batch so they could carry out more testing but your recollection is different, is it?

A. Yes. So as far as I am concerned, this batch was manufactured to be the first commercial batch, so I think I have explained but I will explain again. So this batch was manufactured to be the first commercial batch. You would normally manufacture three batches for a commercial release but they only ordered one batch to make sure this one was okay, the assay issues were resolved before they moved into the next batches.

THE PRESIDENT: So a batch has a particular size does it?

A. Yes, yes.

THE PRESIDENT: Just give me a ...

A. I honestly cannot remember what -- it could be -- a typical batch size is probably, I do not know, anything from 500,000 tablets to 1.2 million tablets, so ...

THE PRESIDENT: Right. But they, AMCo, computed batches at a particular size and they would not say, let us have an extra large batch, they would say how many batches?

A. It is very, very specific, so a batch size is validated

on the equipment that you manufacture. So as soon as you start making smaller, making bigger you have to revalidate the following whole process.

THE PRESIDENT: And that causes all these to be auditable?

A. Absolutely.

THE PRESIDENT: I see. That is very helpful.

MS DEMETRIOU: Can I take you briefly to what Mr Middleton says about this. So if you go to {B2/5/4}. If you look near the top of the page he says:

"We also explained to Aesica at the meeting on 5 February ..."

Have you got that, Ms Lifton?

"...that our order for a further batch ..."

A. Sorry, which part am I looking at?

Q. So if you go to the top of the page. We are in the very top paragraph, above paragraph 14 and about five lines up in that paragraph. It starts:

"We also explained to Aesica at the meeting on 5 February..."

Do you have that?

A. Yes.

Q. "...that our order for a further batch [that is the October batch] was for testing to ensure that the assay issues were resolved before we moved to larger scale manufacture. This was standard practice for a product

that was still under development and where most of the batches were not passing the assay specifications ..."

So do you agree with him or disagree with that statement?

A. That is not my recollection of the --

Q. All right. I think that is as far as I can take that. Is that a convenient moment to stop?

THE PRESIDENT: Indeed, Ms Demetriou. Thank you very much.

Ms Lifton, we will adjourn until five past 2. Please do not talk to anyone about your evidence. I hope that does not extend to getting someone to get you a sandwich in the short adjournment. I do not see why you should hunt around for that but not your evidence.

We will resume at 2.05. Thank you very much.

(1.05 pm)

(Luncheon adjournment)

(2.05 pm)

THE PRESIDENT: Good afternoon, Ms Demetriou.

MS DEMETRIOU: Thank you. Ms Lifton, let us look at paragraph 24 of your statement which is at {B2/3/6}. It is really just to place us in time. So January 2014 AMCo reissued the PO for the manufacture of a single batch of Hydrocortisone packaged as 30 tablet bottles.

So this related, did it not, to the batch that had

already been manufactured in October?

A. Correct, yes.

Q. Let us go to {H/305/1} and the bottom of page 5. {H/305/5}. So this is an email from Dr Pattrick and she is asking for details, she is saying:

"Could you tell me the exact date when the Hydrocortisone bulk was manufactured please? I am just discussing internally with the team the next steps on this but it would be helpful to have some details.

"Also, do you have the ... quote for the finished product packed in blisters of 30?

"Any light you can shed on this would be most appreciated."

You can see the date of that is 17 December 2013, yes?

A. Yes.

Q. If you go to page 4 Mr Ross quickly replies and he replies the same day and he explains -- so he replies, giving her an answer, "manufacture commenced on 2 October" but then seeking confirmation about the packaging which Aesica still had not got ..."

So he is asking her as well:

"Can you confirm if the 30 tablet blister format will be the preferred pack for this current batch?"

Then he is asking her also for a purchase order. Do

you see that?

"... A PO against the cost, this can be closed out..."

Do you see that?

A. Yes.

Q. Then if we look at what Dr Pattrick says in response. She says:

"Hi David

"Thanks for getting back to me. I will try and get the PO sorted but in order to do this, the project needs visibility at board level (which I am doing tomorrow), hence my pestering you with questions ..."

He says then -- we can see that he replies saying:

"No problem, I will look to provide a rough cost asap."

If we then go to the top of page 3, {H/305/3}. It is an email from Dr Pattrick on I think -- if we go up we can see the date is 6 January. It should be if we scroll up. Yes, so you see that at the bottom of the page, and then we will go back to the email. So 6 January 2014. And she says:

"Can you give me a call. I am getting the PO raised for the latest batch that has been manufactured and I will send across to you the PO number as soon as I have it. Could we have this batch packed into

blisters of 30, please?

"How soon could this be done?"

"As there are some other issues around the project, I was wondering whether it would be worth me coming to visit you early next week."

Then if we go to page 2, {H/305/2}, the email is then forward by Dr Pattrick to somebody else at Aesica whose name has been redacted and she says:

"I have just sent the below message to David, but it seems he is out of the office."

So that is why she has forwarded it.

"I know this project has been rumbling on for some time (our fault), but we'd actually like to push this ahead quite urgently now. Is this something I can take forward with you until David's return?"

We see the response the next day and he says:

"Thanks for your email. I can confirm that to pack the bulk 10mg Hydrocortisone we have on hand the cost is ..." and he explains.

"To ensure we can get it packed as soon as possible please submit a PO for this as soon as possible."

Then Dr Pattrick says an hour or so later that she will arrange -- do you see that in the middle of the page:

"Thanks for this I will arrange this."

So looking at this, I think it is fair to say, would you not agree, that this exchange demonstrates a new urgency by AMCo in pushing this forward?

A. Yes, I would say that, yes.

Q. Now, you refer to the purchase order issued in January 2014 for the packaging of these tablets at paragraph 24 of your statement. I think if we go to paragraph 24 you refer there to them being packaged as 30 tablet bottles and I think that must be a mistake because by that stage we have seen that it is 30 blister packs. We saw that from Dr Pattrick. But anyway, let us look at the document that you refer to. It is {C2/3/22}.

You can see the date. This is the document you refer to, so it is 21 March 2013 in the top right-hand corner. So a long time before. But then there is a date below at the bottom of the document which says -- you can see that above the black square -- 16 January 2014. This is a purchase order, we can see, for 15,170 tablets. Can you see that under "Quantity"?

A. Yes.

Q. Packaged as 30 tablets. So to be clear, this relates to the tablets which have been manufactured in October 2013, does not it?

A. That is correct.

Q. Which were being packed into blisters.
A. Correct, yes.
Q. Back to paragraph 24 of your statement. You explain there that there was an additional PO, do you see that a few lines up from the end of the paragraph, an additional PO was issued by AMCo for a further two batches to be packaged as three times 10 tablet blister packs?
So these are tablets which would need to be manufactured and packaged, are they?
A. That is correct, yes.
Q. And your recollection is that they wanted two of the new batches, is it? Is that based on the documents that Advanz gave you? You say two further batches?
A. Two further batches which makes sense because that would be three batches in total which would be the three batches to complete the packaging validation.
Q. So three in total, you mean including the October?
A. Including the October. The October batch plus the two batches would be the three batches required to complete the packaging validation.
Q. Let us look at {IR-C2/3/32}. If we go to the bottom of page 32. So we see there is an email from Dr Pattrick to Mr Ross. Do you see that?
A. Yes.

Q. And if we go down so she says:

"It was nice to chat to you earlier. As discussed, this project has become a priority within AMCo right now and therefore the board are keen to know how we can expedite things in terms of the investigation."

What she is wanting to expedite, so the investigation, that is the investigation to understand the cause of the assay problem, is it not? Do you remember that?

A. I remember that. I do not -- I cannot -- I am not Nicky so I can't comment on what she is talking about there.

Q. No, all right. Let us go down a bit on this page. So you can see the context -- sorry, to the bottom of page 34.

{IR-C2/3/34}. Here do you see that you -- this is an email to you. Do you see that?

"Dear Kelly and David.

"Below are my notes/actions from the call. Let me know if I have missed anything."

It is talking about an ongoing investigation.

"Reviewing how this work will be expedited to complete investigation by the end of next week ... to be confirmed by Friday."

If you look at under "packaging of 1st batch" that says:

"We will go ahead and plan for packing the batch ... which will be cancelled if investigation indicates manufacturing issues."

That must be relating to the assay?

A. Yes, I would assume from that that is the assay that they are talking about.

Q. Right. So what Dr Pattrick is asking about is the possibility of an expedited process for investigating the assay issue, is she not? That is what she seems to be asking about?

A. Could we go back to, so I can read what she said again, please.

Q. Yes. {C2/3/32}. It is the same document. But it is further down, and a bit further down.

So she says:

"This project has become a priority and the board are keen to know how we can expedite things in terms of the investigation."

So it is the same document. So putting investigation together with the way investigation was used elsewhere in the chain it must be the investigation in relation to the --

A. Yes, I would agree, yes, that she's talking about the assay investigation.

Q. Okay. It is true, is it not, that there are no emails

from AMCo in the course of 2013 that suggested that AMCo wanted to pay Aesica to expedite the investigation of the assay issue?

A. Yes, I would believe that is correct, yes.

Q. Okay. Then if we go to {C2/3/31}. It is the same document, page 31. The next email is an email from Mr Ross on 21 January. So it is page 31 in this document. Thank you. And that is from Mr Ross on 21 January, and so he is saying:

"Hi Nicky, an update on estimated timing ..."

So we can just skim that. So he is explaining what has been happening.

Then again we see if we go up what Dr Pattrick says, so if we scroll up a little, please.

So she says:

"Hi David, many thanks for providing these timelines -- I appreciate they are an estimate for now. Just to give you the heads up that the Hydrocortisone project was approved at the board today."

So the AMCo board have approved it.

"Obviously the technical investigation is still ongoing ..."

So that is the assay issue, yes?

A. Yes, I would assume that is what that means.

Q. "... but due to the high strategic importance of this

project to us, it was decided that we'd like to manufacture further batches at risk."

So we have seen at paragraph 22 of your witness statement you said that production had been stopped in December 2013 pending the resolution of the assay issue. But now in January 2014 AMCo are saying that it wants to order the further batches despite the fact that the assay issue has not yet been resolved. That is what it means by "ordering at risk", is it not?

A. Yes.

(Short pause due to technical issue)

Q. So we were just looking at what is meant by manufacturing further batches at risk and I think we agree, do we not, that what they are doing is doing the two things in parallel. So they are resolving the assay issue, but they are at the same time ordering new batches and what they mean by "at risk" is that if the assay issue is not fixed then the new batches, well, as the word suggests, they have been ordered at risk because they should not be ordered if they would be wasted.

A. Yes, that is -- from my recollection we had -- we had started to look at that assay issue in December or the AMCo technical team had started to look. So at that point, I would say, although they are saying at risk, we

were more comfortable that there was a resolution and that would not be a problem.

Q. You are more comfortable in December, are you, that there would be a resolution?

A. No, by the time they were placing those batches -- I believe from recollection the work started with AMCo technical team towards the very end of December.

Q. I will come back to that, because I think that -- I will come back to that on the timing. But what we then see on {C2/3/29}, so on page 29, is that Mr Ross replies -- well, yes, we can just look at this. So there is an email from Mr Dhorajiwala on 27 January and he says, if you look three paragraphs down:

"That AMCo are in the process of raising the purchasing order for a further three batches and would like to explore the possibility -- so we would like these batches manufactured as soon as possible and would like to further explore the possibilities of an expedited supply to shorten the standard 12 week lead time."

So the first point is it looks like there are three further batches, yes, to the batch, so I think probably that is an error in your witness statement, where you say two further batches. Do you think that is right?

A. Can I just -- I need to read it.

Q. Of course. (Pause).
A. Can I just go back to the witness statement, is that okay?
Q. Of course.
A. Is it possible to go back to the PO, please?
THE PRESIDENT: Of course.
MS DEMETRIOU: Yes. The PO for the further three batches.
A. For the further batches, yes, please.
Q. I am not sure we have looked at that yet, but it is at {H339/1}. Do you see the quantities 45,000?
A. Yes, so I would suggest then that is a mistake in my -- it should be three batches, not two batches, based on that information.
Q. Now, and then, again, just going back to Mr Dhorajiwala's email of 27 January, so that is at {C2/3/29}. He is saying:

"We would like these batches manufactured as soon as possible and you would like to further explore the possibilities of an expedited supply to shorten the standard 12 week lead time."

Again, I think you would agree that that is different, is it not, to 2013 when we saw they were not pushing you to shorten the lead times. You accept that, do you?
A. Yes.

Q. Now, the next email is from you on 28 January. That is on page 28. You had spoken -- you can see you had spoken to Mr Dhorajiwala. That is Rahul, is it not?
A. That is correct, yes.
Q. If you scroll up to the middle of page 27, there is an email from him to you on the same day and he is saying there that there is a further order coming for the 45,000 packs, yes? So you had -- I think this goes to the same point about the small error in your witness statement, but you had exhibited a purchase order for 30,000 tablets. We can see that at page 24 of this document; do you see that? That is for 30,000 tablets.
A. Yes.
Q. The delivery date here is given as 17 July 2014. So is that why you say at paragraph 28 of your witness statement that AMCo wanted delivery no later than around mid July? Presumably, that is why you are saying that, because this is the PO you have exhibited. Maybe you cannot remember?
A. No, I honestly do not remember.
Q. If you go back to that. If you look at the bottom right-hand corner of that PO, you can see the date on the document of 30 -- of 3 July -- sorry, this must be further down on the document. Yes, so right at the bottom it says 3 July 2014. Do you see that? So next

to the page?

A. Yes, I would not have said that.

Q. So we think that the actual PO for the order that Mr Dhorajiwala is talking about is the one at {H/339/1} which I took you to?

THE PRESIDENT: Just on date. The 3 July date is not that simply the date this document was printed for.

A. That is what I would say.

THE PRESIDENT: If you go right up to the top, there is another date and you see that the date there is 27/1/2014. Then there is an endorsement for and on behalf of Amdipharm also dated 29/1/2014.

MS DEMETRIOU: Yes.

THE PRESIDENT: It may not matter.

MS DEMETRIOU: I think there are two and we can see, if we go to the -- so there it is a little bit confusing and it may be this witness -- with the passage of time I just wanted to --

THE PRESIDENT: Indeed.

MS DEMETRIOU: If we go to {H/339/1}, perhaps I can show you the equivalent. This is the one we think is the purchase order. It may not matter very much.

THE PRESIDENT: Ms Demetriou, the only point I was making was I wasn't sure the date you took the witness to was one of any great significance so far as the date of the

invoice was concerned, but that may not matter. That is all I am saying.

MS DEMETRIOU: I think what I just wanted to show you, sir, {H/339/1} if we go to the very bottom and look at the equivalent printed date on this one, do you see that that is 30 January 2014. It is printed on that date.

THE PRESIDENT: Right.

MS DEMETRIOU: So I do not think -- when it is printed I do not think that is printed for the purposes of litigation. I think that is printed at the time and so that is why there may be some significance to it, but this, in any event, is the order for three batches which is 45,000 packs. This may not matter very much, but that is -- I think this is the --

Do you agree that this is likely to be the purchase order that was issued in January 2014?

A. Can I look at the purchase order. This is very confusing for me. I did not deal with purchase orders. I am not supply chain. I was the project manager. So I would just have done what was placed into the system. It seems that I have looked at three different purchase orders now and for different quantities, so if I could go back to the first one.

THE PRESIDENT: Could we put the two side by side. Is it possible?

A. It is very confusing. They are just flipping from one to the other.

MS DEMETRIOU: Maybe we could put them side by side. If we could put {C/3/24} next to -- you are ahead of me. So the one on the right is the one that you have exhibited and the one on the left is the one we think it is and the reason why we think it is this one is because Mr Dhorajiwala talks about ordering 45,000 packs and that is what this one says. So it is a little confusing. It is a little confusing to us as well.

THE PRESIDENT: I mean, just ...

A. So, okay, I believe I can understand why there is confusion now. So the one that I have exhibited would be for two batches.

MS DEMETRIOU: Right.

A. Because it is 30,000 tablets, so that would be 15,000 per batch I assume. Then I would say that that has been reissued for three batches.

MS DEMETRIOU: Thank you. That makes sense.

A. Does that make sense?

Q. It does make sense, yes?

THE PRESIDENT: Is there anything to be read into the delivery because the 30,000 quantity is a delivery to Union Drug Distribution Limited and the second one is to Waymade in Basildon. Is there anything that that tells

us about these two documents?

If you do not know, please say.

A. I honestly -- they are AMCo purchase orders, so I do not know the significance of that.

THE PRESIDENT: No, very good.

MS DEMETRIOU: So Ms Mackersie has just worked out what this might be. It might be -- do you recall that one of the batches was cancelled later on? So at this stage we can see three further batches, so there would be four batches in total, and then later there was a batch that was cancelled and so this may be the re-issue to reflect --

A. It could be the other way round.

Q. The other way round, okay.

A. It is very confusing and, yes --

Q. All right. So let us look at the one for 45,000 packs. While we are looking at that, you can see that the delivery date is said to be 7 May 2014. Do you see that?

A. Yes.

Q. That was subsequently delayed to July, was it not? Do you remember there was a delay?

A. Yes, that is correct, yes.

Q. In fact, the product -- maybe you do not recall this, but the product was delivered in August 2014. Do you

remember that?
A. Yes, I do remember that.
Q. So stepping back from the detail, what we see from all of these various documents is that in January 2014 AMCo got board approval for this project, that was referred to in the correspondence, yes?
A. Yes, that is correct.
Q. Seven days later submitted a purchase order for 45,000 packs, yes?
A. That would seem to be what that says, yes.
Q. Our point really is that this is now showing a greater degree of urgency. They are showing a greater degree of urgency at this stage to get on with the ordering, are not they?
A. Yes.
Q. Could it be then, Ms Lifton, so in your statement you talk about them wanting to push the project forward and that being your recollection. Could it be that what you are recalling is mostly -- so when you recall all of the urgency, that really you are thinking about this period in January 14 and the early part of 14 when they really are trying to push it forward and that is what you are remembering when you think back to all that time ago?
A. It would be correct to say that they pushed it more at this time, but, as I said earlier, I always recollect

that throughout the whole process it was being pushed, so ... but certainly there was more intensity at this time I would say.

Q. Then if we look -- if we go back to your witness statement, paragraphs 28-29, so {B2/3/7}, and so in these paragraphs you are explaining that there were delays to the delivery of the product in the first half of 2014, yes?

A. Yes, that is correct, yes.

Q. You refer to problems with the blister feeder and you also refer to problems with the quantities of the active ingredients or API?

A. Yes, that is correct.

Q. I do not need to ask you about those, because the CMA agrees with you on that and has identified them in the Decision. We have seen the earliest date on the PO that AMCo were targeting for delivery was 7 May 2014. We just saw that?

A. That is correct.

Q. We know that the product was shipped, was received, from Aesica on 8 August 2014. Does that sound right to you?

A. That sounds correct, yes.

Q. So actually, standing back, there was a manufacturing delay of just three months, was there not, at this stage as against the date that AMCo had originally hoped for

in its PO?

A. Yes, that would be correct.

Q. Now, I do want to ask you about one other thing that you do not refer to in your evidence and I will go to -- if we go to paragraph 32 of your statement, you exhibit an email chain. You exhibit an email chain here, so it is one of these exhibits and let us go to that. So {C2/3/58}. This is part of the way through a long chain and there is an email it says:

"Dear Genevieve ... "

Do you see that? That is from you and the date is 23 June. You are copying in various other people, including Mr Ross at Aesica and Mr Belk at AMCo. Do you see that at the top of the page?

A. Yes.

Q. This is a status update on the project and you can see that just by scanning down, yes?

A. Yes, that is correct, yes.

Q. If we go to the bottom of page 57, {C2/3/57}, the next email in the chain is on 1 July and it is from you, again, to the same people, the same people are in copy and they include Mr Ross and Mr Belk. Those were two people that you were in contact with during this period in relation to the project, were they not, Mr Belk at AMCo and Mr Ross at Aesica?

A. So I wasn't directly in contact with either -- well, with David I would have been, because he was our sales. Mr Belk, no, I wasn't in direct contact with. My contacts were the project managers, so Genevieve and Rahul. He would have been copied out of professional courtesy.

Q. What you are talking about here is the commissioning of the tablet feeder being delayed until Friday. We have encountered some problems again. We know that this is not a tablet issue.

So you are effectively updating them all as to the status of the project, yes?

A. Yes.

Q. If we go to {H/539/3}. This is an email to Mr Ross from Karl Belk, do you see that, on 27 June 2014. So just as a matter of timing, it came between the two emails that we have seen that we just looked at, your status updates, so, one, they were the 23 June and the 1 July. This is 27 June.

You can see there that what Mr Belk is saying is he says:

"Dear David.

"It is with disappointment and regret that I must write to inform you that our Hydrocortisone tablet project will be suspended in the UK territory."

He refers to various unfortunate delays and then he says:

"I would like to thank you and the Aesica team for the efforts over the course of this project with special mention to Kelly Lifton who has been our key contact throughout.

It is feasible, if circumstances change, that we may resurrect the project in the future and we would look forward to working with you again on this product for the UK."

If you then -- he then says, that they remain committed to their relationship with Aesica:

"Please be assured that the suspension of this project is not a reflection of any dissatisfaction with Aesica and will not be any way affect our decision to work on new projects with Aesica in the future. In the meantime we would like to close off this project in a neat and mutually acceptable way. To that end, the following is proposed:

"The three validation batches should be fully completed, packed, released and prepared for delivery ...

"AMCo wish to ensure that Aesica's is fully compensated for the work and efforts ..."

And:

"Please provide your estimate for the cost."

And:

"Please cancel your plans for the manufacture of further batches. AMCo will provide a formal PO cancellation ..."

So you do not mention the suspension of the project in your witness statement, Ms Lifton. Did you know about it?

A. No, I did not.

Q. You did not know that it was suspended?

A. No, I would have been over the moon.

Q. It would have been a relief?

A. It would, I can assure you.

Q. Let us scroll up. Let us have a look. So if you look at that email, that says:

"I have heard from our project That there are going to be no further requirements for the Hydrocortisone tablets beyond the current campaign. Please could you confirm if this is correct?"

But you were part of the project team, right, you were the project manager?

A. I do not know what he is referring to there. I have no idea, because I did not know that.

THE PRESIDENT: We probably ought to see this unredacted.

MS DEMETRIOU: Let us go to that. That is at {IR-H/539/2}.

Presumably you know the people whose names are redacted there at Aesica, do you, you knew them?

A. So Daniel Martin, yes, I do know, yes. So that is not me he is heard that from. So when he is saying "I have heard from our project team" he is not referring to me there. He must be referring to David Ross.

Q. Can we go to {IR-H/598/5}. If we look -- so that is from you, yes, to various people at Aesica:

"Please see attached below the notes from our meeting this morning."

So that is Compliance Event Meeting, 4 September 14:

"I think I have covered the keys points -- but please let me know if you think I have missed anything."

If we go to page 3 {IR-H/598/3}. If we go to the bottom of the page, you are in copy there, do you see that? There is an email form somebody at Aesica who is redacted and you are in copy. This is:

"Subject: Compliance Event Meeting."

Then if we scroll down, please, so you see there:

"Please --"

If you look at "I have tried to reach you by telephone" and then count down three paragraphs:

"Please could you review if these packs have been distributed from AMCo. Aesica management believe you have not distributed this as AMCo has cancelled all

orders going forward."

So you would have seen that at the time, yes? So presumably at the time you would have known that the orders had been cancelled going forward? At least in September you would have known that? Do you just not have any recollection of that?

A. I do not have any recollection of it to be honest with you. It was -- yes, it was fraught with issues and I was dealing with the issues, so ...

Q. Let us look at your statement, paragraph 38 of your statement. {B2/3/11}. So:

"In short, my experience of my dealings -- "

This is your summary:

"My experience of my dealings with AMCo was that it was always trying the push development and manufacture of its 10mg HT product along as quickly as possible and became very frustrated with our inability to provide it with saleable product."

You said you found that understandable, but I think you would accept, would you not, that suspending the project cannot be described as pushing the project along as quickly as possible?

A. From my perspective on this, as far as I was concerned, I was pushing on with the project. There were a number of issues at Aesica that were, as project manager,

extremely embarrassing to me and it was -- we kept encountering issues that delayed and delayed and delayed. They were constantly asking for updates. At probably towards the back end of the project I was literally on a daily teleconference with Genevieve and Rahul trying to give them updates telling them what was going on. So from me I would I can understand why they were frustrated and -- I was embarrassed and that is as much as I can say. That is my recollection of it.

Q. The recollection, just in terms of the documentary record, the documents certainly show that they were chasing you every week at the -- in the first part of 2014, but there are no documents to that effect in 2013. Do you accept that?

A. I accept that. It was a different team of people, completely different team of people managing it.

Q. Do you also accept, having seen these -- some of the internal AMCo documents and having seen that the project was suspended, that you simply were not aware of a lot of the strategic decisions that were going on at AMCo at the time?

A. No, I would not -- I worked for Aesica. I would not expect to be party to AMCo's strategic decisions. I worked for Aesica.

Q. Just in terms of that sentence in your evidence where

you say that it was always trying to push the development along, I think you would accept, would you not, that suspending the project is not the same as pushing the project along?

A. I cannot comment on that. I do not know what their reasons. For me, their reasons for suspending the project could possibly have been what a disastrous mess we made of it.

Q. But the reasons for suspending the project do not -- we can see those from internal documents. We have explored them. It is because they entered into a supply agreement with Auden, but of course you would not have known about that. But I am not asking you about the reasons, Ms Lifton. I am saying you have said in your evidence that they were always trying to push the project along. Do you accept that suspending it is not pushing the project along?

A. From the involvement that I had in the project, all of the involvement, they were pushing it and they were pushing it along. So my involvement would have ended after we had produced those first saleable batches and if they then did not progress that with Aesica after that, that is a commercial decision and that would have been nothing to do with me. So from my experience of the project the part that I was involved in it was

pushed, definitely.

MS DEMETRIOU: All right, Ms Lifton, that is it from me. Thank you very much.

PROFESSOR MASON: Might I just briefly ask a clarification question on your last statement, Ms Lifton. Do you recall exactly or approximately when your involvement as project manager finished? You started, as I recall, late 2012.

A. Late 2012.

PROFESSOR MASON: When did you finish being project manager?

A. So after the first batch is released so that sort of July/August timeframe, 2014.

PROFESSOR MASON: July/August 2014. So by September 2014 would you have still been project manager?

A. I was not project manager then.

PROFESSOR MASON: All right, thank you.

THE PRESIDENT: Ms Lifton, your statement contains a large amount of reference to documents and they are helpfully set out there, but where they go from the documents is to "value judgment" I am going to call them, to sort of drawing together the threads, sets of statements.

One is about AMCo pushing the project forward and we can see examples if we get your statement up and we move to paragraph 23, the last sentence there you can see you are saying, in terms:

"The AMCo team were serious and pushing us to resolve the issues".

Equally, if you go back to paragraph 15, there is a statement as early as December 2012. Again, the implication is it is being driven forward. Equally, paragraph 31, you can see there that you are saying that AMCo would regularly take issue with the continued delays at Aesica.

So that is, as it were, one package of judgmental statements that you are making.

The other value judgment, I will call it, that you are making is in paragraph 34. If we can just go to that. No, 37 I am so sorry. Go to 37. What we see here is an explanation from you that this was Aesica's problem, effectively, the reason for the issues in producing matters?

A. That would be the way it felt to me definitely.

THE PRESIDENT: This is your evidence and that is what it says.

A. Yes.

THE PRESIDENT: The problem that one has with witness statements is that giving evidence is not a memory test and so you inevitably need to be shown documents in order to give the statement. The trouble with reconstructing memory in this way is that the documents

sometimes lead us to draw effectively false memories. So the question I am going to ask is a very hard one, but I will ask it nonetheless.

If before you were shown any documents in this case, you were asked in general terms what your views were of this project, you would not of course have been asked the specifics, but if in general terms you were asked, what was your recollection about this particular project, what would you have said?

A. It was an absolute nightmare.

THE PRESIDENT: Thank you. That is very clear.

A. I can put it no clearer than that.

THE PRESIDENT: But it was an absolute nightmare in the two respects that you have described. You had a client pushing and --

A. Yes.

THE PRESIDENT: And you had your company not delivering?

A. Absolutely, yes, yes. It -- it is scarred in here forever.

THE PRESIDENT: No, that is very helpful.

A. It was not an easy project to manage at all.

THE PRESIDENT: Just to sort of test that. If one were to ask someone else in Aesica in roughly your position, someone like Ms Parent perhaps, would they, do you think, agree with your assessment or do you think you

are an outlier?

A. No, no. It -- Aesica was a very overstretched company to work for. They took on too much work. They were extremely under-resourced, so -- I mean, my employed role was as a regulatory affairs person and they were so short of people to manage projects, I picked up project management as well as my day job and that Hydrocortisone was not the only project I was managing. There were other projects as well so ... more -- you have seen from the emails, Morphgesic -- so the equipment was old. There was not a lot of investment made in the plant. We worked for a number of pharmaceutical companies, some of them big pharma companies, and be it right or wrong, hierarchy's decision was that big pharma came first. AMCo was not big pharma, so, yes, so it was not an easy company to work for with the resources. The manufacturing equipment was shared from development and commercial so you are always -- and commercial would always be given priority, because that is where the money comes from. So you were always fighting various other people for the same pieces of equipment, same packaging lines. So it was a very difficult place to work.

I think if you asked anybody who worked there at that time and later, they would -- if they told you

something different, they would be doing it for the company not for themselves, so ...

THE PRESIDENT: Mr Brealey, Ms Demetriou, do you want to take that any further? No. Just checking that there is not any other. No, I did not think so. Mr Brealey.

Re-examination by MR BREALEY.

MR BREALEY: We are almost finished. I just have a couple of questions about what was put to you before lunchtime, because Mr Middleton's witness statement was put to you. I will come to that. Could we just go to the transcript, please on page 71. This relates to the one batch, the October batch. So on page 71. Question:

"Normally when -- so when they actually did in 2014 tell you ... "

We go on, yes, and then:

"-- if it had wanted to sell the product, it would have ordered more than one batch, would it not?"

Then you say to Ms Demetriou:

"No. My recollection is that because of the issues there were around the stability at the time they wanted to manufacture one batch, prove that everything was okay and then from there, we would move on to manufacturing the next batches for commercialisation."

"All right", says Ms Demetriou:

"I think that we can agree on that. So this batch

was not to be sold. It was to be tested and then commercialisation would follow if the testing was successful."

You query:

"Of this batch?

"Yes.

"So this batch would be manufactured, tested, if everything was okay this would have been commercialised."

So, in other words, you have got a batch and how big is the batch?

A. I think -- I honestly do not remember. 15,000 packs, 30 tablets a pack.

Q. So you test a small bit, is that right? How big is the -- I think you have already given evidence on this, but how big is the part that you test?

A. So you take a representative sample of the batch and test it, so it could -- it depends how many tablets you need to do the testing, but let us say, I do not know, for argument's sake, you need 100 tablets to do the testing. So from that bulk batch, you would take a random sample of 100 tablets. If the batch size was across several containers, you might take some from there, some from there, some from there so you have got a representative sample from the batch and then that

sample would be tested.

Q. Right. So you can test that. So you say:

"It was to be tested and then commercialisation followed if the testing was successful on this batch."

So you are saying this batch would be manufactured, tested. If everything was okay, this would have been commercialised. So you take the representative sample. That is your evidence. What happens to the rest of the batch according to your evidence there?

A. According to?

Q. What you are saying there. You say it gets commercialised?

A. Yes.

Q. That means it gets released or --

A. Yes, so -- yes, so it would have been -- if everything was okay with it, ultimately, it would have been packed into its commercial pack and released for sale. That is what I mean by that.

Q. So Ms Demetriou said that was not Mr Middleton's evidence.

MS DEMETRIOU: Can you read the next sentence. The next question is about timing. I was asking about the decision to commercialise. So you need to read the next question.

MR BREALEY: If you want me to.

MS DEMETRIOU: My question was about the time she was told it was going to be commercialised.

MR BREALEY: I will do. But she has already given evidence on the question. What I want to do is go to what you were then asked.

MS DEMETRIOU: I am so sorry. What she was then asked -- what Ms Lifton was then asked was about the timing, when she was told that this was going to be commercialised. It is not about -- that is the important point, when she was told that this batch was going to be commercialised. That is the point I put to her on Mr Middleton's evidence so she does need to be taken to that question, with respect.

THE PRESIDENT: Mr Brealey, take your own course, because you want the witness to clarify something. It may be that what the witness clarifies is -- bears no relation to what she was asked, in which case we can live with that.

MR BREALEY: I do not think it is for timing. We can see what it is.

THE PRESIDENT: Well --

MR BREALEY: If we go then to page 99. So that was your evidence. If we go to page 99 just before lunch. Just before lunch Ms Demetriou takes you to Mr Middleton's witness statement. What I would like to do is take you

to his witness statement and then the passage that she showed you.

The first passage I would like to show you is at paragraph 22, because essentially Ms Demetriou was putting to you that Mr Middleton's evidence was that the first batch was for testing. What I would like to -- and she said "this was his evidence".

What I would like to do is go to paragraph 22 of Mr Middleton's witness statement which is {B2/5/7}. If you could read paragraph 22, please. (Pause).

A. Of?

Q. Of the witness. That is Mr Middleton's witness statement. So just read that. You were not taken to this paragraph. (Pause).

A. Yes.

Q. Do you read that evidence -- how do you read that evidence in the sense of was this one batch for commercialisation or only for testing? He says:

"This meant that the product Aesica had manufactured was not ready for release in any presentation."

Was it your impression from Mr Middleton that he wanted to commercialise it?

A. From this statement that he is saying that the October batch was intended for commercial release.

Q. Thank you. So when you -- that was that. If you go now

to {B2/5/3}, paragraph 13 if you read paragraph 13, please. (Pause).

A. Yes.

Q. If you go to there, we -- I think what Ms Demetriou was putting to you -- we can see in a minute -- she refers to paragraph 22 of Mr Middleton where he says --

"We also explained to Aesica at the meeting on 5 February that our order for a further batch of 10mg HT was for testing to ensure that the assay issues were resolved before we moved to larger scale manufacture."

What was being suggested to you that in this statement the one batch was only for testing and not for commercialisation.

MS DEMETRIOU: I am very sorry to rise, but that wasn't what I suggested. Can we go to what I suggested, because I think this is inappropriate re-examination. Mr Brealey is prompting the witness to change her answer. Can I show you what was put?

MR BREALEY: I am just about to.

THE PRESIDENT: Let us let Mr Brealey finish and then we will see what we make of it.

MS DEMETRIOU: Just to say, I simply showed the witness the end of paragraph 13 and I said do you agree or disagree and now she is being prompted to change her answer, which is not re-examination.

MR BREALEY: The whole purpose of re-examination is to see whether the witness actually meant to disagree.

MS DEMETRIOU: It is not.

MR BREALEY: Well, I am afraid it is.

If you go to the transcript at 98, so --

THE PRESIDENT: Let us see the questions before that.

(Pause). Now move down. Okay, have you read that?

MR BREALEY: So --

THE PRESIDENT: Ms Lifton, have you got that?

A. Yes, thank you.

MR BREALEY: At 98, line 7:

"Yes. So far as I am concerned, this batch was manufactured to be the first commercial batch, so I think I have explained, but I will explain again. So this batch was manufactured to be the first commercial batch. You would normally manufacture three batches for a commercial release but they only ordered one batch to make sure this was okay, the assay issues were resolved before they moved into the next batches".

Then the President:

"So a batch has a particular size does it? Yes, yes."

Then: "No".

Then question, this is Ms Demetriou:

"That is Mr Middleton's evidence. You disagree with

him, do you? He says it was the assay issue that led them to order this batch so they could carry out more testing, but your recollection is different, is it?"

So the simple point is do you understand Mr Middleton, because his evidence is being put to you, do you understand his evidence to be that the first batch was only for testing or was it for testing and if it passed, would be for commercialisation? Was it only for testing, this first batch, or was it -- if it was for testing would it also be commercialised if it passed the relevant tests?

A. So, but you are asking me to comment on his witness statement.

THE PRESIDENT: The witness has --

MR BREALEY: You have been asked whether -- it was undoubtedly implicitly put to you that this evidence was that the first batch was only for testing.

THE PRESIDENT: Mr Brealey, is this really a matter for this witness what Mr Middleton meant in his statement? Surely the question that the witness can answer is her understanding as to what, amongst other things, the first batch was being put to. I think she did answer that question.

MR BREALEY: She did.

THE PRESIDENT: Let us get the answer on the record again.

But I am not sure that we are going to be assisted by what, with great respect to Ms Lifton, what she thinks about what Mr Middleton says the batch meant.

MR BREALEY: I am only putting this in re-examination, because that was the cross-examination: Look at what Mr Middleton says, do you agree or disagree?

THE PRESIDENT: Sure.

MR BREALEY: So in order to agree or disagree you actually have to understand what he was saying.

THE PRESIDENT: What was being put was that the first batch was only being used for testing and not for any commercial purpose and what I got from the witness was, no, it is comprising such a large amount of material that although it was being tested, it was also being flogged if it passed the testing.

MR BREALEY: Yes.

THE PRESIDENT: Have I got that right, Ms Lifton?

A. Yes.

THE PRESIDENT: In your view?

A. In my understanding, that batch was manufactured to be a commercial batch, obviously as long as it passed the testing. If Mr Middleton believed it was only for testing, that is his belief. That is not my belief. My belief was it was a commercial batch.

MR BREALEY: Mr Middleton was not asked what he meant by

that question.

MS DEMETRIOU: Can I clarify? I did not put the question that it was only for testing. So if you look at my question. It maybe this is not for this witness at all, but I think Mr Brealey is misunderstanding my question. So I have asked at page 98 line 3:

"He says it was the assay issue that led them to order this batch so they could carry out more testing. But your recollection is different."

I put that to her and she said "Yes, it is different."

If you then go down to page 99, line 13, I just showed her the end of paragraph 13 of Mr Middleton's statement. I did not make any comment and I asked her to read it and I said "Do you agree or disagree?" So that was really the limit of my questioning. I think it has become rather confused in the retelling.

MR BREALEY: Okay, then I take it no further. I have no further questions.

THE PRESIDENT: I am very grateful to you all. Ms Lifton, thank you very much.

A. Thank you.

THE PRESIDENT: Very grateful for your help and you are released from the witness box. Thank you very much.

(The witness withdrew)

THE PRESIDENT: I will let Ms Lifton leave, unless you want to stay to listen to housekeeping that we have got, but I expect you will want to flee the courtroom but you are entirely welcome to stay if you wish.

A. I will go.

(The witness withdrew)

HOUSEKEEPING

THE PRESIDENT: Now, I had a couple of points, I do not know if anyone else has any points to raise with the Tribunal. We are now moving to the expert evidence on Tuesday.

MS DEMETRIOU: Sir, just to flag -- the Tribunal has probably apprehended that Mr Holmes KC is pleading the case for the CMA on excessive pricing aspect and so just to flag that I will not be here for every day of the evidence going forward, although I might be here for some of it, but I just wanted to apologise in advance. There is no discourtesy intended to the Tribunal.

THE PRESIDENT: Not at all. We quite understand and we are quite sure that you will be present as appropriate and that is entirely understood. So thank you for that.

Regarding the expert evidence, we have got, I think, five experts coming in the course of the next week and a bit. I just want to ensure that the parties are thinking about the lines of cross-examination. I mean,

we have got various different interests involved. I do not know whether there is going to be multiple cross-examination of experts. If there is, then I would very much not want to have duplication of cross-examination, but if there are separate areas that need to be articulated by different parties then of course that would be entirely appropriate. But I want thought to be given to that. I have no idea whether that is a problem or not, but I thought I had better raise it in case it has not crossed the radars of the parties.

If there is a problem about multiple attacks, then I would rather it was raised with the Tribunal first than it simply emerging in the course of cross-examination, but, obviously, I do not want anyone shut out from making their points, but I do not think it would be helpful for the Tribunal to hear, as it were, the same point being examined upon several times.

So that is just a marker, which I hope it is certainly intended to assist.

Secondly, and this is simply a flagging up of a question that is likely to emerge in the course of closing submissions and it bears no relationship to the factual evidence we have heard. We flag it up now so that the parties get advance notice. There is no

significance in the timing of this point.

It is very clear from Allergan, for example, written closing that one of the points that is going to be pressed very hard is the absence of an influence by a parent company on the subsidiary and the significance of that in terms of fine. That is clear from Mr Jowell's written submissions and it is a point that crops up elsewhere.

The question that we will be having is where one has a buying and selling of companies in a sort of commercial way, whether the decisive influence test for imposition of fines is the sole test for working out what the fine ought to be. Let me unpack that a little bit. I do not want submissions on it and you can tell me that I am completely wrong and barking up the wrong tree and it is a bad point later on.

But what the Allergan submissions gave rise to was this thought: if one has got a parent company that is effectively trading, buying in, selling on a subsidiary and is making money thereby, if that subsidiary is engaged in anti-competitive conduct such that you are getting value, but you are not paying the price of the anti-competitive conduct, should the fine actually reflect the commercial dealings in the company so that you do pay a price for the acquisition and on selling of

a company at what would be an inflated price, because the anti-competitive corner has not been spotted.

So that is the issue. I lay it out there, because it has crossed our minds and what crosses our minds as something that we want to know the answer to is something we feel we ought to communicate to you. So for better or worse that is the point.

The last point does arise out of the factual evidence and it is this: we have had a pre-taster of the debates that we are going to have in closing about who has and who has not called which witnesses and what inferences can be drawn from that and what inference cannot be drawn from and, again, that is a debate which we will welcome and we will have at the appropriate time.

In connection with that though, we have been sent, I am sure it is in the bundles anyway, but we have been sent the statement of Mr McEwan that the CMA obtained in the course of its investigation and I think the point that is being made, or that will be made, is that if someone should have called Mr McEwan then it should have been the CMA rather than someone else.

Now, that is not an argument I want to have today. What I do want to be put on the record is an offer to see whether it would assist along these lines: it is

quite clear that we have got a very difficult question of evaluation in terms of Mr Sully and Mr Beighton's evidence. That is obvious to everyone in this room. It follows from that that the more assistance we get absent inference the better. We have of course got, as the parties will all know, the power to require the attendance of a witness.

Would it assist if we exercised that power, or offered to exercise that power, in relation to Mr McEwan? I appreciate that it is not the way in which one normally conducts these matters and so I am putting it forward somewhat tentatively and the Tribunal is not in the business of exercising its powers without hearing from the parties in relation to it.

But it seems to us that the appropriate point to air this is now when the factual evidence is concluded, but before we get into the arguments about inferences to be drawn from evidence that could have been called and was not.

Now, I do not think it would be appropriate, unless you want to, to have responses now on this. I do not see any harm if it is something that is to be taken forward that we cannot evade the mechanics of, including who is cross-examining and who is not cross-examining later on. But I did think it appropriate at this stage

to raise it and what I would suggest is that the parties think about their response and we address it first thing on Tuesday morning.

MS DEMETRIOU: Thank you very much. We will certainly consider that, sir, and we will revert as soon as we can for our part.

THE PRESIDENT: Thank you very much. I think the same goes for you, Mr Brealey.

MR BREALEY: It would have to be.

THE PRESIDENT: I do not think there is any other interest I may be wrong about that. I certainly do not intend to close anyone out who has anything to say about this.

MR O'DONOGHUE: We would partially join the interest.

THE PRESIDENT: You are. Mr O'Donoghue, I am sure you will be speaking to your twin about that in due course, but if there is anyone else who has anything to say on this we are obviously not in the business of not hearing from you.

MS DEMETRIOU: Sir, just to flag that of course we have asked that an adverse inference also be drawn from the absence of Mr Amit Patel for Auden and so that may engage Ms Ford.

THE PRESIDENT: Clearly the pool of witnesses that could be drawn are considerable. I think the -- I may be wrong, I do not know if Mr Patel has given a statement. What

I think makes this suggestion or offer a little more possible to make is because there has been this statement from Mr McEwan which provides sort of a peg on which to make the offer. We obviously would not close out further suggestions but the reason I am making this offer, as tentatively as I am, is because the way in which our proceedings are conducted, generally speaking, is that we receive what the parties have served up for us and we evaluate it and we reach a decision on that material.

We have these powers to require further evidence, but the practice, at least so far, has been only exceptionally to use them.

If there is to be a wider take up of the offer, we would obviously hear on that as well, but it was Mr McEwan and the statement that triggered this, but, yes, if there is going to be a suggestion that further evidence effectively be compelled, then we would think about it and, to be clear, we will be very happy to hear opposition to this course. One point might be made, look, the CMA could have called Mr McEwan. I am saying nothing about the possibility. They got the statement from him, they did not and we should not be going down the route of inserting new evidence in the middle of a hearing. So we understand the point, but it is the

inference question that has, I think, triggered this suggestion.

I will say no more than that and the parties can push back in any way they like on Tuesday morning or later if you need more time to think about it, but Tuesday probably would be the best time to deal with it.

MR BREALEY: Just you may remember, sir, that we were promised a bundle of documents that were going to -- if any documents are going to be put to Dr Newton, so she wasn't taken by surprise. It is coming today, is it? It is fine then. Thank you.

THE PRESIDENT: Very good. Any other points that we need to deal with? I think we can resume then at 10.30 on Tuesday morning. Thank you all very much.

(3.25 pm)

(The hearing adjourned until Tuesday, 29 November at 10.30 am)